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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 2, 2017
9:50 a.m.
TRIAL VOLUME 6
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 ERIC M. SPRAGUE, ESQ.

6 MARKUS H. MEIER, 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 ON BEHALF OF IMPAX LABORATORIES:

16 EDWARD D. HASSI, ESQ.

17 MICHAEL E. ANTALICS, 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

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1	FEDERAL TRADE COMMISSION				
2	I N D E X				
3	IN THE MATTER OF IMPAX LABORATORIES, INC.				
4	TRIAL VOLUME 6				
5	PUBLIC RECORD				
6	NOVEMBER 2, 2017				
7					
8	WITNESS:	DIRECT	CROSS	REDIRECT	RECROSS VOIR
9	BINGOL	1259	1311		
10	NOLL	1341	1489		
11					
12					
13	EXHIBITS	FOR ID	IN EVID	IN CAMERA	STRICKEN/REJECTED
14	CX				
15	(none)				
16					
17	RX				
18	(none)				
19					
20	JX				
21	(none)				
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1 P R O C E E D I N G S

2 - - - - -

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

4 We discussed last week that pending motion to
5 compel needing to be -- you're going to file a motion
6 of withdrawal -- or a notice of withdrawal, not a
7 motion, a notice. I saw one on Bingol.

8 What happened to the notice of withdrawal on
9 Reasons? It doesn't matter that he's testified.
10 There's a pending motion to compel that's on file with
11 the commission.

12 MR. LOUGHLIN: Your Honor, as I understand it,
13 we never actually filed the motion against Mr. Reasons
14 because we had difficulty with the e-filing system, and
15 we worked it out with respondent's counsel before we
16 actually technically filed it.

17 JUDGE CHAPPELL: Can you verify that and let me
18 know after the next break? I want to make sure it
19 wasn't filed.

20 Bingol was filed?

21 MR. LOUGHLIN: Bingol was filed and we filed a
22 notice in response to that.

23 JUDGE CHAPPELL: I saw that.

24 MR. LOUGHLIN: And my understanding is that we
25 never actually filed the one against Mr. Reasons.

1 JUDGE CHAPPELL: It's your understanding, but
2 you're going to verify.

3 MR. LOUGHLIN: I will -- that's my belief, but
4 I will verify that.

5 JUDGE CHAPPELL: That's the rule. If it's been
6 filed, it must be withdrawn.

7 MR. LOUGHLIN: Understood.

8 JUDGE CHAPPELL: All right. Next witness.

9 MR. LOUGHLIN: Your Honor, complaint counsel
10 calls Demir Bingol.

11 And my colleague, Eric Sprague, will conduct
12 the examination.

13 - - - - -

14 Whereupon --

15 DEMIR BINGOL

16 a witness, called for examination, having been first
17 duly sworn, was examined and testified as follows: Is

18 MR. SPRAGUE: Good morning, Your Honor.

19 May it please the court.

20 My name is Eric Sprague, representing
21 complaint counsel, to examine Mr. Bingol.

22 - - - - -

23 DIRECT EXAMINATION

24 Q. Good morning, Mr. Bingol. How are you?

25 A. Good. Thank you.

1 Q. Over the course of this examination, we'll
2 likely discuss some documents. They will be displayed
3 on the screen in front of you, but if you'd rather look
4 in the binder that's to your left, you can use that
5 instead. And there's water next to you.

6 A. Thank you.

7 Q. Mr. Bingol, who do you currently work for?

8 A. A company called Grünenthal.

9 Q. And what is your title at Grünenthal?

10 A. Vice president of business development and
11 licensing for the Americas.

12 Q. What kind of company is Grünenthal?

13 A. It's a pharmaceutical company.

14 Q. When did you start at Grünenthal?

15 A. In 20- -- I have to go back now. It will be
16 five years in June.

17 2013.

18 Q. 2013?

19 A. Correct.

20 Q. Thank you.

21 Have you worked at any other companies in the
22 pharmaceutical space?

23 A. Yes.

24 Q. Which ones?

25 A. AstraZeneca.

1 Adolor.

2 aaiPharma.

3 Endo Pharmaceuticals.

4 Q. In total, for how many years did you work at
5 companies in the pharmaceutical space?

6 A. Approximately 18.

7 Q. And during those 18 years, what job function
8 did you hold?

9 A. Traditional sales and marketing roles.

10 Q. When did you work at Endo?

11 A. From 2006 to 2011.

12 Q. When you worked at Endo, what position did you
13 hold?

14 A. Senior director of marketing for the oral
15 analgesics business.

16 Q. As senior director for marketing of the oral
17 analgesics business, what products did you have
18 responsibility for?

19 A. A number of products. Opana. Opana ER.
20 Percocet. The other one escapes me at the moment but
21 triptans for migraines.

22 Q. What is Opana ER?

23 A. Opana ER is a long-acting oral analgesic.

24 Q. What class of drugs does Opana ER belong to?

25 A. It's a mu agonist, so it's an opioid.

- 1 Q. Is Opana ER a long-acting opioid?
- 2 A. Correct.
- 3 Q. What is Opana ER's active ingredient?
- 4 A. Oxymorphone.
- 5 Q. What other long-acting opioids contain
- 6 oxymorphone as the active ingredient?
- 7 A. Well, today or --
- 8 Q. Well, when you were at Endo.
- 9 A. When I was at Endo?
- 10 Q. Yes, sir.
- 11 A. Oxymorphone was the only one or Opana ER was
- 12 the only one.
- 13 Q. What about today?
- 14 A. I'm not quite sure how many variations there
- 15 may be.
- 16 Q. Do you know what variations you're aware of?
- 17 A. I just know that there's some generics on the
- 18 market. I haven't kept up with it since I left.
- 19 Q. Understood.
- 20 When you were at Endo, was Endo planning to
- 21 launch a reformulated version of Opana ER?
- 22 A. Yes.
- 23 Q. Were you yourself involved in those plans?
- 24 A. Yes.
- 25 Q. What role did you have with respect to Endo's

1 plans to launch a reformulated version of Opana ER?

2 A. Well, I provided the commercial support,
3 insights into, you know, what we should be doing and
4 how we should be formulating it, what the product
5 profile might look like, the opportunity that that
6 presents, et cetera, et cetera, so just general
7 commercial guidance for the development team.

8 Q. And when you say "commercial guidance," what
9 specifically do you mean by "commercial"?

10 A. Those things that reflect the market interests,
11 activities, you know, like I said, product profile,
12 making sure that you're not -- that you're meeting all
13 the needs of the marketplace really.

14 Q. When you were at Endo, do you know what Endo's
15 number one selling product was?

16 A. Sure.

17 Q. What was that?

18 A. Lidoderm.

19 Q. And what was the second biggest selling product
20 at Endo when you were there?

21 A. At the time it was Opana ER I believe.

22 Q. When you were there, was Opana ER an important
23 product for Endo?

24 A. Sure.

25 Q. Why was Opana ER an important product for

1 Endo?

2 A. Well, as with all the products that they had,
3 you know, each one was important in its own way, but in
4 this case this was a product that we had some patent
5 life on still and therefore able to make sales and
6 continue in the -- reaching the sales objectives that
7 we had planned for the product.

8 Q. What relationship, if any, does your current
9 employer Grünenthal have with Endo?

10 A. Actually, Grünenthal manufactures the
11 technology that Opana ER currently or was using. I'm
12 not sure what the status is today, but the
13 reformulation of that product was using the Grünenthal
14 technology to help make it crush-resistant.

15 Q. Was there some sort -- was there any sort of
16 license arrangement between Grünenthal and Endo?

17 A. Yes.

18 Q. Thank you for telling the court about your
19 background. I'd like to shift gears and talk more
20 about the drug Opana ER.

21 When you were senior marketing director at Endo
22 with responsibility for the Opana franchise, what
23 responsibilities did you have specifically with respect
24 to Opana ER?

25 A. Well, my, again, responsibilities were

1 commercially focused, so responsible for creating the
2 marketing plans, for understanding all the elements in
3 the -- that affected it in the marketplace and trying
4 to guide and direct the business in an appropriate and
5 meaningful way.

6 Q. When you would create marketing plans, what
7 types of plans would you create? Specifically, how
8 would you market Opana ER?

9 A. Well, in general, marketing any pharmaceutical
10 product, of course, you're looking at the different
11 customer types. You're looking at the competition.
12 You're looking at, you know, macro elements of the
13 marketplace that may have effect on trends.

14 So, I mean, you take all this together and you
15 create different strategies or promotional tactics in
16 order to be able to effectively communicate why your
17 product is different and why it would be needed by
18 certain patient types.

19 Q. And who would you communicate that the product
20 was different to?

21 A. Well, different -- to constituents in the value
22 chain. That can go from everyone from the wholesaler
23 to the pharmacy to the physician to the patient, if
24 you're engaging in direct-to-consumer type of
25 communications, to the payers. There's really kind of

1 a matrix of constituents that you communicate these
2 things to.

3 Q. And how would you communicate these differences
4 to the various constituents?

5 A. Again, it depends. You have a lot of
6 different tactics, a lot of different channels to
7 communicate through, so it can be through something as
8 simple as a pharmacy letter, it can be with a sales rep
9 standing in front of the physician with a sales
10 brochure and everything in between, digital or --

11 JUDGE CHAPPELL: Can we hear about the drug at
12 issue in this case rather than all the drugs the man
13 worked on?

14 MR. SPRAGUE: Yes. I'm sorry, Your Honor. I
15 will specifically ask.

16 BY MR. SPRAGUE:

17 Q. With respect to Opana ER, how did you
18 communicate differences to the various constituencies?

19 A. Again, the same answer. It could be a number
20 of different channels to -- that we use, but in
21 general, through sales reps, through written
22 communication and even digital communication.

23 Q. What do you mean by "digital communication"?

24 A. Well, if you have a website or otherwise people
25 opt into a program whereby you might send

1 communications to them directly.

2 Q. Thank you.

3 And specifically with respect to Opana ER, what
4 were the characteristics that you hoped would
5 differentiate it in these constituencies' minds?

6 A. Well, there were a number of different
7 potential differences in the drug in terms of the way
8 it's metabolized, is it actually being consumed as per
9 the label in terms of the number of doses per day, are
10 the safety profiles quite the same, and these
11 differences can be -- can be meaningful for certain
12 patient types. And the trick, of course, is to match
13 up the right patient type with the right difference so
14 that the patient gets the appropriate therapy.

15 Q. When you were Endo's senior marketing director
16 with responsibility for the Opana franchise, did you
17 ever use the term "playbook"?

18 A. Yes.

19 Q. And what is a playbook?

20 A. Well, I think we used it in the context of one
21 particular document, but that was an idea that we had
22 to kind of simplify the brand plan to make it a little
23 bit more digestible, so rather than calling it a brand
24 plan, we said it's the playbook, and then we tried to
25 make it a little bit more consumer friendly at least

1 from an internal perspective so people who were
2 reading it could kind of see what you meant at a
3 glance perhaps rather than going through a
4 traditional, you know, 90-page, 80-page or whatever
5 brand plan.

6 JUDGE CHAPPELL: Sir, I've heard you a couple
7 times start your answer with "I believe" or "I think."
8 Can we stick to what you actually know rather than what
9 you think or believe?

10 THE WITNESS: Sure.

11 JUDGE CHAPPELL: Thank you.

12 BY MR. SPRAGUE:

13 Q. Who would be within Endo the internal consumers
14 of a playbook or a brand plan for Opana ER?

15 A. A number of different constituents. That
16 would include cross-functional team members who are
17 responsible for implementing and helping to implement
18 some of the brand plan items to people who would be
19 responsible for reviewing and having appreciation for
20 what you're trying to do in order to approve the
21 strategy moving forward.

22 Q. Did you yourself create the playbook with
23 respect to Opana ER?

24 A. I did in conjunction with an ad agency who
25 helped us. They're the ones who technically created

1 it.

2 Q. Would you use the playbook in making your own
3 decisions?

4 A. Well, by default, having been creating or
5 participated in the creation of the playbook, you are
6 ostensibly enacting your own decision, right, so you --
7 yes.

8 Q. Are you familiar with the term "Revopan"?

9 A. Yes.

10 Q. What is Revopan?

11 A. It was a potential name for the follow-on
12 product that we were developing with Grünenthal for the
13 crush-resistant formulation.

14 Q. And just so the record is clear, when you say
15 "follow-on product," does that refer to the
16 reformulated version of Opana ER?

17 A. Correct.

18 Q. Ms. Allen, could we please bring up CX 2610.
19 002.

20 Mr. Bingol, do you recognize this, CX 2610?

21 A. Yes.

22 Q. Can we please move forwards to CX 2610-014.

23 I'd like to focus on the material that's on the
24 left of the chart here that says "Heritage of
25 Oxymorphone."

1 What does "heritage of oxymorphone" mean in
2 this playbook?

3 A. It's referring to the intrinsic qualities of
4 oxymorphone as a molecule that might have had -- that
5 might have meaningful importance to clinicians or
6 patients. And simply put in this case, in this
7 context, part of the benefits of a reformulated product
8 would be that we would retain these intrinsic
9 properties.

10 Q. What does "true 12-hour dosing" mean?

11 A. That referred to how the product was consumed.
12 You can -- in this case it was our contention that
13 Opana ER actually was dosed every twelve hours as per
14 its label maybe compared to the competition in some
15 cases where it might have been used more frequently, so
16 this was an actual benefit for patients looking for
17 every -- you know, twice-a-day dosing.

18 JUDGE CHAPPELL: You were in sales; right?

19 THE WITNESS: I started off in sales. Yes,
20 sir.

21 JUDGE CHAPPELL: And you were in sales until
22 when?

23 THE WITNESS: From '96 to '98.

24 JUDGE CHAPPELL: And what was your title when
25 you left?

1 THE WITNESS: Left sales?

2 JUDGE CHAPPELL: No. When you left the
3 company.

4 THE WITNESS: Senior director of marketing.

5 JUDGE CHAPPELL: You just said -- you just
6 referred to your competition.

7 What drugs do you consider the competition for
8 Opana ER?

9 THE WITNESS: At that time there were a number
10 of competitors.

11 JUDGE CHAPPELL: Let's say 2010.

12 THE WITNESS: It was OxyContin, maybe Avinza
13 and Kadian, generic long-acting morphine. Exalgo
14 perhaps was on the market then. I don't recall if it
15 was there then or not.

16 So there are a number of other long-acting
17 opioids that a clinician can choose from.

18 JUDGE CHAPPELL: Was that your job to know what
19 the competition was?

20 THE WITNESS: Yes, sir.

21 JUDGE CHAPPELL: Thank you.

22 MR. SPRAGUE: Thank you, Your Honor.

23 BY MR. SPRAGUE:

24 Q. Was true twelve-hour dosing a characteristic
25 that you hoped to differentiate Opana ER from these

1 other long-acting opioids?

2 A. It was one of several. As you see, obviously,
3 maybe not one in particular is ever the most important
4 but rather a constellation of characteristics that may
5 fit a patient type.

6 Q. And how did communicating the true twelve-hour
7 dosing characteristic of Opana ER assist your efforts
8 to market and differentiate Opana ER?

9 A. I'm sorry. Can you repeat your question.

10 Q. Sure.

11 How did this -- how did communicating this
12 characteristic of true twelve-hour dosing assist in
13 your efforts to differentiate Opana ER?

14 A. So this particular message might mean
15 different things to different constituents.

16 So for -- from a payer perspective, it was
17 reassuring perhaps to know that the drug wouldn't be
18 used more frequently than as prescribed, from a cost
19 perspective.

20 From a clinician or a patient perspective, it
21 had more of a clinical message to know that their pain
22 could be controlled with a reliable dosing scheme of
23 every -- you know, every twelve hours rather than
24 having to maybe rely on breakthrough medications, or if
25 the other long-acting opioids weren't maybe holding up

1 their value proposition, it might be dosed three times
2 or maybe up to four times a day.

3 Q. What does the term that's three bullets down,
4 "No CYP450 PK DDIs," mean?

5 A. That's referring to the metabolic pathway in
6 which several opioids are metabolized. And "DDIs"
7 really means drug-drug interactions.

8 So, again, because pain patients are often on
9 multiple medications, you -- the idea here is that the
10 one that has the least, let's say, or fewer drug-drug
11 interactions may be beneficial to certain patients on
12 different combinations of drugs.

13 Oxymorphone is metabolized through the liver
14 through glucuronidation, not through the
15 CYP450 enzymatic pathway, thereby potentially being
16 safer in some regards.

17 Q. Was that another characteristic that you hoped
18 would differentiate Opana ER from the other LAOs?

19 A. Yes. And again, in combination -- not any one
20 alone but certainly in combination as a total package,
21 if you will.

22 Q. How would communicating this lack of drug-drug
23 interactions differentiate Opana ER from other LAOs?

24 A. Again, other ones are metabolized through
25 the -- this particular enzymatic pathway, and

1 therefore you might have interactions with other drugs
2 that they may be taking. Or the patients may be fast
3 metabolizers or slow metabolizers through this
4 pathway, and if you're avoiding it, then you're
5 potentially able to avoid certain types of
6 interactions, potentially making a safer choice for a
7 patient.

8 Q. What does "low euphoria" mean?

9 A. In this context with this --

10 Q. Yes, sir.

11 A. Yeah -- it means that we were -- at that point
12 in time we had a study indicating that there was
13 perhaps less euphoria associated with patients taking
14 Opana ER versus I believe it was OxyContin at the
15 time -- in fact, it was OxyContin -- demonstrating I
16 believe that on every-twelve-hour dosing you were able
17 to function a little bit more clearheaded.

18 Q. And again, just for the record, why would that
19 be a benefit or why would that be a differentiating
20 characteristic that would assist you in marketing
21 Opana ER?

22 A. Well, the -- really the whole goal of effective
23 pain management is to help improve the patient's
24 quality of life. Pain is a symptom, not a condition
25 in and of itself, so when you're treating pain you want

1 to be able to improve their overall quality of life.
2 You don't want other things to be -- you know, to
3 inhibit their quality of life, so this is one thing
4 that would help them be more perhaps clearheaded and be
5 able to function more normally.

6 Q. Understood.

7 We can take that down, Ms. Allen.

8 Mr. Bingol, when you were senior marketing
9 director with responsibility for the Opana ER brand,
10 did you ever send e-mails to the sales leadership at
11 Endo?

12 A. Yes.

13 Q. Who were the sales leadership, as in what was
14 their function?

15 A. So sales leadership, of course, their primary
16 role is to manage the sales force, right. The
17 typical -- the typical structure of a sales
18 organization is that you have sales reps throughout the
19 country who report in to a district manager, district
20 managers will report in to a regional manager, and then
21 the regional managers will report in to the national
22 sales director or vice president of sales, as the case
23 may be.

24 Q. And generally, what would be your purpose in
25 communicating with the sales leadership?

1 A. It could be a variety of reasons, frankly. It
2 can be anything from updating on a change in
3 promotional message to sales training to -- to,
4 you know, having a two-way conversation with the sales
5 force to understand what the patients and/or clinicians
6 are saying about our product, so it's -- it's really a
7 two-way channel of communication back and forth between
8 sales and marketing.

9 Q. Understood.

10 Ms. Allen, could you please bring up CX 2731.

11 Is CX 2731 one of the e-mails that you sent to
12 the sales leadership?

13 A. Yes.

14 Q. I'd like to direct your attention to the first
15 full paragraph in the e-mail. It begins with "Please
16 see the news item below regarding another generic
17 OxyContin entrant."

18 A. Yes.

19 Q. Why are you forwarding a news item about
20 another OxyContin generic entrant to the sales
21 leadership?

22 A. Well, we forward all sorts of information to
23 the sales leadership when it concerns competitive
24 issues.

25 Q. So in this specific case, what was the purpose

1 of forwarding this? What were you trying to
2 communicate to the sales leadership?

3 A. In this particular case, it was a -- regarding
4 a generic form of OxyContin that was coming to the
5 market, and we wanted to let them know in case they
6 were asked questions by their customers about these
7 types of products.

8 Q. In the next paragraph, you told the sales
9 leadership, "This will no doubt increase the amount of
10 generic OxyContin in the market, but it does not change
11 our strategy."

12 Why was it your perspective that an increase in
13 the amount of OxyContin on the market does not change
14 your strategy?

15 A. Well, to be precise, it was about the amount of
16 generic OxyContin in the market and because a generic
17 OxyContin would potentially be a draw for clinicians to
18 prescribe because it would be cheaper than regular
19 OxyContin, and so as a -- a sales force typical
20 response would be, well, now we have something else to
21 have to deal with, and I was simply trying to explain
22 that the benefits of our product are the same whether
23 there's a generic or not, it doesn't matter, we should
24 be -- we should still be selling all the benefits of
25 our product to our clinicians.

1 Q. I see. Thanks for that -- thank you for that
2 clarification.

3 The next sentence reads, "Opana ER has
4 continued to grow in 2009 even though generic
5 OxyContin has been back in the market on a limited
6 basis."

7 How much did Opana ER grow in 2009 even though
8 generic OxyContin was on the market?

9 A. I don't recall the specific increases back
10 then.

11 JUDGE CHAPPELL: Let me make sure I understand
12 what you said.

13 Did I understand you to say basically OxyContin
14 was already on the market and adding a generic wouldn't
15 change the market share?

16 THE WITNESS: No, sir. I said it wouldn't
17 change our strategy in how we communicate the benefits
18 of our product to our customers.

19 JUDGE CHAPPELL: So from a purely marketing
20 standpoint, you would still push the benefits of your
21 drug to your customers?

22 THE WITNESS: The benefits of our product, if
23 you -- if you think about it on a molecular basis,
24 whether there's a brand or generic of OxyContin doesn't
25 really matter. It's still oxycodone which is the

1 active ingredient. And those intrinsic values that we
2 were discussing earlier on that slide compete -- we
3 were competing against their intrinsic value of their
4 molecule, so -- so whether or not there's a generic
5 OxyContin or a branded OxyContin in the marketplace, we
6 would still compete in some -- in some part based on
7 the -- those intrinsic qualities of the molecules.

8 Our molecule was still the better fit for
9 different types of patients. Whether there's generic
10 OxyContin or not didn't necessarily change that
11 dynamic.

12 JUDGE CHAPPELL: So whether there was one or a
13 thousand generics coming in didn't change that.

14 THE WITNESS: It doesn't change the underlying
15 characteristics of the molecules, no, which was the
16 point I was trying to make.

17 BY MR. SPRAGUE:

18 Q. Ms. Allen, we can take that down.

19 Thank you, Mr. Bingol, for telling the court
20 about Opana ER.

21 At this point I'd like to move on to talk about
22 a different court proceeding.

23 Mr. Bingol, when you were at Endo, did Endo
24 ever sue Impax?

25 A. Yes.

1 Q. Were you involved in that lawsuit?

2 A. Yes.

3 Q. In what way?

4 A. I -- I believe it was technically called an
5 expert witness, but I was -- I testified in that case.

6 Q. Did you testify in written form?

7 A. No. I appeared in a court in New Jersey.

8 Q. Did you also submit a declaration in that
9 lawsuit?

10 A. Yeah. I think there was a deposition
11 involved.

12 Q. I'm sorry.

13 A. I think -- I think a deposition was involved
14 beforehand.

15 Q. Thank you, sir.

16 Before the deposition, did you submit a
17 declaration?

18 A. I don't recall that.

19 Q. If I were to show you a document, might that
20 refresh your recollection?

21 A. It could.

22 Q. Ms. Allen, can we please bring up CX 3273.

23 Mr. Bingol, could you please take a look at
24 CX 3273.

25 (Document review.)

1 Your Honor, does CX 327- -- oh.

2 Does CX 3273 refresh your recollection as to --

3 JUDGE CHAPPELL: Is this in evidence?

4 MR. SPRAGUE: Yes, Your Honor. It was admitted
5 into evidence pursuant to JX 002, and it is not subject
6 to Your Honor's in camera order.

7 JUDGE CHAPPELL: Go ahead.

8 THE WITNESS: It doesn't refresh it
9 necessarily. I mean, obviously, there is one. I don't
10 know necessarily the technical difference between what
11 a declaration versus a deposition is, but clearly this
12 is what it says it to be.

13 BY MR. SPRAGUE:

14 Q. Can we please go to page 010 of CX 3273.

15 Mr. Bingol, is this your signature?

16 A. It is.

17 Q. Okay. Does that refresh your recollection as
18 to whether you submitted a declaration in the matter?

19 A. Clearly I did.

20 Q. Okay. You can take that down, Ms. Allen.

21 Do you recall signing CX 3273?

22 A. Not particular -- no, I don't recall it.

23 Q. Would you have signed a declaration if it did
24 not accurately reflect your knowledge and
25 understanding?

1 A. No.

2 Q. Ms. Allen, can we please bring up CX 3273 at
3 page 002.

4 Mr. Bingol, if you could please review
5 paragraph 2 of CX 3273.

6 You stated in the declaration --

7 JUDGE CHAPPELL: Do you want to give him time
8 to look at it? You asked him to review it.

9 MR. SPRAGUE: I apologize, Your Honor. Yes,
10 sir.

11 (Document review.)

12 THE WITNESS: Okay.

13 BY MR. SPRAGUE:

14 Q. Have you had a chance to review paragraph 2 of
15 CX 3273?

16 A. Yes.

17 Q. The first sentence reads, "I have been asked
18 to assume that Impax will make an at-risk launch of a
19 generic substitute for Opana ER around the
20 June 2010 time frame and to describe the impact of such
21 an at-risk launch on Endo's Opana business."

22 What is an at-risk launch?

23 A. That's a -- that's a potential launch by a
24 generic competitor prior to patent expiring.

25 Q. In the next sentence, you go on to say, "I note

1 that the factual circumstances I describe here will not
2 change substantially if Impax launches a generic
3 Opana ER substitute anytime later in 2010."

4 What did you mean with that sentence?

5 A. Actually, I'm not quite sure in this context
6 how that -- what that means.

7 Q. Ms. Allen, could we please move to page 004 of
8 CX 3273.

9 Mr. Bingol, could you please review
10 paragraph 8 and just let me know when you've had a
11 chance to review it, please.

12 A. Sure.

13 (Document review.)

14 Okay.

15 Q. The very last sentence of paragraph 8 reads,
16 "In fact, despite the presence of new entrants in the
17 market who are actively promoting their new products
18 (Embeda and Exalgo) and despite the fact that Endo's
19 promotional spend has declined, Endo's share of the
20 market with Opana ER continues to grow at a steady
21 rate."

22 What is the significance of that statement?

23 A. I think just what it says, that the product
24 continues to grow in the marketplace despite certain
25 competitive pressures and perhaps even internal

1 pressures in terms of budgets and whatnot.

2 Q. How were you able to grow Endo's sales of
3 Opana ER despite those competitive pressures?

4 A. It's due to a lot of different reasons.

5 It can be effective targeting of your messaging
6 to your clinicians and being consistent and steady in
7 that regard.

8 It can be as a result of your managed markets
9 rebating, you know, the rebates that you offer payers
10 in order to ensure that you have a competitive place on
11 formularies.

12 It can be because of certain competitors coming
13 and going that your product becomes a natural next
14 choice in the -- in their choice set.

15 A number of reasons.

16 JUDGE CHAPPELL: The first sentence in that
17 paragraph you were just telling us about starts out by
18 talking about the LAO market.

19 For the record, tell us what you mean by
20 "LAO."

21 THE WITNESS: Long-acting opioid.

22 BY MR. SPRAGUE:

23 Q. Mr. Bingol, the first reason you mentioned was
24 I believe effective targeting of your messaging to your
25 clinicians and being consistent and steady in that

1 regard.

2 What would be the components of that messaging
3 to your clinicians?

4 A. Again, it can be varied. If you're -- if
5 you're -- depending on, you know, understanding
6 geographically where a clinician is, that message might
7 be a little different. You might have a message where
8 you're talking again about the clinical benefits of the
9 product, but also you might combine that with a
10 formulary message because, you know, in -- maybe you
11 have a positive formulary position on a particular
12 healthcare plan that's relevant to that market or
13 Medicaid has decided to cover the product.

14 So there's a lot of different types of
15 messages. The effective part is to know kind of which
16 messages to kind of put together for the right
17 clinician given their particular needs in the
18 marketplace.

19 Q. Would the clinical benefits you just mentioned
20 be the same as those points of differentiation that we
21 were discussing earlier?

22 JUDGE CHAPPELL: Hold on a second.

23 You've got a document on the screen. You've
24 been asking the witness about a declaration. You need
25 to make it clear in the record, are you asking him

1 still about this declaration or what happened in the
2 context of his job at the time?

3 MR. SPRAGUE: I'm asking --

4 JUDGE CHAPPELL: You need to make it clear with
5 the witness, not me.

6 MR. SPRAGUE: I apologize, Your Honor.

7 JUDGE CHAPPELL: So the record is clear.

8 MR. SPRAGUE: Thank you, Your Honor.

9 BY MR. SPRAGUE:

10 Q. You mentioned generally that a strategy for
11 growing Opana ER sales might be message -- effective
12 messaging of clinical benefits; correct?

13 A. That is perhaps --

14 JUDGE CHAPPELL: Again, are you asking him
15 about the declaration or not? It's still on the screen
16 in front of him.

17 MR. SPRAGUE: Okay. I'm sorry, Your Honor.

18 Can we please take the CX 3273 down.

19 JUDGE CHAPPELL: Because when you said "you
20 mentioned," how does he know whether you're talking
21 about the declaration or his testimony.

22 MR. SPRAGUE: Thank you, Your Honor.

23 BY MR. SPRAGUE:

24 Q. I'm now going back to your testimony, sir.

25 Would these clinical differences you mentioned

1 be the same as these points of differentiation we were
2 discussing earlier in your testimony today?

3 A. They are part of the differentiation.

4 Q. And they were part of the differentiation,
5 would that be specifically with respect to Opana ER?

6 A. I don't understand that question. The
7 product -- the differentiation of the product --

8 JUDGE CHAPPELL: Hold it, hold it.

9 If you begin with "I don't understand it," then
10 don't answer.

11 THE WITNESS: Okay.

12 BY MR. SPRAGUE:

13 Q. I'm sorry. I'll rephrase.

14 Would communicating clinical differences of
15 Opana ER be part of the communicating the -- would --
16 excuse me. Let me strike that.

17 Would these points of differentiation of
18 Opana ER be part of the message of these clinical
19 differences you were communicating with respect to
20 Opana ER?

21 A. Yes.

22 Q. Ms. Allen, could we please pull up page 006 of
23 CX 3273.

24 Mr. Bingol, could you please take a minute to
25 review paragraph 15 of CX 3273.

1 (Document review.)

2 A. Okay.

3 Q. You stated in paragraph 15 that "Endo projects
4 that the Opana franchise, led by sales of Opana ER,
5 will continue to contribute significantly to the sales
6 revenue and profitability of Endo."

7 Why was the Opana franchise a significant --
8 and specifically led by sales of Opana ER, a
9 contribute -- a significant contributor to the sales
10 revenue and profitability of Endo?

11 A. Because it had been a successful product.

12 Q. Ms. Allen, could we please move to
13 paragraph 15, page 007, of CX 3273.

14 And if you need to read the first part of the
15 paragraph, we can go back to the prior page, please.

16 (Document review.)

17 A. I'm sorry. Were you going back to the first
18 part of the --

19 Q. Yeah. Can we please go back to the prior page
20 and so he can read the first part of the paragraph,
21 Ms. Allen. Thank you.

22 (Document review.)

23 Please let me know when you are ready to go to
24 the next page.

25 A. Okay. Thank you. Now I see. Next page is

1 fine.

2 Q. I'd like to ask you about the sentence -- it's
3 about halfway down, starts about halfway down, that
4 reads, "In addition, Endo routinely is involved with
5 and supports numerous medical education programs to
6 allow doctors to learn the benefits of Opana ER for
7 managing their patient's pain."

8 Were these medical education programs a
9 component of your marketing efforts?

10 A. Yes.

11 Q. How did they assist your marketing efforts?

12 A. By being able to describe the clinical benefits
13 of the product to the -- to the clinicians.

14 Q. And who would be the audience for these medical
15 education programs?

16 A. In this case, this would be peer to peer. If
17 you had a dinner somewhere, another clinician would be
18 discussing how they used the product and what they
19 found in their own practice with the product.

20 Q. Ms. Allen, can we please move to page 008,
21 paragraph 18.

22 And please take your time to review this
23 paragraph.

24 (Document review.)

25 A. Okay.

1 Q. Mr. Bingol, I'd like to focus on the first
2 sentence of this paragraph, which reads, "Endo
3 anticipates that upon launch of generic Opana ER by
4 Impax, Impax will set the price 15-20 percent lower
5 than the price of Endo's branded price during Impax'
6 180-day period of exclusivity."

7 What was the factual basis for your perspective
8 that Impax would set the price 15 to 20 percent lower
9 than Endo's branded price?

10 A. I don't recall a factual basis. It is --
11 traditionally in our market what happens is what's
12 described here. When a generic comes to market and
13 they have some exclusivity, they set the price lower
14 but not, let's say, significantly lower, because they
15 don't have to, so this was the assumption here that
16 15 to 20 percent would be lower.

17 Q. The next sentence --

18 JUDGE CHAPPELL: Let me clarify something for
19 the record here.

20 We have a fact witness here. He's sitting
21 here in court. Why don't you ask him what he knows
22 rather than talking about a declaration that was years
23 ago filed in another matter. What's the point of this?
24 Why don't you ask him the questions you want to ask
25 him.

1 MR. SPRAGUE: Certainly.

2 BY MR. SPRAGUE:

3 Q. Mr. Bingol, have you ever heard the term
4 "tier status"?

5 A. Yes.

6 Q. What does "tier status" mean?

7 A. It generally refers to formulary tiers through
8 a managed care plan, a payer of -- I guess it can be
9 also the -- government tiers. Maybe they have
10 Medicaid or Medicare. But they have tiers in which
11 they reimburse for different levels of your product.

12 Q. And what's the significance of these tiers?

13 A. Well, generally speaking, if a product is in
14 tier one, that's usually the easiest and fastest way
15 for the patients to gain access to your product at the
16 lowest cost possible.

17 Tier two usually is for a product that may be
18 unique but still maybe not a generic, and therefore
19 there may be different types of slightly stronger
20 restrictions to that product.

21 And then tier three and four, and so forth, it
22 gets more difficult, more restrictions in order to
23 reach -- for that product to reach the patient.

24 Q. Based on your experience in the pharmaceutical
25 industry, if a generic -- when generics are launched,

1 do they have any -- where are they placed on the
2 tiers?

3 A. Often they'll be at tier one.

4 Q. When you were at Endo, did you ever see any
5 forecasts about -- that modeled what would happen if
6 Impax launched a generic version of Opana ER?

7 A. Yes.

8 Q. What conclusion did those forecasts offer with
9 respect to what would happen to Endo's Opana ER market
10 share?

11 A. I would have to see them again to refresh my
12 memory, but in general, we modeled a number of
13 different scenarios, of which generic entry was one of
14 a number of different potential outcomes over the
15 course of years. As a brand leader, brand marketing
16 director, you have to plan for all the contingencies.

17 MR. SPRAGUE: Understood.

18 May I have a moment to consult with counsel,
19 Your Honor?

20 JUDGE CHAPPELL: Go ahead.

21 (Pause in the proceedings.)

22 MR. SPRAGUE: Ms. Allen, could we please bring
23 up CX 3273 page 008.

24 JUDGE CHAPPELL: You never answered my
25 question earlier. You need to tell me why you keep

1 asking the witness about a document from a prior case,
2 if you're going right back to it again and you never
3 answered my question. What's the point of this?

4 You didn't lay a foundation for this
5 declaration. There's no foundation at all. I'm not
6 going to let you read from this with the witness
7 sitting right here. He's a fact witness, so explain it
8 to me or move on.

9 MR. SPRAGUE: Your Honor, it reflects the --

10 JUDGE CHAPPELL: Take the document down.

11 MR. SPRAGUE: Your Honor, it reflects the
12 understanding and expectations of Endo at the time when
13 launch of Impax' generic was a possibility.

14 JUDGE CHAPPELL: Yet you haven't asked the
15 witness this question. You don't know what his answer
16 is. Why don't you ask him, before you bring up a
17 document that's 10 so many years old to feed it to him.
18 Let's see what he knows. Stop leading.

19 MR. SPRAGUE: Yes, Your Honor. I'll do that.

20 BY MR. SPRAGUE:

21 Q. Mr. Bingol, as of 2009, had Endo offered
22 any -- had Endo -- had you seen, while you were at
23 Endo, any forecasts about the impact of generic entry
24 by Impax?

25 A. I recall forecasts for assuming generic entry.

1 I don't recall if it was specific to Impax or there
2 were a number of potential competitors at the time.

3 Q. What did those forecasts suggest would be --
4 what did those forecasts indicate would be the impact
5 on Endo's market share if a generic were to enter the
6 market?

7 A. Again, I don't recall the specifics at this
8 point. I would need to refresh my memory by seeing a
9 forecast.

10 Q. In 2010, what was your expectation of what
11 entry by Impax would do to Endo's sales of Opana ER?

12 A. Again, in general, any generic entry would
13 have a negative reduction in sales on a branded
14 business, and those were the basic assumptions that we
15 were operating under in terms of, you know, trying to
16 plan for this particular contingency.

17 Q. Understood.

18 Mr. Bingol, I would like to move on from this
19 topic to the topic of reformulated Opana ER.

20 Do you recall, was there a project name for
21 Endo's efforts to launch a reformulated version of
22 Opana ER?

23 A. I don't recall the specific project name, but
24 there probably was one.

25 Q. Why did Endo undertake these efforts to

1 reformulate Opana ER?

2 A. Well, it's part of really our -- you know, as a
3 marketing director, you're looking out for trends in
4 the marketplace. You're trying to see where the market
5 is heading.

6 This particular reformulation was going to
7 potentially offer a safer product to the market and
8 therefore allowing us to offer the best product and
9 safest product that we could for our customers.

10 Q. Was it a goal of yours to launch this safer
11 product as soon as you were able to?

12 A. Yes.

13 Q. Why was that the case?

14 A. You -- one always does. You know, when you
15 have a product launch opportunity, the quicker you can
16 get to market, the better.

17 Q. During the time you were at Endo, was it always
18 your goal to launch reformulated Opana ER as soon as
19 Endo was able to?

20 A. I -- yes. From the moment that I was aware of
21 the project. When I first got to Endo, of course, I
22 was not aware that there was a reformulation project
23 underway.

24 Q. I think earlier we talked about that it was
25 potentially a scenario that Impax could launch a

1 generic in 2010?

2 A. Yes.

3 Q. Do you recall?

4 A. Yes.

5 Q. Okay. Was Endo expecting at any point to
6 launch reformulated Opana ER prior to 2010?

7 A. At different points in time, you know, you have
8 assumptions around when you can launch, and maybe a
9 development program doesn't go quite the way you like,
10 so I mean, there are different -- probably different
11 points in time when we thought we might launch that,
12 but...

13 Q. Were there any scenarios in forecasts at Endo
14 at the time you were there when it was possible Impax
15 could launch its generic version of Opana ER before
16 Endo launched reformulated Opana ER?

17 A. I believe there was a scenario like that.
18 Yes.

19 Q. During the time you were at Endo, what was
20 your anticipated launch date for reformulated
21 Opana ER?

22 A. When I left, we had yet to file or were just
23 filing, so the actual anticipated launch date was
24 sometime after I left the company.

25 Q. And if I -- can you tell me again when you left

1 the company.

2 A. June 2011.

3 Q. When you were at Endo, did you provide
4 commercial updates with respect to reformulated
5 Opana ER?

6 A. Yes.

7 Q. What was the purpose of a commercial update?

8 A. It depends on the topic at hand, so it could be
9 anything that's relevant that needs to be communicated
10 to either management or other cross-functional team
11 members.

12 Q. I understand.

13 Ms. Allen, could we please bring up CX 2573.

14 Your Honor, CX 2573 has been admitted pursuant
15 to JX 002 and is not subject to Your Honor's in camera
16 ruling.

17 JUDGE CHAPPELL: Thank you.

18 You still need to foundationally connect this
19 witness to the document rather than just have him agree
20 to it. Keep that in mind.

21 MR. SPRAGUE: Yes, Your Honor.

22 BY MR. SPRAGUE:

23 Q. Mr. Bingol, have you seen EN3288 Commercial
24 Update -- CX 2573 before?

25 A. Yes.

1 Q. What is CX 2573?

2 A. It's an update on the project EN3288, which is
3 the project for the reformulated product.

4 Q. What is EN3288?

5 A. That's the project name that -- the internal
6 project name for the reformulated project -- product,
7 rather.

8 Q. This notes under the -- CX 2573 notes under
9 your name "EN3288 Launch Leader."

10 What is a launch leader?

11 A. That just was the designation, that somebody
12 has to be the project leader for each individual
13 project, and in this case to prepare for launch it was
14 me.

15 Q. CX 2573 at 002 is dated February 24, 2010.

16 Was that approximately the time you were
17 providing this particular commercial update?

18 A. That's what it says. Yes.

19 Q. Can we please move to page 004, Ms. Allen.

20 JUDGE CHAPPELL: Excuse me. Put that screen
21 back up.

22 What does it say at the bottom in red?

23 THE WITNESS: "Draft - Not Approved by
24 Management."

25 JUDGE CHAPPELL: And you just asked him when he

1 provided this update. Why don't you clarify for the
2 record, because it says it's a draft. Why would he
3 have presented a draft to anybody?

4 BY MR. SPRAGUE:

5 Q. Mr. Bingol, did you present this draft to
6 anyone?

7 A. I don't recall to whom this would have been
8 shared with in this version.

9 Q. Do you recall creating this document?

10 A. No, I don't recall it specifically.

11 MR. SPRAGUE: Your Honor, may I have an
12 opportunity to consult with co-counsel?

13 JUDGE CHAPPELL: Go ahead.

14 (Pause in the proceedings.)

15 BY MR. SPRAGUE:

16 Q. Mr. Bingol, did you routinely mark documents
17 "Draft - Not Approved by Management"?

18 A. When they were draft and not approved by
19 management, yes.

20 Q. Did you ever take that, that language, off of
21 this particular document?

22 A. I don't recall.

23 Q. Prior to launching reformulated Opana ER, did
24 you ever see forecasts of the sales of reformulated
25 Opana ER?

1 A. Yes.

2 Q. Did those forecasts vary depending on the
3 scenario?

4 A. Yes.

5 Q. Why would you develop forecasts for various
6 scenarios?

7 A. It's part of the job. You have to try to plan
8 ahead, see the future if you can, know what's -- what
9 might impact your business and try to articulate that,
10 and it usually comes out through a forecast
11 ultimately.

12 Q. And what were the different assumptions made in
13 creating these various forecasts relating to
14 reformulated Opana ER?

15 A. I mean, there's a lot of different assumptions
16 that can go into the forecast, so I wouldn't be able to
17 tell you exactly which ones today.

18 Q. Ms. Allen, can we please pull up CX 2724.

19 Mr. Bingol, could you please review CX 2724.

20 (Document review.)

21 Your Honor, CX 2724 has been admitted into
22 evidence and is not subject to Your Honor's in camera
23 order.

24 JUDGE CHAPPELL: Are you going to ask the
25 foundational question before you refresh recollection

1 rather than just flashing this up on the screen and
2 letting him read it?

3 MR. SPRAGUE: Yes, Your Honor.

4 BY MR. SPRAGUE:

5 Q. Mr. Bingol, have you seen CX 2724 before?

6 JUDGE CHAPPELL: I didn't mean that. I meant
7 the question that most attorneys ask, like is there
8 something that would refresh your recollection. I
9 didn't hear that. I haven't heard that all day today.

10 MR. SPRAGUE: Okay.

11 BY MR. SPRAGUE:

12 Q. Mr. Bingol, is there something that would
13 refresh your recollection as to what different
14 assumptions went into forecasts relating to
15 reformulated Opana ER?

16 A. Yes.

17 JUDGE CHAPPELL: Let me just say, the witness'
18 last answer before that was "I wouldn't be able to tell
19 you exactly which ones today." You don't go from that
20 answer, sir, to putting a document up, right into
21 asking him questions about it. A foundation is
22 required in this court.

23 MR. SPRAGUE: Yes, Your Honor.

24 JUDGE CHAPPELL: Go ahead.

25 MR. SPRAGUE: Okay.

1 BY MR. SPRAGUE:

2 Q. Sitting here today, do you remember what --

3 JUDGE CHAPPELL: Because otherwise you're
4 leading the witness, which you're on direct exam,
5 you're not allowed to do.

6 MR. SPRAGUE: Yes, Your Honor. Thank you.

7 BY MR. SPRAGUE:

8 Q. Mr. Bingol, sitting here today, do you recall
9 what assumptions went into the forecasts relating to
10 reformulated Opana ER?

11 A. Not all of them, no.

12 Q. If you were to look at a document, might that
13 refresh your recollection?

14 A. Yes.

15 Q. Ms. Allen, can we please put up CX 2724.

16 Mr. Bingol, can you please review CX 2724.

17 (Document review.)

18 A. Okay.

19 Q. Does this refresh your recollection as to the
20 assumptions that went into forecasts relating to
21 reformulated Opana ER?

22 A. It refreshes my recollection of these
23 particular assumptions. Certainly there are more than
24 just these that go into a forecast.

25 Q. Thank you.

1 I'd like to understand these particular
2 forecasts a little better.

3 Do you recall sending CX 2724 to Dave Holveck?

4 A. No, I don't recall that.

5 Q. Who is Dave Holveck?

6 A. He was the CEO of Endo at the time.

7 Q. When you provided information to Mr. Holveck,
8 were you trying to provide him with information that
9 was as accurate as possible?

10 A. It was based on scenarios that we had created,
11 I mean, the accuracy of which are always debatable.

12 Q. Do you have any reason to believe you did not
13 send this e-mail to Mr. Holveck?

14 A. No.

15 Q. The first sentence of this e-mail reads, "Brian
16 asked me to follow up with you in his absence regarding
17 the potential launch curves for EN3288."

18 Who is Brian?

19 A. That would refer to Brian Lortie.

20 Q. And what was Mr. Lortie's position?

21 A. He was my direct manager. I believe his title
22 was vice president of commercial products at that
23 time.

24 Q. In the third sentence of this e-mail, you note,
25 "We forecast a conversion of about 25 percent of all

1 existing oxymorphone business with EN3288 (the black
2 line on the graph below) if we launch after the advent
3 of generics."

4 What does "advent of generics" mean?

5 A. It means the introduction of a generic or
6 generics, products in the market.

7 Q. Why did you estimate about 25 percent
8 conversion if Endo launched its reformulated version of
9 Opana ER after the advent of generics?

10 A. That was referring to the reformulated product
11 having the potential for a safer product based on its
12 crush-resistant formulation, we would be able to -- to
13 retain roughly 25 percent of the existing oxymorphone
14 business if -- on a molecular basis again, based on
15 clinicians' and patients' desire to have a
16 crush-resistant tablet.

17 Q. Can we please move to page 005 of CX 27- --
18 well, excuse me. Let's go to 002 of CX 2724.

19 What does "commercial strategy scenarios"
20 mean?

21 A. Different scenarios that were potential to be
22 considered by the marketing group.

23 Q. Did you prepare CX 2724?

24 A. I don't recall.

25 Q. Is there anything that would refresh your

1 recollection as to whether you prepared it?

2 A. Perhaps. But we had a -- you know, a brand
3 team. It could have been prepared by somebody else in
4 the team. It certainly came from the commercial
5 group.

6 Q. Okay. Were you part of the commercial group?

7 A. Yes.

8 Q. Can we please move to page 005.

9 Have you seen this chart that's on page 005 of
10 CX 2724 before?

11 A. Yes.

12 Q. What does the column Scenario mean?

13 A. Well, these are basic scenarios or differences
14 that can happen in order to generate maybe a different
15 view of the business.

16 Q. What does the column --

17 A. Different events that could occur. Excuse me.

18 Q. Thank you.

19 What does the column Launch Date mean?

20 A. It's a -- again, a potential launch date for
21 that particular scenario.

22 Q. And does -- what -- launch of what product?

23 A. I would have to -- let me reread it to make
24 sure.

25 This is regarding the reformulated product.

1 Q. What does the scenario "With Claims/Ahead of
2 Generics" mean?

3 A. This is referring to the potential for FDA
4 acknowledging the tamper resistance or the crush
5 resistance of the product and allowing it to have
6 specific statements in its product label that would
7 differentiate this product.

8 JUDGE CHAPPELL: What does "claims" mean here?
9 Just the word "claims," what does that mean?

10 THE WITNESS: Labeling claims.

11 So if it was in the label that it was a
12 crush-resistant product, that would be a claim you
13 would make, be able to make promotionally. If it had
14 any other kinds of attributes that the FDA would
15 acknowledge in the label, we would consider that a
16 claim that you could then promote on to the market.

17 JUDGE CHAPPELL: So here are you referring to
18 claims that you would like to make as the marketer of
19 the drug?

20 THE WITNESS: Whether you would like to or
21 whatever the FDA grants you, as long as your label was
22 different and highlighted those characteristics in a
23 way that was meaningful, then that would be considered
24 a claim.

25 So we could -- we could demonstrate that the

1 product had this quality or attribute in terms of crush
2 resistance and what that might have -- you know, what
3 data supported that could also be in the label, and
4 then you could promote with that.

5 JUDGE CHAPPELL: And there are three scenarios
6 here?

7 THE WITNESS: Yes.

8 JUDGE CHAPPELL: And in all three scenarios the
9 claims you referred to are the same?

10 THE WITNESS: Yes.

11 JUDGE CHAPPELL: Tell me again what were just
12 the claims you're referring to.

13 THE WITNESS: Correct.

14 JUDGE CHAPPELL: Tell me what they are again.

15 THE WITNESS: Well, you don't really know until
16 you get the labeling from the FDA, but probably --

17 JUDGE CHAPPELL: Okay. Well, I don't want you
18 to guessing, so according to this document, whatever
19 those claims were you didn't know.

20 THE WITNESS: Well, we would be -- that's
21 correct. You really don't know until the FDA gives
22 them to you, but we would be submitting data on its
23 tamper-resistant qualities and whether or not we have
24 drug liking studies and things of that nature that you
25 conduct in order to prove that you have a better -- or

1 the benefits of tamper resistance was there. You would
2 want those data in your label to be able to promote
3 them.

4 JUDGE CHAPPELL: And I tried to get this answer
5 earlier, but I may not have asked it clearly.

6 You're a marketing person; right?

7 THE WITNESS: Correct.

8 JUDGE CHAPPELL: And again, aren't the claims
9 you're referring to claims that you would like to make
10 from a marketing perspective?

11 THE WITNESS: Correct.

12 BY MR. SPRAGUE:

13 Q. With respect to this particular slide, what
14 does the whole phrase "With Claims and Generics" mean?

15 A. It's a scenario in which you -- we were granted
16 the claims that we were seeking and the generics were
17 already on the market or about -- launching about the
18 same time.

19 Q. Can we please move to page 006 of 2724,
20 Ms. Allen.

21 Do you recall seeing this slide before?

22 A. Yes.

23 Q. What does the gold line in this chart depict?

24 A. That is the assumed trend of the potential
25 sales if the product were launched with claims and

1 ahead of generics.

2 Q. To be precise, when you say "potential sales,"
3 what potential sales are you talking about?

4 A. The forecasted sales, estimated sales of the
5 reformulated product.

6 Q. What does the purple line in this chart
7 depict?

8 A. That would be launching a product without any
9 claims whatsoever, so the label would be identical to
10 the current label of the current product.

11 Q. And the legend on the right, the purple line
12 says "No Claims (AB-Rated)"?

13 A. Correct.

14 Q. What does "AB-rated" mean?

15 A. That's a term that's used to describe the ease
16 with which -- it's a regulatory term, but it basically
17 is talking about the ease of substitutability at the
18 pharmacy. If a product is AB-rated one to another,
19 the pharmacists can make a distinction or
20 determination as to which product they would like to
21 fill, whether it's a brand or generic or any other
22 AB-rated product that's been considered therapeutically
23 equivalent.

24 Q. What does the blue line in this chart depict?

25 A. It's green on my screen, but do you mean the

1 green line?

2 Q. Green.

3 A. That's a scenario in which we have Opana ER
4 only, the current formulation, with generics.

5 Q. And finally, what does the black line depict?

6 A. It depicts the reformulated product with claims
7 and the advent or the launch of generics.

8 MR. SPRAGUE: Your Honor, may I take a moment
9 to consult with my co-counsel?

10 JUDGE CHAPPELL: Yeah.

11 Before you do, so if I understand this, you
12 were looking at any possible scenario.

13 THE WITNESS: Yes.

14 JUDGE CHAPPELL: For example, you really
15 thought there was a scenario where you would have to
16 launch what you considered a differentiated version of
17 the drug that's crushproof without being able to put
18 that on the label or tell people about that?

19 THE WITNESS: We have to consider all
20 scenarios, and that was one particular scenario that
21 was available to us.

22 JUDGE CHAPPELL: Thank you.

23 (Pause in the proceedings.)

24 MR. SPRAGUE: Thank you, Mr. Bingol.

25 At this time, Your Honor, I have no further

1 questions for Mr. Bingol.

2 JUDGE CHAPPELL: Any cross?

3 MR. ANTALICS: Yes, Your Honor.

4 JUDGE CHAPPELL: Go ahead.

5 - - - - -

6 CROSS-EXAMINATION

7 BY MR. ANTALICS:

8 Q. Good morning, Mr. Bingol.

9 A. Good morning.

10 Q. You recall I think we met once at your
11 deposition?

12 A. Yes.

13 Q. During your direct examination, Mr. Bingol,
14 Judge Chappell asked you to name some of your
15 competitors.

16 If I were to show you a document where you
17 listed your direct competitors, would that refresh your
18 recollection to more fully answer that question?

19 A. Yes.

20 Q. Okay. Can you put up 26- -- CX 2610, please,
21 page 24.

22 JUDGE CHAPPELL: Well, actually, I asked a
23 follow-up. He mentioned competitors but didn't tell us
24 who they were.

25 MR. ANTALICS: Right. I think he mentioned a

1 couple of them.

2 JUDGE CHAPPELL: He brought up the competitors.

3 I followed up.

4 MR. ANTALICS: Right. That's what I meant to
5 say, Your Honor.

6 BY MR. ANTALICS:

7 Q. This was from a document that you looked at
8 earlier today, the playbook; correct?

9 A. Yes.

10 Q. Yeah. Okay.

11 Okay. If you could, highlight the first
12 column, please.

13 Now, Mr. Bingol, are those the companies -- in
14 the column that's labeled Direct Competitors, are those
15 the ones that you were referring to when you began to
16 answer Judge Chappell's question?

17 A. Yes.

18 Q. Okay. Now, just to clarify a little bit more
19 the second column then, could you highlight that.

20 Okay. And the second column, could you
21 describe what that is meant to portray.

22 A. Those are the active ingredients of those
23 particular products.

24 Q. Okay. So for example --

25 JUDGE CHAPPELL: Hold on a second.

1 Just so we're clear, why do you consider those
2 in that column direct competitors to Opana ER?

3 THE WITNESS: For a couple of reasons. Two --
4 well, primarily because they are all long-acting opioid
5 formulations, so --

6 JUDGE CHAPPELL: What you called LAOs earlier
7 today?

8 THE WITNESS: Yes, sir.

9 And then these are also the ones that I
10 believe at the time were actively promoted, and so they
11 had -- you know, we would have share of voice in the
12 market trying to separate our product from other
13 actively promoted products.

14 For the sake of completeness, you would also
15 then add in as another potential competitor would be
16 generic long-acting morphine, which is not on this list
17 because it's generic, nobody is promoting, it and we
18 didn't see that as a potential direct competitor in
19 that context.

20 JUDGE CHAPPELL: Go ahead.

21 BY MR. ANTALICS:

22 Q. Okay. Now, could you highlight the column all
23 the way to the right.

24 Now, Mr. Bingol, you talked earlier on direct
25 about differentiating your product.

1 Would this column be an example of how you
2 might differentiate your product against the
3 competitors?

4 A. Correct. These would be, as it says, key
5 advantages. It doesn't necessarily mean it's all of
6 the advantages but what we kind of -- if you tried to
7 simplify and distill down to kind of the essence of
8 how you're going to compete against these, these were
9 the elements that we thought offered the best
10 opportunity to compete against those products based on
11 their profile and what they brought to the market.

12 Q. So is the point of differentiating your product
13 then -- could you describe what the main point of
14 differentiating your product is.

15 A. Well, you always want to make -- there always
16 has to be a reason to prescribe your product, and if
17 you're not different from others, then there's
18 essentially no reason to prescribe it. These are the
19 features that help to highlight those differences so
20 that the clinician can make the best choice for the
21 patient.

22 JUDGE CHAPPELL: I want to make sure the record
23 is clear.

24 Are you saying that these drugs that are
25 listed here are competitors in the market for Opana ER

1 or just for what's going to be the new crushproof
2 version?

3 THE WITNESS: Both actually.

4 So when you're competing in the long-acting
5 opioid space, you're competing against at least -- and
6 as a marketer, you have the purview to kind of define
7 your market and your competitive set as you like. In
8 our case, this is how I was defining the market,
9 long-acting opioids. And therefore, once we introduced
10 the reformulated Opana ER, these would still be the
11 same direct competitors.

12 BY MR. ANTALICS:

13 Q. Okay. That's enough of that document.

14 Mr. Bingol, do you recall what Opana ER's
15 market share of the long-acting opioid market was back
16 in the early part of 2010?

17 A. I don't recall specifically.

18 Q. If I would show you a document where you
19 calculated that, would that help refresh your
20 recollection?

21 A. Yes.

22 Q. Okay. Could you show -- pull up the document
23 that we've seen before. It's CX 3273, which was your
24 declaration that you spoke about at length.

25 If you could just turn to page 3, please, of

1 that declaration.

2 And if you could highlight the chart on the
3 bottom there. Okay.

4 So -- okay. Is that -- that's Opana ER down on
5 the left column, the fourth drug down?

6 A. Correct.

7 Q. Okay. And then if you scroll over to the last
8 column, where it says March of 2010, does that indicate
9 to you what Opana ER's market share was in March of
10 2010?

11 A. Yes.

12 Q. And how much was that?

13 A. 3.4 percent.

14 Q. And that's of the long-acting opioid market?

15 A. Yes.

16 Q. Now, you also talked at some length earlier
17 about some forecasts that might show that -- no, if you
18 could keep that up, please, I think just for one more
19 question or so.

20 You talked earlier about some forecasts where
21 if Impax entered with a generic version, how it would
22 impact Opana ER's sales; correct?

23 A. Correct.

24 Q. Okay. And Opana ER's sales would go down if
25 Impax entered with a generic product?

1 A. Yes.

2 Q. Okay.

3 JUDGE CHAPPELL: Hold on a second.

4 Since we're hearing so much about this
5 declaration, and again, you weren't even sure you had
6 signed a declaration, and I believe you were asked if
7 you submitted it, you in fact didn't submit it,
8 somebody else would have submitted it to the court;
9 correct?

10 THE WITNESS: I don't recall exactly.

11 JUDGE CHAPPELL: If it was submitted, you
12 didn't actually submit it yourself.

13 THE WITNESS: No.

14 JUDGE CHAPPELL: But you don't argue the point
15 whether it was actually submitted in court.

16 THE WITNESS: No.

17 JUDGE CHAPPELL: Do you know enough about the
18 case that the declaration is involved or refers to?
19 What was the case?

20 THE WITNESS: The case was the patent
21 infringement suit.

22 JUDGE CHAPPELL: And what was -- it was a
23 patent infringement case by your company Endo against
24 respondent here, Impax?

25 THE WITNESS: Yes.

1 JUDGE CHAPPELL: And what was the point your
2 side was trying to make in that case?

3 THE WITNESS: Honestly, I don't recall what the
4 overall point in the case was. I was there
5 representing the commercial interests or being an
6 expert witness on the commercial aspects of the
7 product.

8 JUDGE CHAPPELL: So you're not sure, at least
9 as of today, what the point was of the case?

10 THE WITNESS: Well, I think in general we
11 wanted obviously to not have a -- you know, to not have
12 a generic come to market or to stop Impax from bringing
13 a generic to market, as we would with any other generic
14 competitor.

15 JUDGE CHAPPELL: But again, if I asked you what
16 position your side was advocating at the time you would
17 have signed this declaration, do you know the answer to
18 that?

19 THE WITNESS: I don't recall off the top of my
20 head.

21 JUDGE CHAPPELL: Go ahead.

22 MR. ANTALICS: Thank you.

23 BY MR. ANTALICS:

24 Q. Okay. So we were talking about losing some --
25 potentially losing sales to a generic from Impax if it

1 entered the market. And I just want to put it in
2 context.

3 So what we're talking about then is, looking at
4 the market share chart here, we -- you would be losing
5 some of that 3.4 percent market share to Impax; is
6 that -- is that what would happen?

7 A. Correct.

8 Q. Okay.

9 Okay. That's enough on that.

10 You talked a little bit about formularies on
11 direct examination.

12 Could you describe the different tiers of a
13 formulary, please.

14 A. There -- well, the first tier -- there's
15 multiple tiers, and different payers may have
16 different tiers. Not all of them have the same number
17 of tiers.

18 But in general, the first tier is usually
19 reserved for, let's say, generic products. And
20 you know, that might be something that gets
21 automatically bestowed upon a generic upon entry.

22 The second tier is usually reserved for
23 products that are unique without maybe other
24 competitive products in the set or may be first to
25 market in a category. However, to get to those you

1 have to maybe have different restrictions or a slight
2 restriction. Maybe you fail a tier one product first.
3 Maybe you can go right to a tier two product depending
4 on the diagnosis or the need of the -- what's -- in
5 terms of alternatives.

6 Tier three usually is more restrictive. You
7 may be competing with something that's in a tier two,
8 and you have to fail that product in a tier two first
9 before you can get to a tier three.

10 But it's all about access. What these tiers
11 really are from managed care, it's their way of trying
12 to control costs in the marketplace by restricting
13 access to certain categories of products.

14 Q. So the -- does the -- the insurance company
15 then tries to encourage people to use the top tier, the
16 most preferred tier; is that what you're saying?

17 MR. SPRAGUE: Objection, Your Honor.
18 Foundation.

19 JUDGE CHAPPELL: Response?

20 BY MR. ANTALICS:

21 Q. Mr. Bingol, do you have an understanding of how
22 formulary tiers work based on your work for Endo?

23 A. Yes.

24 JUDGE CHAPPELL: So your response was: I'll
25 lay a foundation? You didn't respond to the

1 objection.

2 MR. ANTALICS: Oh. I think the -- yes. The
3 response to the objection is he -- Mr. Bingol, as part
4 of his business, works with formularies and has to
5 understand how formularies work on a day-to-day basis.
6 I think he can describe how they work.

7 JUDGE CHAPPELL: I'm not sure that was clear.
8 I would have sustained the objection, but you asked a
9 foundational question and he said, "Yes."

10 Go ahead.

11 BY MR. ANTALICS:

12 Q. So is the idea that the insurance company --
13 you mentioned they're trying to control costs.

14 Are they trying to steer the business towards
15 the most preferred tier?

16 MR. SPRAGUE: Objection, Your Honor. Leading.

17 JUDGE CHAPPELL: He's on cross.

18 MR. SPRAGUE: Your Honor, Mr. Bingol is the
19 respondent's witness.

20 JUDGE CHAPPELL: I understand that. But I
21 listened to the man all morning, and he was not adverse
22 or hostile or uncooperative to you in any way.

23 Overruled.

24 MR. SPRAGUE: Yes, Your Honor.

25 THE WITNESS: Generally speaking, they use the

1 tiers as a way to control their costs, and therefore,
2 they tend to steer their patients to the higher tiers.

3 BY MR. ANTALICS:

4 Q. What is a copay in the context of a formulary?

5 A. "Copay" particularly refers to that portion of
6 the product expense that the patient bears.

7 Q. Okay. And will --

8 JUDGE CHAPPELL: Hold on a second.

9 Stand up.

10 MR. SPRAGUE: Yes, Your Honor.

11 JUDGE CHAPPELL: Where do you come off saying
12 it's respondent's witness? Didn't you call this
13 witness?

14 MR. SPRAGUE: Yes. But he's also listed on
15 respondent's witness list as well. That's what I meant
16 by he's respondent's witness. And they're doing direct
17 right now, Your Honor.

18 MR. ANTALICS: I think these are all --

19 JUDGE CHAPPELL: Are you doing direct right
20 now?

21 MR. ANTALICS: I think I'm doing cross to all
22 of the areas I would have covered on his direct
23 examination.

24 JUDGE CHAPPELL: Are you still within the scope
25 of direct?

1 He's allowed to cross within the scope of your
2 direct, just so we're clear.

3 MR. SPRAGUE: Yes, Your Honor. I don't believe
4 we discussed copays in his direct.

5 JUDGE CHAPPELL: I heard you ask him about
6 tiers, but I don't remember copays. Foundation.

7 Bring it within the scope of the direct with
8 foundation.

9 MR. ANTALICS: Thank you, Your Honor.

10 BY MR. ANTALICS:

11 Q. Is the term "copay" something that is used in
12 connection with formulary tiers?

13 A. Yes.

14 MR. ANTALICS: Okay. May I proceed,
15 Your Honor?

16 JUDGE CHAPPELL: Go ahead.

17 BY MR. ANTALICS:

18 Q. Can you describe how copays work in a fashion
19 that might affect, if it does, the particular drug that
20 a patient will be prescribed?

21 A. So copays vary according to tiers, they can,
22 and they can be in various amounts even within a
23 particular tier.

24 Generally speaking, a tier one patient or
25 product, I should say, may have zero copay because it's

1 considered the most economically advantageous to the
2 plan or to the payer.

3 There may be a copay for a tier two product
4 that could be anywhere from \$10 to \$20-25.

5 A tier three, it goes progressively higher and
6 the copays get more restrictive, the idea of course
7 being to try to manage those costs and to get patients
8 to select the more economical -- what the plan deems to
9 be the more economical choice for the patient.

10 Q. Now, from Endo's perspective, would Endo try to
11 be placed on any particular tier in a formulary?

12 A. Yes.

13 Q. Could you describe how that works.

14 A. That's -- that's part of the competition that
15 goes on in the marketplace, because the way our system
16 is set up, of course, the payers are not the ones
17 consuming the products, so there's an element of
18 competition that goes on at the managed care level, and
19 so companies jockey for trying to get the most
20 advantageous tier they can to have greater access of
21 their product to patients.

22 Q. How would you go about trying to get to a
23 better tier?

24 A. Typically by offering rebates to the payers.
25 If you don't -- if your product is not a generic and

1 you're not automatically on tier one, then you are
2 looking at tier two or three typically. And if there
3 is a choice to be made amongst multiple products, then
4 you rebate within that category and create a financial
5 position for the payer that is justifying their putting
6 you on tier two or three or four or five. Sometimes
7 today there's four or five tiers.

8 Q. Is the concept of couponing related to
9 formulary tiers?

10 A. Yes. It can be.

11 Q. Okay. In what sense are coupons related --
12 first describe what a coupon is and how it's related to
13 a formulary tier.

14 A. There are probably a number of different ways
15 to coupon, but generally speaking, you're offsetting
16 the copay for the patient through a coupon.

17 So if a patient has a copay of \$25, then you
18 may offer that \$25 coupon to the patient so that their
19 net out-of-pocket is going to be zero, or you reduce
20 their copay significantly enough such that the --
21 the -- the impact on them, regardless of your tier,
22 becomes mitigated somewhat or eliminated even.

23 Q. So does that mean you're going somehow directly
24 to the consumer?

25 A. There is an element of that of course that you

1 would offer those types of rebates or coupons, I should
2 say, to consumers directly, either online or through
3 physicians' offices.

4 Q. Okay. So you mentioned that you're jockeying
5 for position with other insurance companies.

6 Are you competing with other insurance
7 companies for favorable access?

8 A. No. You're competing with other --

9 JUDGE CHAPPELL: Hold on a second.

10 Other insurance companies? I don't think he's
11 an insurance company.

12 MR. ANTALICS: I'm sorry. I'm sorry,
13 Your Honor. I misspoke.

14 BY MR. ANTALICS:

15 Q. Are you competing with other manufacturers of
16 long-acting opioids for more preferred access?

17 A. That is correct.

18 Q. Okay. So are you competing with other
19 manufacturers of branded long-acting opioids for more
20 favorable access?

21 A. Yes.

22 Q. Okay. And do you also compete with
23 manufacturers of generic companies for access to
24 patients?

25 A. You do in a clinical sense.

1 Q. Okay. Do you ever offer discounts in order to
2 compete with generic companies?

3 A. Yes. If you're offering a discount, you're
4 hopeful that that discount will also then be an
5 incentive regardless of which product they may be
6 considering in their choice set.

7 Q. If in a situation where a generic company comes
8 on the market and has a hundred (sic) days of
9 exclusivity as a generic, does Endo generally offer any
10 additional discounts during that period of time?

11 MR. SPRAGUE: Objection, Your Honor. This is a
12 hypothetical, speculation.

13 JUDGE CHAPPELL: Sustained.

14 MR. ANTALICS: Your Honor, I don't think it's
15 hypothetical.

16 JUDGE CHAPPELL: That's sustained. He's a fact
17 witness.

18 MR. ANTALICS: Right.

19 JUDGE CHAPPELL: You're going to have to
20 rephrase that.

21 BY MR. ANTALICS:

22 Q. Okay. Let me rephrase it.

23 Do you --

24 JUDGE CHAPPELL: The objection is sustained.

25 We're not going to sit here and let you ask

1 hypotheticals of a fact witness.

2 BY MR. ANTALICS:

3 Q. In your experience, has Endo in the past, while
4 you were at Endo, offered discounts during that 180-day
5 exclusivity period on its branded product?

6 A. I can't -- I don't know what they've done in
7 the past with products. You know, they have a lot of
8 products there, and I don't know what Endo's position
9 is on discounting during that particular period.

10 Q. Okay. Okay. You talked earlier about some
11 various forecasts and scenarios. Do you recall that?

12 A. Yes.

13 Q. Okay. And you said that -- I believe you said
14 you created many forecasts and scenarios. Correct?

15 A. Correct.

16 Q. Okay. What is the purpose of creating large
17 numbers of forecasts and scenarios?

18 A. To be prepared. Our job -- you know, part of
19 the job of being a marketing director is to try to
20 understand what's happening not only today but,
21 you know, two, three, seven years from now and trying
22 to anticipate what those changes are going to be and to
23 create a scenario to reflect that so that you can make
24 better business decisions.

25 Q. And those various scenarios, they contained

1 different assumptions?

2 A. Correct.

3 Q. Did they have different assumptions about the
4 date of potential generic entry from Impax?

5 A. Yes.

6 Q. Okay. What, if you recall, is the earliest
7 date you put in there as an assumption for the entry of
8 Impax?

9 A. The earliest? I don't recall what that would
10 be.

11 Q. Okay. Do you recall what it would be tied to?

12 A. I guess it would be tied to -- well, I
13 shouldn't say that. I recall that there were a number
14 of potential dates that it could have been launching
15 at risk, loss of patent exclusivity on our side, so
16 there's probably a number of different potential dates
17 that we were looking at.

18 Q. So any potential date when they could enter.

19 A. Correct.

20 Q. Okay. Does that mean that you thought that
21 Impax would in fact enter on any particular date?

22 A. I don't know what Impax would do really, but we
23 had to anticipate and try just to be prepared so that
24 we weren't surprised.

25 Q. Okay. Could you put up RX 086, please.

1 JUDGE CHAPPELL: To be fair to government
2 counsel, if you --

3 MR. ANTALICS: Oh, I'm sorry. This is the
4 first document that I -- wasn't there because I wasn't
5 even planning to use --

6 JUDGE CHAPPELL: I believe I was in the middle
7 of a sentence.

8 You've got a bad habit of speaking while I do.

9 MR. ANTALICS: I apologize, Your Honor.

10 JUDGE CHAPPELL: To be fair to government's
11 counsel, if you decide to move beyond cross-exam of
12 direct testimony and move into any direct of your own
13 because this witness is listed on your witness list,
14 you need to let us know, so they know whether to object
15 to leading or not.

16 MR. ANTALICS: I'll do that, Your Honor.

17 (Pause in the proceedings.)

18 JUDGE CHAPPELL: Yes, you may approach the
19 witness.

20 I believe you handed a binder to the witness?

21 MR. ANTALICS: I'm sorry.

22 JUDGE CHAPPELL: Let's just make sure before
23 you proceed -- consult with people at the table there
24 on my right -- that the witness has in front of him
25 what you want him to have so we can save some time.

1 MR. ANTALICS: Okay.

2 You have a binder in front of you there, sir.

3 Your Honor, I do not believe complaint counsel
4 went into this on direct. I'd like to show, if I may,
5 Your Honor, the witness a document and just ask him to
6 identify some individuals in it, if that's okay?

7 JUDGE CHAPPELL: With a proper foundation, that
8 will be okay.

9 MR. ANTALICS: Okay. Thank you, Your Honor.

10 Could you put up on the screen RX 086.

11 This has been received into evidence,

12 Your Honor. And it's not confidential.

13 BY MR. ANTALICS:

14 Q. Mr. Bingol, this is a document titled
15 Opioid Pain Marketplace Assessment from June of 2010,
16 and it's -- the vendor is FULD & Company.

17 Just -- do you know who FULD & Company is?

18 A. Yes.

19 Q. And could you describe to the court what
20 FULD & Company does in connection with Endo.

21 A. What they did in this case was to do research
22 for us on certain aspects of the long-acting opioid
23 marketplace.

24 Q. Okay. Thank you.

25 I'd like to just ask you to identify -- I'm not

1 going to get into the substantive information in the
2 document, but on page 10 of the document -- if you
3 could put page 10 up, please -- it's a little bit hard
4 to read on the printed version, but on the screen, the
5 top bullet, could you describe who Roth Capital
6 Partners is.

7 MR. SPRAGUE: Objection, Your Honor. I don't
8 believe that respondent's counsel has established that
9 there's any foundation to answer questions about this
10 document.

11 MR. ANTALICS: I thought I did, Your Honor.
12 Did I not go far enough?

13 JUDGE CHAPPELL: You asked him if he knew who
14 FULD was.

15 MR. ANTALICS: Right.

16 JUDGE CHAPPELL: That's not a proper foundation
17 for the pending question. Sustained.

18 MR. ANTALICS: Your Honor, I asked a follow-up
19 as well.

20 JUDGE CHAPPELL: Sustained.

21 Lay a foundation or move along.

22 BY MR. ANTALICS:

23 Q. Could you describe the purpose of this document
24 from FULD for Endo.

25 A. It was to help us to try to better understand

1 potential competitive threats or marketplace challenges
2 that we were facing.

3 Q. Is this the type of work that FULD would do for
4 Endo from time to time?

5 A. It's the work that we hired them to do for
6 our -- for the Opana franchise at that time.

7 Q. And does work such as contained in this
8 document -- is that some of the information that you
9 considered in performing your job responsibilities at
10 Endo?

11 A. Yes.

12 JUDGE CHAPPELL: Go ahead.

13 MR. ANTALICS: Thank you, Your Honor.

14 BY MR. ANTALICS:

15 Q. Okay. Now, my question back on page 10 was
16 just if you could identify who Roth Capital Partners
17 is.

18 A. I'm not familiar with this particular company
19 in general, but they're capital partners or an analyst
20 group. I don't have any personal connection or
21 knowledge of them.

22 Q. It's an analyst group that follows the
23 pharmaceutical industry?

24 MR. SPRAGUE: Objection, Your Honor.
25 Foundation.

1 JUDGE CHAPPELL: You mean leading?

2 MR. SPRAGUE: And leading, Your Honor, yes,
3 sir.

4 JUDGE CHAPPELL: Sustained.

5 MR. SPRAGUE: Thank you, Your Honor.

6 BY MR. ANTALICS:

7 Q. Does this -- Roth Capital Partners, do they
8 follow the pharmaceutical industry, in your
9 understanding?

10 JUDGE CHAPPELL: He said he doesn't know about
11 Roth Capital Partners, so you need to move on from
12 there. I heard him say that some moments ago. And if
13 you'd like, I'll remind you what he said: "I'm not
14 familiar with this particular company."

15 Next question.

16 After that answer, anything you suggest to him
17 is leading, and I've already sustained that objection.

18 MR. ANTALICS: I'm sorry, Your Honor. I'm not
19 sure I understood your -- your last --

20 JUDGE CHAPPELL: The witness said, "I'm not
21 familiar with that company." Don't ask him anything
22 about that company. He's a fact witness. Is that
23 clear?

24 MR. ANTALICS: That's clear now, Your Honor. I
25 thought you were instructing me with respect to the

1 rest of the document.

2 BY MR. ANTALICS:

3 Q. Mr. Bingol, do you know who UBS is, who is at
4 the bottom of the second blue bullet there?

5 MR. SPRAGUE: Objection, Your Honor. Leading.

6 JUDGE CHAPPELL: "Do you know who UBS is?"
7 Overruled.

8 THE WITNESS: Yes.

9 BY MR. ANTALICS:

10 Q. Does UBS follow the pharmaceutical industry?

11 A. Yes.

12 Q. Okay. Do you know who -- moving down to the
13 third bullet, do you know who Collins Stewart is?

14 MR. SPRAGUE: Objection, Your Honor. It's
15 leading insofar as he's using the document. I don't
16 understand what the purpose of using the document to
17 ask him --

18 JUDGE CHAPPELL: What he's saying is, the
19 document shouldn't be in front of the witness while
20 you're asking these questions. Having the document up
21 is leading.

22 MR. ANTALICS: Okay, Your Honor.

23 Could you take the document down.

24 JUDGE CHAPPELL: I'm not saying you can't ask
25 the witness what he considered, did he look at the

1 report, et cetera.

2 MR. ANTALICS: Okay.

3 JUDGE CHAPPELL: But counsel's point is, as
4 I've been trying to impress on attorneys in this case,
5 when you have the document in front of the witness,
6 you're feeding him the information. That's classic
7 leading.

8 MR. ANTALICS: May I re-ask the question now,
9 Your Honor?

10 JUDGE CHAPPELL: I'm checking to see if he
11 answered it.

12 We didn't get an answer. Go ahead.

13 BY MR. ANTALICS:

14 Q. Do you know who Collins Stewart is,
15 Mr. Bingol?

16 A. No.

17 MR. SPRAGUE: Your Honor, we object to the
18 document being displayed at this point.

19 MR. ANTALICS: I'm finished with the
20 document -- you can take it down -- Your Honor.

21 JUDGE CHAPPELL: According to him, it's not
22 supposed to be on the screen.

23 MR. SPRAGUE: Yes, Your Honor. Thank you.

24 BY MR. ANTALICS:

25 Q. In the various forecasts and scenarios created

1 in the years before the settlement agreement was signed
2 with Impax, were assumptions included about the
3 possibility of Endo entering with an authorized
4 generic?

5 A. I'm sorry. Can you ask that again, please.

6 Q. In the various forecasts and scenarios created
7 in the years before the settlement agreement was signed
8 with Impax, were assumptions created -- included about
9 the possibility of Endo entering with an authorized
10 generic?

11 A. I don't recall specific forecasts about an
12 authorized generic.

13 Q. Okay. Are you saying you don't recall specific
14 ones with or without? I didn't understand.

15 A. I don't recall specific forecasts that included
16 an authorized generic --

17 Q. Okay.

18 A. -- from Endo.

19 Q. Okay. Well, if Endo had launched a
20 reformulated crush-resistant product, would it have
21 launched an authorized generic of the original
22 Opana ER?

23 MR. SPRAGUE: Objection, Your Honor.
24 Speculation.

25 JUDGE CHAPPELL: As phrased, the question is

1 speculation. You need to limit your questions to what
2 he planned for and what he actually did, not
3 speculation.

4 BY MR. ANTALICS:

5 Q. Endo I believe you -- I believe you testified
6 earlier that Endo had plans to launch a reformulated
7 crush-resistant product. Correct?

8 A. Correct.

9 Q. Okay. Did Endo at that time have any plans to
10 launch an authorized generic of original Opana ER at
11 that time?

12 A. I don't know what Endo was planning to do in
13 that regard. But I don't recall that we were going to
14 launch both at the same time, no, or that that was a
15 consideration to launch both at the same time.

16 Q. Did Endo --

17 JUDGE CHAPPELL: Do you recall those charts you
18 were looking at earlier with the colors on them, the
19 graphs?

20 THE WITNESS: Yes, sir.

21 JUDGE CHAPPELL: Any of those scenarios include
22 an authorized generic, as you recall?

23 THE WITNESS: The one -- the one chart with the
24 multiple lines that was all around the launch of the
25 reformulated product, and one line in there was about

1 Opana ER without claims, with no claims, if you -- in
2 the generic space, rather.

3 JUDGE CHAPPELL: So did that encompass an
4 authorized generic?

5 THE WITNESS: Not on that slide, no.

6 JUDGE CHAPPELL: So you planned on a scenario
7 that included no claims whatsoever but not on one
8 including an authorized generic.

9 THE WITNESS: We had discussed internally
10 certainly that as an option potentially, but as far as
11 we took it, it was never -- to my knowledge, it never
12 fully realized as a plan or an idea.

13 JUDGE CHAPPELL: All right.

14 BY MR. ANTALICS:

15 Q. When the crush-resistant formulation was
16 introduced, was it Endo's position that the
17 crush-resistant formulation was safer than the original
18 version?

19 A. Yes. That was the -- essentially the added
20 value that the original -- or that the reformulated
21 version was bringing to the marketplace, that it would
22 be crush-resistant, therefore making it more difficult
23 for potential abusers to prepare it for snorting or
24 injecting.

25 MR. ANTALICS: Your Honor, I have nothing

1 further, Your Honor.

2 JUDGE CHAPPELL: Any redirect?

3 MR. SPRAGUE: Your Honor, may I briefly consult
4 with my co-counsel?

5 JUDGE CHAPPELL: Go ahead.

6 (Pause in the proceedings.)

7 MR. SPRAGUE: Your Honor, we have no further
8 questions for the witness at this time.

9 JUDGE CHAPPELL: Thank you. You may stand
10 down.

11 We're going to take a short break, come back,
12 take our next witness. We'll reconvene at 11:55.

13 We're in recess.

14 (Recess)

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

16 Next witness.

17 MR. LOUGHLIN: Your Honor, before we call our
18 witness, can I just confirm what I said this morning?

19 JUDGE CHAPPELL: The motion to compel Reasons?

20 MR. LOUGHLIN: Yes, Your Honor. We did not
21 file that motion. We didn't get it in on the e-filing
22 system, and so we did not file it.

23 JUDGE CHAPPELL: Bingol did get filed and
24 Bingol has a notice to withdraw.

25 MR. LOUGHLIN: Correct.

1 JUDGE CHAPPELL: We just can't have a motion to
2 compel hanging out there because there are a lot of
3 deadlines that come into play, including for the judge.
4 A motion to compel has very, let's say, short-fused
5 deadlines.

6 MR. LOUGHLIN: Understood, Your Honor.

7 JUDGE CHAPPELL: So that's clear. All right.
8 Thank you.

9 MR. LOUGHLIN: Your Honor, complaint counsel
10 calls Professor Roger Noll.

11 Your Honor, my colleague, Markus Meier, will
12 conduct the examination.

13 - - - - -

14 Whereupon --

15 ROGER GORDON NOLL

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

18 MR. MEIER: Good morning, Your Honor.

19 And may it please the court.

20 - - - - -

21 DIRECT EXAMINATION

22 BY MR. MEIER:

23 Q. Good afternoon, Professor Noll. How are you?

24 A. Good afternoon. Well.

25 Q. Professor Noll, would you please introduce

1 yourself by stating your full name.

2 A. Roger Gordon Noll, N-O-L-L.

3 Q. How are you employed?

4 A. Well, I'm now retired. I'm called professor
5 emeritus, which means old professor.

6 Q. And where are you a professor emeritus?

7 A. I'm in the Department of Economics at
8 Stanford University.

9 Q. So you're a professor emeritus of economics?

10 A. That's correct.

11 Q. Do you still teach any courses at
12 Stanford University?

13 A. Normally I teach one course a year.

14 Q. And is that the same course or do you teach
15 different courses?

16 A. I teach a course that has variable content.
17 It's an upper division undergraduate research seminar,
18 and the topic is usually something to do with the
19 economics of sports and entertainment.

20 Q. Professor Noll, there's a binder of exhibits,
21 including your two reports, on the table to your left.
22 You don't need to look at it right now, but we may be
23 referring to it during the course of this examination.

24 There's also a bottle of water there on the
25 table for you, and please take it whenever you need

1 it.

2 And just for the record, I've also given
3 Mr. Hassi a binder of the exhibits.

4 Professor Noll, I'm going to start by
5 reviewing the issues the FTC asked you to assess in
6 this case.

7 Without actually stating your opinions at this
8 time, what did the FTC ask you to do?

9 A. The FTC asked me to undertake an economic
10 analysis under the rule of reason of the competitive
11 effects of the patent settlement agreement between Endo
12 and Impax.

13 Q. What specifically were you asked to do? And
14 again, just at a high level.

15 A. I was asked to undertake the normal steps of a
16 real rule of reason analysis in antitrust economics,
17 the economic analysis that fits into a rule of reason
18 analysis, which includes market definition, the
19 presence of market power and the conduct of the
20 defendants, whether -- and that conduct was
21 anticompetitive and whether it caused harm in a
22 relevant market.

23 Q. Again, without actually stating your opinions
24 at this time, have you formed opinions concerning these
25 issues?

1 A. Yes.

2 Q. Are you having difficulty hearing me?

3 A. Yes.

4 Q. I will try to speak up.

5 Before we get to your opinions in this case,
6 I'd like to ask you about your academic credentials and
7 your research and publications and professional
8 experience that qualify you to reach the opinions
9 you'll be giving.

10 Before retiring and becoming a professor
11 emeritus at Stanford, what was your position at the
12 university?

13 A. I was the Morris M. Doyle Professor of Public
14 Policy in the Department of Economics. And I was also
15 the director of the Public Policy Program, which is an
16 undergraduate major at Stanford.

17 And I was the director of the Program in
18 Regulatory Policy of the Stanford Institute for
19 Economics Policy Research, where I also was a senior
20 fellow.

21 Q. What courses would you typically teach as an
22 economics --

23 JUDGE CHAPPELL: Can we put some dates in here?

24 BY MR. MEIER:

25 Q. When did you retire?

1 A. I retired in 1966 -- 1966 -- 2016.

2 Q. But you still have an office at the university;
3 correct?

4 A. Yes, I do.

5 2006. Excuse me. 2006. I'm getting confused
6 here. 2006 is my formal retirement date.

7 I have retained my office in the Department of
8 Economics and retained my role in teaching ever since
9 then.

10 Q. What courses would you typically teach as an
11 economics professor at Stanford University?

12 A. My formal teaching requirement at Stanford
13 always included two courses. One is a course called
14 Economic Policy Analysis, which included things like
15 benefit-cost analysis and risk analysis. And the other
16 was a course in antitrust and regulation.

17 Q. When you said "risk analysis," what would be in
18 that course?

19 A. The -- the -- there was a part of the course
20 that dealt with the fundamentals of policy evaluation
21 in the federal government as it's been practiced since
22 the 1960s, and that includes risk analysis, which is
23 how do -- how does one attempt to estimate the benefits
24 and costs of a policy in an environment in which
25 there's risk.

1 The most obvious places are environmental
2 health and safety regulation, where the government
3 imposes regulations on an industry because the product
4 itself is risky. And the object of the game there is
5 to evaluate the reduction in risk arising from the
6 regulation and compare it with its cost.

7 Q. Over the course of your career, have you
8 taught at any other universities in addition to
9 Stanford?

10 JUDGE CHAPPELL: Before that question, that's
11 pretty broad, government regulation. In any
12 particular fields, like environmental, banking? What
13 fields?

14 THE WITNESS: I actually -- I think we'll get
15 to that in my research.

16 In teaching the course, it was a general
17 course about regulatory policy, so it included
18 economic regulation, environmental regulation, and
19 safety regulation. There was a bit of financial
20 institution regulation, but that was not a major part
21 of the course.

22 Mostly it was price regulation and things like
23 Interstate Commerce Commission or the -- and/or
24 Federal Communications Commission, and also it included
25 EPA and OSHA and Consumer Product Safety Commission,

1 and it also included antitrust.

2 JUDGE CHAPPELL: Pharmaceuticals?

3 THE WITNESS: Yes.

4 JUDGE CHAPPELL: Hatch-Waxman in 1984?

5 THE WITNESS: Yes.

6 BY MR. MEIER:

7 Q. Over the course of your career, have you
8 taught at any other universities in addition to
9 Stanford?

10 A. Yes.

11 I spent the first part of my career at
12 Cal Tech, and then I moved to Stanford in 1984. And my
13 permanent positions have been either at Cal Tech or
14 Stanford.

15 And then I have been a visiting professor at
16 several other universities: University of Michigan,
17 European University Institute, London School of
18 Economics, University of California at San Diego.

19 And then I've also had sort of honorific
20 lectureships that lasted a week or two at several
21 universities, University of Chicago and
22 University of Rochester. There's some others, but
23 those are the ones off the top I can remember.

24 JUDGE CHAPPELL: UC San Diego -- and just as an
25 observer, I mean, I hear about UC San Diego,

1 UC Santa Barbara, UCLA. Are there any cities in
2 California that don't have a University of California?

3 THE WITNESS: There are nine UC campuses, and
4 there are more than nine cities. But in terms of the
5 California State University system, there are 30 of
6 them, so it's really hard to find a city that doesn't
7 have one.

8 JUDGE CHAPPELL: All right.

9 BY MR. MEIER:

10 Q. All told, how many years have you been working
11 as a university professor?

12 A. I took my original appointment as a faculty
13 member at Cal Tech in 1965, so it's been over
14 50 years.

15 Q. And just real briefly, what is your
16 educational background?

17 A. I have an undergraduate degree in mathematics
18 from the California Institute of Technology, Cal Tech,
19 and I have a Ph.D. in economics from Harvard.

20 Q. Does your academic experience relate to any of
21 the opinions you intend to give in this case?

22 A. Yes.

23 Q. What is -- what do you consider to be your
24 primary field in economics?

25 A. My primary field in economics is the field of

1 industrial organization, which includes antitrust
2 regulation and technology policy.

3 Q. And just briefly, what is industrial
4 organization economics?

5 A. Industrial organization is the study of
6 individual markets and firms that participate in a
7 particular market and also includes the effect of
8 government policy on the strategies of firms in those
9 markets, and that's how antitrust regulation,
10 technology policy and tax policy come in.

11 So if you're an industrial organization
12 economist, what you're trying to do is explain why a
13 particular market performs the way it does and how that
14 performance is affected by public policy.

15 Q. And also just real briefly -- you used the term
16 "technology policy" -- what is technology policy?

17 A. Technology policy is a range of policies that
18 have to do with the progress of science and the useful
19 arts, as it says in the constitution. It's anything
20 that the federal government does that either directly
21 or indirectly has a significant effect on the
22 advancement of knowledge and the creation of new
23 products.

24 So, as an example, part of it is to study
25 basic research, study what's going -- you know, what

1 is the process for supporting research in physics by
2 the federal government. And at the other end of the
3 spectrum is commercialization projects, such as the
4 role the government had in creating solar energy or
5 satellites, communication or nuclear power.

6 Q. Have you written any books or research articles
7 in the field of antitrust and regulation and
8 technology policy?

9 A. Yes.

10 Q. How many books have you written?

11 A. 15.

12 Q. And is that as an author or a coauthor?

13 A. Author, coauthor or an editor of a book that
14 includes something I wrote. I never have a book that
15 doesn't have something I wrote in it, but sometimes
16 it's a collection of studies that are related to each
17 other on the same topic, and then I call myself the
18 editor.

19 Q. As a professor for more than 50 years in the
20 field of economics, approximately how many research
21 articles and reviews have you authored or coauthored?

22 A. It's now pushing 400. It's in the high 300s.

23 Q. Do most of your research articles appear in
24 peer-reviewed journals?

25 A. Most of my publications are in peer-reviewed

1 articles, but the main exception to that is I have a
2 lot of publications in law reviews and they're not
3 peer-reviewed.

4 Q. But you're not a lawyer; correct?

5 A. I'm not a lawyer.

6 Q. So although you're not a lawyer, you sometimes
7 write articles that appear in law journals?

8 A. A large fraction of my publications, probably
9 close to a third, are published in law reviews. Or at
10 least law and economics. There's -- like the
11 Journal of Legal Studies, it's not clear whether it's a
12 law review or an economics journal. It combines both.
13 But there's -- broadly speaking, if you talk about
14 journals published under the auspices of a law school,
15 it's a significant fraction of my publications.

16 Q. As an economics professor working in the field
17 of antitrust and regulation, is it common for you to
18 read judicial opinions and regulations?

19 A. I'm sorry. I didn't hear you.

20 Q. I'm going to keep trying harder.

21 As an economist working in the field of
22 antitrust and regulation, is it common for you to read
23 judicial opinions and regulations?

24 A. It's not just common, it's essential.

25 Q. Can you explain that a little bit?

1 A. First of all, when you teach a course in
2 antitrust and regulation, one of the required reading
3 materials that you assign usually is a casebook. It's
4 sort of like teaching in a law school, that economists
5 put together books on -- that review the economic
6 content of cases.

7 A common one that I've contributed to a couple
8 of -- on a couple of occasions is something called
9 The Antitrust Revolution by Lawrence White and -- White
10 and Kwoka, John Kwoka. And it is a series of chapters
11 on recent antitrust cases and what the economic
12 innovation was in -- in -- in those cases. And then
13 those get plugged into courses in teaching antitrust
14 and regulation.

15 So it's an essential part of what you do, is to
16 follow what's going on in the courts and then try to
17 interpret it in the context of the economics that
18 you're teaching in the course.

19 Q. As part of your work as a -- when you were
20 actively working as a university professor before your
21 retirement, did you ever engage in doing any training
22 for federal judges?

23 A. Yes. I have participated in several sessions.
24 Most recently we had -- through the American Antitrust
25 Institute we had a Cy Pres grant from a federal

1 district court, and for three years we ran a seminar on
2 economics of antitrust for federal district court
3 judges at Stanford, and I taught -- I organized it and
4 taught a course in it.

5 Q. When you said the words "Cy Pres," that's C-Y,
6 second word P-R-E- --

7 A. S.

8 Q. -- S; correct?

9 A. Yes.

10 Q. Does your research work inform any of the
11 opinions you intend to give in this case?

12 A. Oh, yes. Sure.

13 Q. In addition to your academic work and your
14 publications and research, have you also served as a
15 consultant to government?

16 A. Yes, I have.

17 Q. Can you just describe at a high level the types
18 of government consulting work you've done at the
19 federal level.

20 A. I have -- I have been a consultant for the
21 Federal Trade Commission obviously, the
22 Antitrust Division of the Department of Justice, the
23 Federal Communications Commission, the Food and Drug
24 Administration, and a long time ago the Senate
25 subcommittee on antitrust and monopoly. That was

1 actually the very first time I ever consulted for the
2 federal government.

3 And I've done consulting for some other
4 congressional committees as well.

5 Q. Would you please provide just a little more
6 detail on the consulting work you've done for the
7 Food and Drug Administration.

8 A. At the Food and Drug Administration, in the
9 late 1970s, the commissioner of food and drugs was
10 Don Kennedy, who later became the president of
11 Stanford. And he and Bill Nordhaus, who was a member
12 of the Council of Economic Advisers at the time, put
13 forth the initial proposal that eventually led to
14 Hatch-Waxman. And I was part of the team that put that
15 together, and then I testified before Congress about
16 the proposal.

17 Q. That was in the 1970s?

18 A. That was, yeah, sometime in the late '70s,
19 '78-79, something like that.

20 Q. Have you also served on any national boards or
21 commissions?

22 A. Yes, I have.

23 Q. Can you just give us just a little flavor of
24 that?

25 A. I have been on the -- on advisory boards of the

1 Department of Energy, the National Science Foundation,
2 the Jet Propulsion Laboratory, the National Renewable
3 Energy Lab, and NASA. And I've been on the -- those
4 are the main -- there's some -- then there's some
5 presidential commissions, National Agenda for the '80s,
6 the presidential commission that established the
7 Public Broadcasting Corporation. Several, you know, a
8 handful of presidential commissions.

9 Q. Have you done any consulting work for private
10 industry?

11 A. Yes, I have.

12 Q. And can you just name a few of the private
13 companies you've consulted for.

14 A. Well, Glaxo Smithkline, which is a drug
15 company.

16 Hewlett Packard.

17 The Minnesota Twins.

18 The Los Angeles Lakers.

19 The Oakland Raiders.

20 United States Football League.

21 There are others. I mean --

22 Q. Any companies in the telecommunications field?

23 A. Oh, yes. AT&T.

24 It's sort of interesting because I was a
25 consultant for the Department of Justice on the

1 U.S. v. AT&T case. I was actually part of the team
2 that developed the initial complaint. And then two
3 decades later, when they were divested, or 15 years
4 later when they were finally divested, then I was a
5 consultant for them about how to adjust to the new
6 environment.

7 Q. You mentioned that you have consulted for at
8 least one pharmaceutical company, GSK.

9 Have you consulted with any others?

10 A. Well, I have -- I wasn't a consultant, but I
11 have received support for my research from Pfizer.

12 Q. Have you ever worked with any nongovernmental
13 think tanks?

14 A. Oh, yes. I spent time at the
15 Brookings Institution, the RAND Corporation, and
16 then -- you know, I don't know how you qualify them --
17 National Research Council and California Council on
18 Science and Technology, which are independent policy
19 research organizations that do studies for in the case
20 of the National Research Council the federal
21 government, in the case of the California Council on
22 Science and Technology the State of California.

23 Q. Does your consulting experience help to inform
24 any of the opinions you intend to give in this case?

25 A. Yes.

1 These experiences are really important to me
2 because they give me contact with business and they
3 give me access to information I would not otherwise
4 have, and they always end up presenting new puzzles or
5 new questions that I hadn't thought of before, so they
6 do -- there's a close interaction between my academic
7 work, my consulting work, my work on government -- for
8 government as a sort of participant in the policy
9 advice process and my consulting on litigation.
10 They're all tied together because they -- every time
11 you do a new activity, you learn something new, and
12 that informs your opinions as you go on.

13 Q. Have you ever served as a testifying expert in
14 an antitrust case in litigation?

15 A. Yes.

16 Q. About how many times have you testified in
17 court in your 50-year career as a university
18 professor?

19 A. Oh, it's like less frequently than once a year,
20 you know, maybe 25, something like that.

21 Q. And that's actually testifying in court like
22 you're doing today?

23 A. Yeah, that's actually -- appearing in an
24 appearance like this, yes.

25 Q. Have you ever served as an expert in a case

1 involving prescription drugs?

2 A. Yes.

3 Q. And what cases would that be?

4 A. Well, there's two. One is the -- as I
5 mentioned before, the GlaxoSmithKline v. Abbott Labs.
6 And the other was the Cephalon case, FTC v. Cephalon.

7 Q. In the GlaxoSmithKline v. Abbott Labs case, who
8 were you working for?

9 A. GlaxoSmithKline.

10 Q. And you testified in trial in that case?

11 A. Yes, I did.

12 Q. And in the FTC v. Cephalon case, who were you
13 working for?

14 A. The FTC.

15 Q. And did you actually end up testifying in that
16 case?

17 A. No. It was just depositions.

18 MR. MEIER: At this time, Your Honor, I tender
19 Professor Noll as an expert in industrial organization
20 economics and submit that he is qualified by reason of
21 his academic credentials, research and publications,
22 and consulting experience.

23 MR. HASSI: No objection, Your Honor.

24 JUDGE CHAPPELL: Any opinions that meet the
25 proper legal standards will be considered.

1 MR. MEIER: Thank you, Your Honor.

2 BY MR. MEIER:

3 Q. Professor Noll, now that we've reviewed your
4 qualifications as an expert in industrial organization
5 economics, let's turn to your opinions in this case.

6 What is your principal opinion in this case?

7 A. My principal opinion is that the settlement
8 agreement in the patent dispute between Endo and Impax
9 caused anticompetitive harm in the relevant market for
10 oxymorphone ER in the United States.

11 Q. And what are your -- and again at a high level,
12 what are your main reasons --

13 A. I'm sorry. I cannot -- you lost me.

14 Q. I'm sorry.

15 At a high level, what are your main reasons for
16 concluding that the Impax-Endo settlement agreement is
17 anticompetitive?

18 A. The -- the principal reason is that it
19 eliminated the possibility of competitive entry by
20 Impax and other generic companies into this market
21 until the date of entry allowed in the settlement
22 agreement.

23 Q. In reaching your principal opinion, can you
24 tell us whether or not you applied standard economic
25 analysis.

1 A. Yes. I did -- I applied the standard rule of
2 reason analysis in economic -- in antitrust economics
3 to reach that conclusion.

4 Q. And do you hold all of your opinions in this
5 case to a degree of certainty reasonable in your
6 professional field?

7 A. Yes, I do.

8 Q. Before we unpack those opinions,
9 Professor Noll, let's talk about how you arrived at
10 these opinions in this case.

11 In addition to your academic consulting work,
12 what are some of the tools and methodologies you drew
13 upon to reach your opinions in this case?

14 A. The tools that I used, the analytic methods
15 that I used, are derived from the research literature
16 in antitrust economics, research publications. And
17 they're -- they first appear in articles in either
18 economics journals or law reviews and then eventually
19 they appear in textbooks that are used to teach both
20 graduate and undergraduate courses in the economics of
21 antitrust.

22 So that's part one. Those are the main tools.

23 In addition to that, I use other information
24 that is either in the public record or is discovery
25 documents in the case. And the public documents

1 include not only court cases but things like the
2 Merger Guidelines of the Department of Justice and
3 Federal Trade Commission.

4 Q. So a moment ago, you said that you reviewed
5 discovery materials from this case as part of your
6 work; is that correct?

7 A. Yes.

8 Q. Did the FTC provide you with all the materials
9 you requested?

10 A. Well, obviously I don't know, but --

11 Q. Well, the question --

12 A. -- certainly they did provide --

13 JUDGE CHAPPELL: Hold it.

14 BY MR. MEIER:

15 Q. My question was whether we provided you with
16 all the materials you requested.

17 A. Yes. I think so, but I -- what I know is that
18 every request I made was followed by a very large
19 number of documents. Whether it was everything I can't
20 testify to because I haven't seen the entire universe,
21 but I think it was.

22 Q. Well, let me ask it this way then.

23 Did the FTC give you access to all the
24 discovery materials you needed to reach your opinions
25 in this case?

1 A. Yes. I mean, they -- more so -- more than
2 that. I mean, I received an extraordinarily large
3 number of documents.

4 Q. Well, approximately how many documents did you
5 review in the process of forming your opinions in this
6 case?

7 A. I would say on the order of a thousand.

8 Q. And approximately how many pages of materials
9 did you review?

10 A. Probably close to 10,000.

11 Q. And did you also review any transcripts of
12 witness testimony?

13 A. Yes.

14 Q. About how many did you review?

15 A. A very large number, dozens. I don't remember
16 them all. They're listed in my expert report, so all
17 the documents I considered are listed in my two expert
18 reports.

19 Q. Did the discovery materials you reviewed
20 include materials from Impax, Endo and others?

21 A. Yes.

22 Q. In addition to the discovery materials from
23 Impax, Endo and others, did you also read the expert
24 reports from any of Impax' expert witnesses?

25 A. Yes, I did.

1 Q. And which ones did you read?

2 A. Dr. Addanki, Mr. Figg and Dr. Michna.

3 Q. Do you recall what Dr. Addanki's area of
4 expertise --

5 A. I'm sorry. There was something happened. I
6 didn't hear it.

7 Q. Do you recall what Dr. Addanki's area of
8 expertise is?

9 A. He is an industrial organization economist as
10 well, specializing in the drug industry.

11 Q. And do you recall what Mr. Figg's area of
12 expertise is?

13 A. A patent lawyer.

14 Q. And do you recall what Dr. Michna's area of
15 expertise is?

16 A. He's a physician engaged in pain management,
17 among other things.

18 Q. In addition to reading Dr. Addanki's report,
19 did you review the discovery materials that he cited in
20 his report?

21 A. Yes.

22 Q. Is there anything you saw in the reports of
23 Impax' experts that caused you to revise any of your
24 opinions in this case?

25 A. No.

1 Q. Why not?

2 A. There's two reasons.

3 The first is that none of the three experts
4 really undertook an antitrust economic analysis of
5 reverse payment settlements in general or the specific
6 one that's in this case. They didn't do the standard
7 economic analysis one would do. All right.

8 And the second reason is that most of the
9 issues that I raised in my preliminary report they
10 didn't even address, all right, so obviously I'm not
11 going to revise the 75 percent or so of my original
12 report that was never mentioned in -- in any of the
13 expert reports of the others.

14 Q. Turning back to your opinions in this case,
15 let's get into a little more detail about the economic
16 framework you used to arrive at your opinions.

17 Did you conduct an economic analysis of the
18 competitive effects in this case?

19 A. Yes.

20 Q. And what is the objective in conducting an
21 economic analysis of competitive effects?

22 A. To determine if the conduct in question caused
23 anticompetitive harm in a relevant market.

24 Q. What does "harm to competition" mean to an
25 industrial organization economist?

1 A. Usually it means that the people on the other
2 side of the market, which is usually buyers, from the
3 entities that engage in the anticompetitive conduct,
4 which is usually the sellers, that they're -- these
5 people are harmed, that -- and they're either harmed
6 because the price goes up or they're harmed because the
7 quality of the product goes down or maybe some
8 combination of both.

9 Q. Are there different approaches in antitrust
10 economics for assessing competitive effects?

11 A. Yes. Competitive effects under the rule of
12 reason, there are two basic ways to do it.

13 Q. And what are those two basic ways just at a
14 high level?

15 A. At a very high level, there's the traditional
16 approach that has been practiced for over 50 years,
17 which is what I just described before, the standard
18 rule of reason analysis where you define a relevant
19 market, demonstrate that the defendants, the people who
20 engaged in the conduct, had market power, demonstrate
21 that that market power was created or maintained or
22 extended by anticompetitive conduct, and then show that
23 that anticompetitive conduct caused harm to
24 competition, caused harm to the other side of the
25 market.

1 Q. And what is the second way?

2 A. The second way is called a direct effects
3 analysis where you essentially skip the market
4 definition/market power part because you have enough
5 information that you can simply directly observe what
6 the effect of the conduct was and that it was harmful
7 to the other side of the market.

8 Q. Going back briefly to the traditional antitrust
9 economic analysis you described a moment ago, did you
10 follow the steps you just outlined in analyzing the
11 competitive effects of the Impax-Endo agreement in your
12 report?

13 A. Yes.

14 Q. And now turning to the direct effects analysis,
15 did you apply that analysis in reaching the opinions in
16 this case?

17 A. Yes.

18 Q. So you did both a traditional economic analysis
19 and a direct effects analysis?

20 A. Yes.

21 Q. Why would a direct effects analysis be
22 appropriate to ascertain the competitive effects in
23 this case?

24 A. Well, to answer that question I have to go back
25 a little bit.

1 The issue of market definition and market
2 power as a necessary condition to -- for an antitrust
3 case is controversial among economists. And that's
4 one of the things I teach in my workshop for federal
5 district court judges, is that it's a -- it's often
6 just a mechanical exercise that doesn't add any real
7 insight.

8 So the -- the key point is, if -- if you can --
9 if you have good enough information, and there's a
10 clear point in time when an act, an anticompetitive
11 act, occurred, sort of a singular act in time, and you
12 can directly observe the state of the world before and
13 the state of the world after, then that is -- can be
14 sufficient.

15 You can show that when the conduct occurred
16 something happened that is easily interpretable as an
17 anticompetitive effect; that is to say, there was no
18 efficiency benefit that -- that -- associated with that
19 conduct.

20 And in that, in that kind of a circumstance,
21 proving that there was -- what the relevant market is
22 is basically irrelevant. It doesn't really matter
23 whether there were three competitors or two
24 competitors or five competitors, and it doesn't really
25 matter if you can prove something about market power.

1 If you can observe that the performance of the market
2 was significantly changed by this event, then that's
3 sufficient.

4 Q. You indicated in answering that that if you
5 have good enough -- if you have good enough
6 information, you can do a direct effects analysis;
7 correct?

8 A. That's correct.

9 Q. Did you have good enough information in this
10 case?

11 A. Yes.

12 Q. So I want to turn now to fleshing out the work
13 you did to analyze the facts in this case using the
14 traditional approach to antitrust economics.

15 You've used the term "relevant antitrust
16 market" a couple times today.

17 What is a relevant antitrust market?

18 A. A relevant antitrust market is -- starts with
19 a reference product or products, which are the
20 products that are at issue in the antitrust
21 litigation, and then those products plus the smallest
22 number of other products that, if they were all sold by
23 the same entity, which we call a hypothetical
24 monopolist, if they were all sold by the same entity,
25 they could successfully implement a profit-enhancing

1 price increase, small but significant and nontransitory
2 increase in price, the SSNIP test, if they coordinated
3 their activity, they merged to monopoly or they engaged
4 in a price-fixing cartel.

5 Q. What is, in your opinion, the key issue in
6 defining the relevant antitrust market in this case?

7 A. The key issue in this case is the degree to
8 which there is price competition that -- among
9 long-acting opioids, that is to say, different APIs in
10 the long-acting opioid category, to cause it to be a
11 competitive market, that is to say, for the prices
12 charged by producers of long-acting opioids to be
13 competitive. That's the crucial issue in market
14 definition in this case.

15 Q. In giving that answer, you used a phrase or
16 term "different APIs."

17 What does "APIs" mean?

18 A. That is the active pharmaceutical ingredient
19 in -- in a drug. There can actually be more than one.
20 Some drugs are compound drugs. In the long-acting
21 opioid case, there are several drugs that are -- that
22 combine an opioid with something else, so it's -- it's
23 either one or more active pharmaceutical ingredients or
24 the elements of the drug that have a therapeutic
25 effect.

1 Q. Do you happen to know what the API is for
2 Opana ER?

3 A. Yes. It's oxymorphone.

4 Q. And what is the -- do you happen to know what
5 the API is for the branded product OxyContin?

6 A. Oxycodone.

7 Q. Yeah, I -- thank you.

8 So how do you start the process of defining a
9 relevant antitrust market?

10 A. Well, you -- it's sort of like unpeeling the
11 skins of an onion. You start with the things that are
12 the best candidates to be close competitive
13 substitutes, to be -- and by "competitive substitutes"
14 I mean in an economic sense, close substitutes in the
15 sense that a small change in relative prices between
16 the two products would switch consumers from buying one
17 to buying the other. All right.

18 And the closest candidates for a competitive
19 substitute are other drugs that are basically the
20 same. And the closest you can possibly come to a
21 given reference product in the drug industry would be
22 another drug that was therapeutically equivalent that
23 used exactly the same APIs in exactly the same doses in
24 exactly the same way. And that -- that -- that is a
25 drug that the FDA would say is AB equivalent or

1 therapeutically equivalent, that they're
2 interchangeable. And that would be the first
3 candidate.

4 And then the second candidate would be a drug
5 that uses the same API in the same dose but has
6 differences in the formulation and other aspects to the
7 formulation so that it's rated as bioequivalent but not
8 therapeutically equivalent.

9 And that distinction is important because a
10 therapeutically equivalent drug is subject to state
11 generic substitution laws where pharmacists can take a
12 doctor's prescription and just substitute the generic
13 for the brand name drug. For bioequivalent drugs
14 that's not true.

15 Q. Okay. So what is the reference product you
16 started your economic analysis with in this case?

17 A. Well, there's -- there's actually -- through
18 time there's two drugs. There's -- they're both
19 called Opana ER, but one of them is the original
20 formulation and the other -- and the second one is the
21 reformulation that the -- sort of what's called in the
22 case the crush-resistant form.

23 So we start off with those. And then of course
24 there's the products that the generic manufacturers
25 produce, which is Impax and Actavis, have been the

1 entities that have produced generic versions of the
2 first version of Opana ER.

3 Q. So after you identify the reference products,
4 what's the next step in the process?

5 A. Well, I just described it. It's to find --
6 it's to find the candidates that are the closest, which
7 are basically the drugs that use the same API in the
8 same way.

9 The next one beyond that would be other drugs
10 that use the same API but in a different formulation.
11 All right. And the best example there would be
12 immediate-release oxymorphone, which would be Opana IR
13 and its generic substitutes.

14 Q. Okay. I'm going to be asking you a little bit
15 more about that in a moment. I'm going to kind of go
16 back to just talking about the process a little bit.

17 A. Okay.

18 Q. These steps that you were just describing, did
19 you go through these steps in forming your opinions
20 about the relevant antitrust market in this case?

21 A. I went through these steps plus some more.
22 Yes.

23 Q. And what opinion have you reached about the
24 relevant product market in this case?

25 A. That the -- that the -- the relevant market in

1 this case consists of the extended-release versions of
2 oxymorphone, and it does not include the
3 immediate-release versions of oxymorphone or the other
4 long-acting opioids.

5 Q. In your opinion, can two drugs be functional
6 substitutes but not necessarily close economic
7 substitutes?

8 A. Of course they can.

9 Q. Well, how -- can you explain that?

10 A. Because the functionality is not the only
11 thing that matters. There are -- there -- in most
12 markets, products are differentiated; that is to say,
13 they have slightly different attributes. And consumers
14 will differ in the values they place upon those
15 attributes.

16 Secondly, the act of switching from one
17 product to another may be costly. That is to say,
18 it's not just that you buy the product itself, but
19 you'd have to undertake other expenditures or take
20 other costly actions like spend time in switching from
21 one to another.

22 And either product differentiation or
23 switching costs can take a market that contains
24 products that are used for the same function but that
25 are not close economic substitutes because of consumer

1 preferences, because of brand reputations, brand
2 loyalties, behavior, sort of being stuck in the mud
3 and, you know, inflexible in behavior, or simply
4 switching costs, for all those reasons, functional
5 substitutes are not necessarily close economic
6 substitutes.

7 A necessary condition for things to be
8 economic substitutes are that they're functional
9 substitutes, but it's not sufficient. You have to go
10 further than that.

11 Q. So how can you test whether drugs that are
12 functional substitutes are or are not in the same
13 economic market?

14 A. The way you do it is you see if -- the -- the
15 first way is you see if changes in the relative prices
16 affect the relative quantities sold. That is, if we
17 think about our SSNIP test, we ask the question, if one
18 product's price goes up relative to the other, does
19 that cause a large enough switch from one category to
20 another that it wasn't profit-enhancing to increase the
21 price.

22 A related test to that is whether events that
23 affect outcomes in the sale of one product are
24 reflected in changes in prices and quantities for the
25 other product, such as generic entry.

1 Now, generic entry is actually a price
2 phenomenon as well as a product phenomenon; that is to
3 say, if generic entry occurs in one drug market, say
4 the morphine -- extended-release morphine, what happens
5 to brand name morphine and what happens to other
6 long-acting opioids and are those effects similar or
7 different. And if they're different, then they're not
8 in the same relevant market.

9 Q. Now that you've described sort of at a high
10 level the process that you went through, which pain
11 relief products did you evaluate as potential
12 candidates to be in the relevant antitrust market with
13 Opana ER?

14 A. In addition to all the drugs I mentioned
15 before that use oxymorphone, I also looked at all of
16 the long-acting opioids that are used to treat severe
17 pain. There's a longer list of long-acting opioids
18 that are used for modest, less intense pain, but I
19 focused on the seven drugs that are used to treat
20 chronic, severe pain.

21 Q. All right. I'm going to hopefully try to
22 unpack a little bit of this and kind of go back over
23 some of the things you talked about --

24 A. Sure.

25 Q. -- in more detail.

1 Looking first at generic versions of
2 oxymorphone, what drugs did you find in this category?

3 A. The -- the -- there are seven different
4 formulations of Opana ER, seven dosage strengths that
5 were at some point on the market, and which ones that
6 are on the market vary through time, but at some point
7 there have been seven dose strengths.

8 The -- initially, using the Hatch-Waxman
9 procedures, Actavis was the first filer for two of
10 those doses and Impax was the first filer for five of
11 them, so one had generic entry initially. The first
12 generic entry that occurred in the Opana ER market was
13 two doses for Actavis and five doses for Impax, and
14 then later Actavis came in in the other five doses.

15 So -- and so the -- the -- that's the
16 category -- that's the universe of drugs. And then, as
17 I mentioned before, there's two versions of Opana as
18 well, the original version and the reformulated
19 version.

20 So if you add up all that together, you have
21 each -- you have each of these companies, these three
22 companies, producing seven different doses of
23 oxymorphone ER.

24 Q. What information did you use to determine
25 whether these different forms of oxymorphone were in

1 the same relevant market as Opana ER?

2 A. I used basically two different kinds of
3 information.

4 The first kind of information I used was to
5 understand the relationship between the
6 characteristics of the products and what was likely to
7 affect the ability to switch from one to the other in
8 response to a small price change. And that has to do
9 with their therapeutic characteristics and their
10 switching costs.

11 And the second thing I looked at was the
12 actual effects of generic entry of both Actavis and
13 Impax on sales of Opana ER at the time that that entry
14 occurred.

15 Q. When you say actual effects of generic entry on
16 sales of Opana, how did you -- how did you get that
17 information? What kind of information were you looking
18 at?

19 A. We looked at the -- at publicly available
20 information and private information produced from the
21 companies about the -- about the number of
22 prescriptions, about the number of -- sort of the
23 quantity of pills sold and the revenues and average
24 prices of each of the dosage strengths for all of the
25 companies, to the extent we could get the data.

1 The data are not complete. We didn't have
2 data for every single month in every single year, but
3 we had enough data to be able to perform an analysis
4 about in general what happened to Opana when these
5 entry events occurred.

6 JUDGE CHAPPELL: I heard you say "we" a lot
7 today. Who is "we"?

8 THE WITNESS: I was helped out in my analysis
9 by economists on the staff at the FTC.

10 So the -- I -- the actual data analysis was
11 done at the FTC, but I supervised it.

12 BY MR. MEIER:

13 Q. Did this data include data from a company
14 called IMS?

15 A. Yes.

16 Q. And what --

17 A. They are -- yes.

18 Q. What is IMS data?

19 A. IMS data is -- there's a whole bunch of IMS
20 data. There's a number of -- there's four different
21 data series they produce.

22 They do surveys of pharmacies, wholesalers and
23 physicians about prescribing behavior. And the IMS
24 produces data about number of prescriptions and
25 revenues of sales for each of the drugs in the case.

1 Q. Is it common for industrial organization
2 economists working on pharmaceutical cases to use IMS
3 data?

4 A. Yes. It's -- well, yeah, it's extremely common
5 because it's really the -- the only game in town and it
6 is the -- it is the -- IMS is the data source that the
7 companies use, and so when you get data from companies
8 about sales and these various measures, frequently it's
9 IMS data that you get. And then, of course, in
10 addition, the FTC acquired some of the data as well
11 directly.

12 But it is -- it is sort of the main source of
13 data not only in the use -- in use antitrust cases, but
14 there's a lot of published empirical research in
15 economics journals that is based on IMS data.

16 Q. And when you said a moment ago that's the data
17 source the companies use, you mean pharmaceutical
18 companies.

19 A. Yes.

20 Q. Pharmaceutical companies like Impax and Endo.

21 A. Impax and Endo have data analyses in the
22 discovery record that use IMS data.

23 Q. Well, what kind of estimates of the effect of
24 generic entry did you see in the Endo data?

25 A. The first -- the first event of course is the

1 entry of Actavis. And when Actavis entered in these
2 two doses, these two low-end doses, which are the
3 smallest sales of all the seven dose strengths, they
4 were AB equivalent to the version of Opana ER that was
5 on the market at the time, so when Actavis entered,
6 they very quickly took almost all of the market away
7 from Endo. And indeed, Endo eventually exited that
8 market, the -- you know, the -- and then it came back
9 later.

10 But that -- that gives you a show of how
11 important generic entry was in those two doses, is
12 that Actavis charged a substantially lower price than
13 Endo and quickly captured almost all of the market.

14 And then the second event is the entry of
15 Impax in January of 2013, which at that time the
16 formulation of Opana ER had changed to the
17 reformulated version, so there was a similar -- a
18 qualitatively similar reduction in sales of Opana ER,
19 and the price of course charged by Impax was lower.
20 But the process of substituting for Opana ER was much
21 slower and took several years to get up to the point
22 where Impax had half of the quantity sold. But there
23 still was this substitution. There was a -- Impax'
24 prices were lower. The average price of a prescription
25 for Opana ER plus the generic version of

1 oxymorphone ER, that price declined, and the market
2 gradually switched from Endo to Impax.

3 Q. So what does the case information you reviewed
4 tell you about the relevant market in this case?

5 A. It tells me two things, one of which is obvious
6 and one of which isn't.

7 The obvious point is that generics are close
8 substitutes for brand name drugs that are
9 therapeutically equivalent, Actavis.

10 It also says that bioequivalent drugs that are
11 not therapeutically equivalent also have a significant
12 competitive effect and are competitive substitutes but
13 that the process doesn't work as well, and that's
14 because you don't have the generic substitution laws
15 going in your favor.

16 The less obvious point is that, at the time the
17 generics entered, the market for Opana ER could not
18 have been competitive or else the price wouldn't have
19 fallen as dramatically as it did and the quantity shift
20 wouldn't have been as great.

21 Q. Can you explain that?

22 A. Yes. Because if the -- if the market already
23 is highly competitive before the generics enter, then
24 you wouldn't expect that there would be any
25 significant effect of generic entry.

1 If -- to take as an example, if -- if generic
2 morphine is a close economic substitute for brand name
3 Opana ER, and that generic entry occurred several years
4 earlier, if they were close economic substitutes, the
5 generic entry in morphine would have had the same
6 effect as the generic entry in oxymorphone, and it
7 didn't. It didn't cause the price to fall because we
8 know that the price didn't actually fall and the sales
9 decline until generic oxymorphone entered.

10 Q. So after assessing whether bioequivalent drugs
11 like generic oxymorphone ER are close economic
12 substitutes for Opana ER, what was the next closest
13 candidate product that you identified?

14 A. I tested whether immediate-release oxymorphone
15 was a close competitive substitute to extended-release
16 oxymorphone.

17 Q. What's the difference between extended-release
18 oxymorphone and immediate-release oxymorphone?

19 A. It's -- it's -- if you're going to -- if
20 you're taking essentially the same dose strength over
21 the course of 24 hours, you would take a larger number
22 of pills more frequently if you were using
23 immediate-release than extended-release.

24 The APIs are the same, but the profile with
25 which the drug is absorbed into the system and then

1 disappears is much shorter for the immediate-release,
2 because there's -- there's nothing in the formulation
3 that sort of drags out the release of the drug into the
4 system.

5 So -- but it's the same drug. It's the same
6 API and it has the same effect. It's just that it's
7 quicker. It comes faster and goes away faster.

8 Q. Well, can a person just take a number of IRs
9 every day?

10 A. That -- yes, one can, although one would not
11 expect that to be the case because pill burden is a
12 serious problem in almost all drugs in that people are
13 more likely to make mistakes in their dosage if they
14 have to take pills frequently, have to take a large
15 number of pills frequently.

16 And in some categories this isn't so bad, but
17 in drugs where your life is at stake, in like the
18 HIV/AIDS drugs that I studied in GlaxoSmithKline and
19 like opioids in this case, if you make a mistake, it
20 can be deadly.

21 And so, you know, doctors, if you're -- if
22 you're going to suffer chronic, long-term pain that
23 requires round-the-clock treatment, they're going to
24 favor an extended-release version, all else equal, over
25 an immediate-release version.

1 Now, having said that, that doesn't mean that
2 economics couldn't affect it, that relative prices
3 couldn't affect it, but that's the fundamental reason
4 you wouldn't expect that these things would be perfect
5 substitutes.

6 Q. So what information did you use in this case to
7 determine whether oxymorphone IR is in the same
8 relevant market as Opana ER?

9 A. We compared the effect of the introduction of
10 generics in the immediate-release version to the -- on
11 the immediate-release sales to the effect of generics
12 in that market on sales of extended-release.

13 Q. And what did you find?

14 A. The result that we found was that essentially
15 immediate-release Opana was essentially driven from the
16 market, that the market was taken over completely by
17 the generics at a much lower price.

18 And while that was going on, there was the --
19 extended-release version of Opana just continued to go
20 up. There was no visible effect at all on sales of
21 Opana ER from generic -- extremely successful generic
22 entry into immediate-release.

23 Q. So if I understand correctly, generic IR
24 affected branded IR; is that correct?

25 A. Generic IR affected Opana IR sales dramatically

1 and --

2 Q. But it did not affect Opana ER sales?

3 A. It had no detectable effect on Opana ER sales.

4 Q. And again, is that based on using IMS data and
5 other data that you --

6 A. Yes.

7 Q. -- were able to look at?

8 A. And my characterization is true whether you
9 use number of pills, number of prescriptions or
10 revenues.

11 Q. So what does that tell you about the relevant
12 product market in this case?

13 A. That tells you that IR is not a close economic
14 substitute for ER, and so my -- the explanation I gave
15 before about why doctors might prefer ER to IR in
16 certain circumstances is sort of confirmed by the data,
17 that that seems to be sufficiently important that it
18 prevents these two drugs from being competitive
19 substitutes.

20 Q. Even though they have the same API?

21 A. Same IPA (sic) and same pharmaceutical use.
22 They're both used to treat severe pain.

23 Q. Same dosages?

24 A. Well, the dosages are different in the sense
25 that if you're going to -- you know, if you're taking

1 an ER tablet that's equivalent to an IR tablet,
2 because you have to take the IRs more frequently, the
3 IRs have lower dosage, but they would have the same
4 cumulative dosage over a long period of time.

5 Q. So after concluding that immediate-release
6 oxymorphone is not in the same product market with
7 Opana ER, what was the next set of candidate products
8 you identified?

9 A. The -- the other long-acting opioids, the
10 extended-release versions of the other opioids that
11 are used to treat severe pain, which is a subset of
12 all long-acting opioids. Some of them are not used for
13 that purpose. But of the drugs that are used to treat
14 severe pain, the extended-release versions of those
15 opioids.

16 Q. What are some of the drugs in this category?

17 A. Well, oxycodone, hydromorphone, morphine.
18 There's -- there's -- tapentadol. There's a bunch of
19 them. They're listed in my report. Exhibit 4 in my
20 report has the list.

21 Q. Do you recall in Exhibit 4 roughly how many --

22 A. Seven.

23 Q. -- different products you identified?

24 A. There's seven.

25 Q. What information did you use to determine

1 whether these other long-acting opioids are in the same
2 relevant market as Opana ER?

3 A. The method is exactly the same for testing
4 whether IR and ER are in the same market. You look at
5 whether events in one market affected sales in the
6 other.

7 So you look at did generic entry in oxymorphone
8 have an effect on morphine and did generic entry in
9 morphine have an effect on oxymorphone.

10 Q. Did you also look at any therapeutic
11 information?

12 A. Yes, I did.

13 I did the same preliminary work, which is to
14 look at all the factors that would both contribute to
15 competition and subtract from it. And the factors
16 that contribute to it are things like formulary rules
17 and placement, things like government procurement
18 rules, the operation and the nature of generic
19 substitution laws, where they affect things and where
20 they don't.

21 So -- and then the clinical guidelines and the
22 testimony of both of the doctors in the case, the
23 research -- the publications by clinical researchers
24 in the field that talk about what the proper way to
25 treat people with long-acting opioids is.

1 And all of this information then produces
2 here's reasons to think they might be competitive and
3 here's reasons to think they might not. And the
4 reasons you would think they might not be competitive
5 would be that they have therapeutic differences, the
6 things that the doctors argue about in their two
7 expert reports, and the issue of switching costs
8 again.

9 And the issue of switching cost is really
10 important here.

11 Q. Well, let's talk about that a little bit.

12 What does "switching costs" mean to an --

13 A. Yes. A switching cost --

14 Q. -- to an industrial organization economist?

15 A. Oh. Sorry. I jumped on you. That's bad.

16 A switching cost is a -- if you are a buyer of
17 a product, then one cost, you know, if you switch is
18 you stop paying X dollars for this product and you
19 start paying Y dollars for that product.

20 But switching costs go beyond any price
21 difference to other costs you might experience because
22 you undertook the switch. And it's these other costs
23 that actually are important here. The -- you know,
24 the price differences in the drugs are small compared
25 to the costs of switching from one drug to another.

1 Q. What role did switching costs play in your
2 product analysis in this case?

3 A. They give me an insight into an economic
4 explanation for why we would not expect pure
5 functional equivalence between two long-acting
6 opioids.

7 Assuming for the sake of argument that all the
8 therapeutic differences that are emphasized by the
9 firms in their promotional activities, assuming that
10 you found two drugs where they all had the same
11 characteristics, then switching costs constitute a
12 reason independent of that that these might not be
13 close economic substitutes because customers get
14 locked in to one drug because of switching drug costs,
15 and they wouldn't really be induced to change unless
16 there was some therapeutic reason that they had to
17 change.

18 Q. What are specifically some of these switching
19 costs that you identified?

20 A. The -- it -- the first part of the switching
21 cost is that you can't just go from the final dose of
22 the first drug to the final dose of the second drug
23 instantaneously. There's -- if you read the testimony
24 of the doctors and the clinical guidelines from the
25 National Institutes of Health about opioids, you're

1 supposed to taper off the dosage of the first drug to
2 avoid withdrawal symptoms, and then you taper up the
3 dosage of the second drug to find the level where you
4 achieve adequate pain relief, and so you -- it is a
5 long and complicated process. It's not just dropping
6 one and taking the other.

7 And then the second part is that the whole
8 process of tapering off and tapering in has to be
9 supervised by a physician, and of course, every time
10 you visit the physician, it's another charge.
11 Somebody has to pay, your insurance company or you have
12 to pay.

13 And so those are the switching costs. It's
14 that you have to invest a significant fraction of your
15 own time and you have to have the supervision of a
16 physician in order to switch from one to the other.

17 Q. Have you seen any discovery materials in this
18 case showing that Endo was aware of the switching costs
19 between different drugs?

20 A. Oh, yes. Not only Endo but everybody. I mean,
21 yes, I have seen such evidence.

22 Q. Okay. Well, can you tell us a little bit about
23 that.

24 A. The -- when the Novartis shortage occurred,
25 Endo reported that event to the Food and Drug

1 Administration, and collectively they decided that a
2 warning had to be issued to physicians to terminate
3 prescribing Opana ER to new patients because of fear
4 that the shortage would -- the supply disruption would
5 create a shortage and they would have to switch people
6 and that would be costly.

7 So that's a -- that's a perfect example of the
8 significance of switching costs. It actually caused a
9 company to say we don't want new customers until this
10 supply disruption is solved.

11 Q. When you conducted your analysis and you took
12 the step from the oxymorphone ER to IR and found
13 that -- and concluded that they weren't good economic
14 substitutes, could you have stopped your analysis right
15 there?

16 A. No.

17 Q. Why not?

18 A. Because whereas the similarity between ER and
19 IR is they use the same API, there still is this pill
20 burden issue. And that doesn't occur in comparing,
21 say, OxyContin to Opana, all right, that they are both
22 long-acting opioids, so the reason for having a
23 preference between OxyContin versus Opana is going to
24 be different.

25 So the fact that pill burden was sufficient to

1 cause a difference between IR and ER doesn't mean that
2 there's going to be a difference between OxyContin and
3 oxymorphone.

4 Q. Okay. So let's get back to this discussion of
5 the long-acting opioids.

6 Did you observe anything in Endo's pricing
7 behavior that gave you any insights into whether
8 Opana ER competes with other long-acting opioid?

9 A. Yes.

10 Q. And what did you see?

11 A. The -- the -- the instincts part of the story
12 is, you know, there's a lot of discovery documents that
13 I have read that basically talk about pricing.

14 All right. And there's just -- there's two contexts in
15 which pricing is discussed.

16 The first is Opana's own -- I mean, Endo's
17 documents and indeed Impax' documents about how they're
18 going to set their prices, all right, and what do they
19 consider.

20 And then the second is, in their promotional
21 documents, the discovery information about how they're
22 going to market their product. They will sometimes
23 mention the price of some other long-acting opioid.

24 And so from those documents you get a sense of
25 the degree to which the prices of other products are

1 perceived by Endo and Impax as important to them. And
2 that -- since we know that these companies engage in
3 extensive modeling, they use the same methods that are
4 used in the economics literature to figure out what
5 their prices ought to be, that this is useful
6 information about who their close economic substitutes
7 are, whose prices they have to take into account when
8 setting their own price.

9 Q. Did you find similar kinds of information in
10 Impax' documents?

11 A. Yes. Because Impax has to set a price for its
12 generics as well.

13 Q. Okay. And what did you see in the Impax
14 documents that helped you --

15 A. Well, Impax never considers anything other
16 than Opana. All right. It's just purely focused on
17 what the price of Opana is, so it didn't regard the
18 price, say, of either generic morphine or a brand name
19 morphine as significant in setting its prices.

20 Q. So to wrap this discussion up a little bit on
21 long-acting opioids, can you summarize the conclusions
22 you reached concerning whether other long-acting
23 opioids are close economic substitutes for Opana ER.

24 A. Well, what I -- what I learned from reading
25 the documents of Endo is that they rarely considered

1 the prices of other drugs, occasionally they did, they
2 rarely considered the prices of other drugs in setting
3 the price of Opana ER.

4 Their promotional documents occasionally
5 mentioned the price of something else, but those
6 promotional documents focused primarily on product
7 differentiation, how their product differs from
8 others, so their promotional activity is oriented
9 towards creating a market niche based on product
10 differentiation.

11 These support the idea that there -- other
12 long-acting opioids are not close economic
13 substitutes. They don't force competitive pricing on
14 Endo.

15 And then the data about what happens to
16 generic entry in other markets for long-acting opioids
17 versus Opana ER, if a morphine generic enters, its
18 effect on Opana ER, that all confirms this, that there
19 is no spillover effect from state of competition for
20 one long-acting opioid into prices and sales of another
21 long-acting opioid.

22 Q. Did you review Impax' economic expert
23 Dr. Addanki's method for opining on the relevant
24 antitrust market in this case?

25 A. Yes.

1 Q. And what is your opinion of Dr. Addanki's
2 method?

3 A. Dr. Addanki does not use the method I just
4 described. He does not actually attempt to show that
5 the competitive -- that there's sufficient competition
6 among various forms of generic -- excuse me -- among
7 various forms of long-acting opioids to cause each one
8 to have competitive pricing based upon what's going on
9 with other long-acting opioids. He doesn't use that
10 method.

11 Instead what he does is he focuses on
12 promotional activity as evidence of competition
13 primarily.

14 Q. So he --

15 A. He has some information about formularies
16 and -- but his main focus is on the evidence that they
17 promote against each other.

18 Q. So you mentioned promotional activities and
19 formularies.

20 Dr. Addanki has a discussion in his report
21 about the placement of long-acting opioids on health
22 plan formularies. Do you recall reading that?

23 A. Yes, I do.

24 Q. So first of all, just real briefly, I think we
25 all probably know this at this point, but what is a

1 health plan formulary?

2 A. A formulary is essentially a list of the drugs
3 that will be covered by an insurance plan. And the
4 insurance plan can be traditional insurance or it can
5 be an HMO like Kaiser.

6 And it basically says -- it ranks -- it puts
7 the drugs in various categories and the -- the -- there
8 are essentially priorities in that the highest category
9 or tier is one in which the patient has the lowest
10 copay and also has the lowest net price to the
11 insurance company as well.

12 And they try to encourage people to use things
13 in higher tiers, and usually the first tier, the
14 highest tier, the one that they encourage you the most
15 use for is generics. And then the -- the action for
16 brand name drugs, if you have generic competition, is
17 usually whether you're in the second or third tier or
18 you're just not included.

19 Most formularies will have four different
20 categories, three tiers which are actually covered by
21 insurance and then a fourth category where you need
22 some special reason and approval in order for the
23 physician to even prescribe the drug.

24 Q. So you agree that health plans use formularies
25 to try to promote competition among drugs.

1 A. I not only agree that they do that, there's
2 actually a discussion in my original report about how
3 they do it and how to some degree it is effective.
4 They do end up having an effect on price by -- by
5 engaging in this behavior.

6 The issue is whether it forces these products
7 to be in the same market, which means that they're
8 competitive, that the pricing is competitive.

9 Q. So where do you take issue with Dr. Addanki's
10 analysis?

11 A. There's no -- there's no -- there's no actual
12 evidence about prices in Dr. Addanki's report. All he
13 does is observe what formularies do and describe it
14 and -- and observe that there's churn in formulary
15 placement among long-acting opioids. And then he
16 concludes from that that they're competitive
17 substitutes in an economic sense, and that conclusion
18 is not justified by the observations.

19 You would have to do something like I did,
20 which he didn't really criticize. He never even
21 mentions it. You'd have to show that indeed there was
22 effective price competition, that it was not just
23 getting a little bit of a discount versus forcing them
24 down to the competitive pricing level like a generic
25 does.

1 When a generic enters, it charges -- when
2 there's generic competition, the price is much lower.
3 And the fact that that's true, the fact that they
4 always put generics in category one and that the
5 prices are a lot lower than the brand name drugs, is
6 simply evidence that the formularies by themselves when
7 there's nothing providing the brand name drugs in the
8 market are not sufficient to drive the price to the
9 competitive level.

10 Q. In giving that answer, you talked about when
11 there's churn within formularies.

12 What did you mean by "churn"?

13 A. By "churn" it means that over time and among
14 formularies are there differences in formulary
15 placements for the same drug.

16 And Dr. Addanki has a lot of tables in his
17 report that show that there is -- there are
18 differences, all right, and he has -- you know, he has
19 a number of different ways of making these comparisons.
20 And there are differences in formulary placements among
21 the drugs he considers through time and through
22 different kinds of plans and et cetera.

23 Q. Do you believe that Dr. Addanki's analysis of
24 formulary placement supports his product market
25 conclusions?

1 A. No. It has nothing to do with whether there's
2 competition or not. It doesn't prove anything and...

3 Q. So other than competition, what other reasons
4 could there be for observing differences among drugs in
5 formulary placement?

6 A. Well, let's start off with the very first
7 important fact about it, that some of his tables
8 compare six drugs and some of his tables compare
9 seven.

10 The cases he looks at are exclusively cases
11 where he had -- observes a year of data for which
12 there's no generic competition, so he's already
13 eliminating from consideration the single most
14 important source of competition in the drug industry,
15 whether it's whether formularies are involved or
16 whether government contracting is involved or whether
17 it's just sort of standard insurance that doesn't have
18 a formulary, Medicare Part B or something like -- or D,
19 rather.

20 So he -- the very first point is, the single
21 most important source of competition isn't even in the
22 analysis. All right.

23 The second fact is that in the six-drug
24 category, three of them are versions of morphine, and
25 in the seven-drug category, four of the drugs are

1 morphine.

2 Q. What's the significance of that?

3 A. Well, the -- two different versions of
4 morphine are much more likely to be competitive
5 substitutes than morphine to oxycodone or morphine to
6 oxymorphone, and he doesn't distinguish between how
7 much of his churning is competition among the various
8 versions of morphine.

9 It strikes me -- I don't -- haven't done the
10 analysis, but a perfectly plausible hypothesis that
11 may turn out to be true is that brand name morphines
12 don't have much market power because there are several
13 of them. All right. And that's different -- that's a
14 different conclusion than looking at a market in which
15 there's only one brand name, which is the case of
16 oxymorphone.

17 So the failure to take into account the
18 difference between competition among drugs that have
19 the same API versus competition between drugs that have
20 different APIs is a fatal flaw. It means that the
21 analysis is useless.

22 Q. But in his report, Dr. Addanki points to
23 statements in Endo's documents that suggest that there
24 is competition between Opana ER and other branded
25 drugs, doesn't he?

1 A. Yes. And -- and he not -- he says it in two
2 ways. But yes, he does.

3 Q. And in your opinion, does his statements about
4 Endo's documents indicating competition between
5 Opana ER and other drugs support his product market
6 conclusions?

7 A. No.

8 Q. Well, why not?

9 A. Because one of the features of monopoly is you
10 cannot charge an infinite price. You can only raise
11 the price up to a level where the price gets so high
12 that people actually start buying other things.

13 So the -- a monopolist price is always one in
14 which you're competing with somebody, but you're
15 competing where one firm is charging a monopoly price
16 and maybe the other firms are charging competitive
17 prices. That doesn't mean you're in a competitive
18 market. It just means you've raised the price as high
19 as you can.

20 This actually is a terminology in economics
21 called the cellophane fallacy, which is that you do
22 not evaluate who the competitors in an economic market
23 are by observing substitution patterns at the current
24 prices if one of those prices -- one or more of those
25 prices could be a monopoly price.

1 What you have to do is go through this
2 analysis to see if changes in characteristics in the
3 market caused that price to go down, because if there
4 are changes in the characteristics of a market that
5 caused the price to go down, then indeed it wasn't
6 competitive before that change occurred.

7 Q. You used the term "cellophane fallacy."

8 Is that from the venerable old Supreme Court
9 case?

10 A. That is from the venerable and not very popular
11 anymore Supreme Court case.

12 Q. Did you observe any other problems with
13 Dr. Addanki's arguments about a firm's perceptions of
14 their competitors, of who their competitors are?

15 A. Yes. I mean, again, it's the story I said
16 before, that -- that he doesn't make the distinction
17 between activities that indicate greater competition,
18 which is competition on the price dimension, versus
19 activities that lead to less competition, which has to
20 do with promotional activities that develop brand name
21 loyalty or emphasize differentiation.

22 Product differentiation -- in business schools
23 you learn that a great competitive strategy to
24 increase your profits is to figure out ways to
25 differentiate your product from others. And a

1 promotional strategy that focuses on product
2 differentiation, it's not anticompetitive in the legal
3 sense, it's not a violation of the antitrust laws, but
4 it's an activity that reduces the intensity of
5 competition, it doesn't increase it.

6 Q. What is the significance of product
7 differentiation to your analysis of the relevant
8 product market in this case?

9 A. Product differentiation provides one of the
10 explanations for why we wouldn't expect two different
11 APIs in the long-acting opioid space to be close
12 economic substitutes.

13 Q. Professor Noll, I'd now like to shift gears
14 and --

15 JUDGE CHAPPELL: If you're shifting gears,
16 we're going to take our lunch break.

17 MR. MEIER: Yes, Your Honor.

18 JUDGE CHAPPELL: We'll reconvene at 2:30.

19 We're in recess.

20 (Whereupon, at 1:24 p.m., a lunch recess was
21 taken.)

22

23

24

25

1 conclusion that Endo enjoys substantial market power,
2 monopoly power, in the market for Opana ER or that for
3 oxymorphone ER.

4 Q. And was that at the time of the settlement?

5 A. That was true at the time of the settlement,
6 and it remained true even after Impax entered.

7 Q. So let's talk about indirect measures of market
8 power first.

9 How did you go about measuring market power
10 indirectly in this case?

11 A. The -- the indirect method relies upon
12 theoretical and empirical research in economics that
13 finds that more concentrated markets have to have --
14 tend to have higher prices or higher price-cost
15 margins.

16 And the -- this is embodied in the
17 Merger Guidelines by setting thresholds for the --
18 something called the Hirschman-Herfindahl Index, which
19 is the sum of the squares of the market shares of the
20 firms. And if the HHI exceeds a certain threshold,
21 then presumptively firms are assumed -- in that market
22 are assumed to have market power, at least the large
23 firms in it.

24 Q. In your opinion, is the market for
25 oxymorphone ER highly concentrated?

1 A. Yes, it is.

2 Q. And was that the case at the time of the
3 settlement?

4 A. It's been -- it's been true throughout the
5 history of oxymorphone ER, right from the beginning to
6 the present.

7 Q. As part of this indirect method of measuring
8 market power, does barriers to entry matter?

9 A. Yes.

10 Q. Can you explain that?

11 A. Yes. That market power is indicated by a high
12 concentration number only if barriers to entry are
13 present, significant barriers to entry are present.

14 And the reason for it is that price is in
15 excess of cost, you know, and the ability to earn
16 excess profits attracts entry. And so unless there
17 are substantial costs to entry that dissuade potential
18 competitors from entering the market, then these high
19 prices and high price-cost margins will induce entry.

20 So barriers to entry is the concept of
21 somebody who wants to enter the market faces some sort
22 of a substantial fixed cost of entry that would
23 dissuade them from entering even if the market was
24 highly profitable.

25 Q. Can you give us some examples of barriers to

1 entry?

2 A. Well, the -- one barrier is patents, that if
3 somebody holds a valid, enforceable patent on a
4 product, then at least you have to figure out a way to
5 invent around the patent in order to enter the market.
6 And perhaps the patent can be blocking. It can be
7 prevent anybody from entering.

8 So that's the first.

9 The second is substantial economies of scale,
10 where you -- a firm, in order to take advantage of the
11 high margins, has to capture a very large fraction of
12 sales in the market in order to be -- to be profitable,
13 and so, you know, that's an unlikely prospect. It has
14 to be an unlikely prospect.

15 A third reason is regulatory entry barriers
16 where you are not allowed to enter the market
17 instantaneously because you need to obtain regulatory
18 approval and the process can be extensive and
19 protracted.

20 Q. In your opinion, were there barriers to entry
21 to the market for oxymorphone ER --

22 A. Yes.

23 Q. -- at the time of the settlement?

24 A. Yes, there were. There are still barriers to
25 entry.

1 Q. And can you just describe some of the barriers
2 to entry that you've observed in this case?

3 A. There's -- first of all, there's the patent
4 barrier to entry, which is the firm's attempt to
5 vigorously enforce their patent rights, and sometimes
6 they win. And when they win, that keeps people out.

7 And the second is the whole Hatch-Waxman
8 process is a regulatory barrier to entry because you
9 have to wait a certain amount of time, depending on
10 the facts, before you can even submit an
11 Abbreviated New Drug Application to enter as a
12 generic. And then once you've submitted it, as long as
13 the brand name firm says that your product would
14 infringe against them and files an infringement suit
15 against you, that delays your entry for another
16 30 months at minimum.

17 So that's a -- those are both examples of why
18 firms cannot respond instantaneously to the incentive
19 to enter a market.

20 Q. In your opinion, are the barriers to entry that
21 you observed in this case significant?

22 A. Of course they're significant.

23 I mean, the fact that you can't enter for at
24 least six and a half years after the brand name drug
25 goes on the market is a huge barrier to entry. It

1 means that there's a long period of time, which is
2 more -- remember, when I talked about the SSNIP test, I
3 talked about nontransitory increase in price, and we
4 normally think of that as a year, maybe under the max
5 conditions two years, as being the period of a
6 successful price increase. And of course, we're
7 talking much longer periods in the case of generic
8 entry into brand name drug markets.

9 Q. You talked earlier about product
10 differentiation and loyalty to products.

11 Can those also be barriers to entry?

12 A. Yes. And they are related to this issue of
13 regulatory barriers to entry in that if you're
14 entering with a different API, even if you believe
15 that it's going to be such a close therapeutic and --
16 substitute and that you are intending to engage in
17 price competition with the brand name drug that's
18 already there, then indeed that -- that dimension of
19 product differentiation that is the specific API in a
20 brand name drug that creates this necessity to get
21 another NDA based on another drug is a barrier to
22 entry.

23 Q. When you say --

24 A. And the API is related to it of course because
25 it's either a different formulation of the same API or

1 a new API that would be the basis for an NDA as opposed
2 to a generic ANDA.

3 Q. You keep saying "NDA." Can you just tell us
4 what that is?

5 A. A New Drug Application is an application to
6 get -- to the FDA to introduce a drug that is new, that
7 is, either the API or the formulation is different than
8 a drug that's currently on the market.

9 And the -- the requirements for you to get
10 approval of an NDA are much more rigorous than the
11 requirements for an ANDA, which ANDA you just have to
12 demonstrate it's the same drug. NDA you have to prove
13 the safety and efficacy.

14 Q. Can an ANDA also be a barrier to entry?

15 A. Of course. Because you -- it takes time, and
16 in a Paragraph IV case, it takes at least 30 months to
17 get approval.

18 Q. You're talking about FDA approval?

19 A. Yes.

20 Q. What does high market concentration and the
21 presence of entry barriers tell you about whether Endo
22 enjoyed market power in the oxymorphone ER market?

23 A. It says that that's the -- that the indirect
24 test is at a certain threshold, which is an HHI of
25 roughly 2500, that further increases in concentration

1 are likely to cause firms that are in the market, the
2 large firms that are in the market, to have greater
3 market power.

4 And the concentration in the market for
5 oxymorphone ER -- if you believe that's the relevant
6 market, then the concentration ratios in that market
7 have always been substantially in excess of 2500.

8 Q. Did you actually calculate HHIs in this case?

9 A. I calculated them a number of ways.

10 There's a number of possible ways to calculate
11 it. You can calculate it based on quantities or
12 calculate it based on revenues, or you can calculate it
13 based on simply the number of firms in the market. And
14 you get different numbers at different times depending
15 on which one of those you use.

16 Q. And did you use all of those measures?

17 A. Yes.

18 Q. And what did you find about the concentration?

19 A. That it was never less than 3333 and it was
20 usually more than that, substantially more than that.

21 Q. "3333" meaning 3,333?

22 A. Yes.

23 Q. Let's turn now from discussing indirect
24 measures of market power to more direct measures.

25 How do economists directly measure market

1 power?

2 A. The -- the first way is actually examples of
3 circumstances where a firm succeeded in excluding a
4 competitor from the market.

5 And the second are measures of profits to show
6 that the profits are supracompetitive.

7 Q. Did you try to directly measure market power in
8 this case?

9 A. Yes.

10 Q. What information did you examine to do that?

11 A. Well, the -- they're different depending --
12 the exclusion part is examples of circumstances where
13 Endo was able to exclude people from the market and
14 that -- their enforcement of patent rights.

15 Q. Okay. And did you also look at direct measures
16 of market power by looking to whether Endo --

17 A. Oh, I forgot. I didn't give you a complete
18 answer to the last question.

19 The other is the 180-day exclusivity window
20 from Impax. It can actually -- once it enters, it can
21 exclude other generics from the market for -- except
22 for authorized generics, for 180 days. That's part of
23 the Hatch-Waxman process.

24 Q. As part of your work in this case did you also
25 look to see whether Endo could profitably set prices

1 above a competitive level?

2 A. Yes, I did.

3 Q. And what did you find with respect to that?

4 A. The method that I used, since profitability is
5 extremely difficult to measure, is the Lerner Index,
6 which is the markup of price over some estimate of
7 marginal cost.

8 Economic theory says that firms will base
9 prices on marginal cost, and the markup of price over
10 marginal cost will depend on the elasticity of demand.
11 The more concentrated the market, the more market power
12 the firm has, the less elastic the demand curve is, so
13 all else equal, you expect firms with greater market
14 power to have higher markups of price over marginal
15 cost.

16 And the Lerner Index is simply the price minus
17 marginal cost divided by the price, in other words, a
18 fraction of price that is operating profit.

19 Q. Where did the Lerner Index come from?

20 A. It comes from an article by Abba Lerner that
21 is very old, that was published decades ago, which was
22 the, you know -- the title of it is An Index of
23 Monopoly Power.

24 And it's been used extensively in economics
25 right up to the present. There are articles published

1 in peer-reviewed journals that measure market power on
2 the basis of the Lerner Index.

3 Q. Is the Lerner Index something that you would
4 teach when you would teach antitrust economics
5 courses?

6 A. Yes. And it's in all the textbooks. You know,
7 this is not only what I would teach but everybody would
8 teach.

9 Q. So maybe you could try to explain a little bit
10 more in a little more detail, what can the Lerner Index
11 tell you about market power?

12 A. It tells you essentially how inelastic or how
13 price elastic the demand curve is if price equaled
14 marginal cost. In a competitive industry, price is
15 driven down to marginal cost. All right.

16 Now, that doesn't work in a
17 product-differentiated market. Usually there are fixed
18 entry costs that firms must recover to be viable in a
19 product-differentiated market.

20 So people don't enter the market unless they
21 expect that there's going to be sufficient market power
22 available to them that they can recover their fixed
23 costs.

24 So it's normal that the Lerner Index is not
25 zero, it's not -- in a perfectly competitive

1 environment, the Lerner Index would be zero, price
2 would equal marginal cost, so price minus marginal cost
3 divided by price would be zero. Usually, as I cite in
4 the report, when you study competitive products, you
5 get Lerner Indexes between 20 and 50, .2 and .5.

6 Q. Does -- sorry.

7 So does a high Lerner Index necessarily mean
8 that a firm has market power?

9 A. No, it doesn't necessarily mean that.

10 What it does mean, however, is that a firm has
11 enough market power to sustain price above marginal
12 cost. Whether they have monopoly power depends on
13 other things, but it's always the case, if we -- if we
14 take an industry where fixed costs are extremely high,
15 no one enters that industry unless they expect that
16 it's not going to be very competitive.

17 And there's nothing particularly wrong with
18 observing a high Lerner Index in something like a
19 software market where all the costs just about are
20 fixed costs. That is to say, you gather around a bunch
21 of people, you write several billion lines worth of
22 code and you produce a program, and then you sell the
23 program. There's almost no marginal cost and very high
24 Lerner Index. No one would enter that market if they
25 thought competition was so intense, it would drive

1 price down to marginal cost.

2 So the normal market outcome in an industry
3 with high fixed costs and low marginal costs is for
4 firms to have a lot of market power to be able to
5 sustain a price that is substantially and above
6 marginal cost. But whether there's monopoly profit or
7 not you don't know, but you do know the firms do
8 possess a lot of market power, that is to say, they do
9 have a lot of ability to control price, because they
10 wouldn't have entered unless they did.

11 Q. Is that a characteristic of pharmaceutical
12 markets like the software market example you gave?

13 A. Exactly. Because the research and development
14 costs and the NDA costs are high, and so firms
15 normally don't enter unless they expect a period where
16 they will enjoy substantial market power.

17 And what that means is, it must be -- they
18 must be entering in a business where the existing
19 products are not close competitive substitutes, they're
20 not going to drive the price down to marginal cost, and
21 where they don't expect that other people are going to
22 come in very soon, because they expect -- they -- in
23 order to enter in the first place, they have to
24 anticipate there's going to be a number of years in
25 which they can charge a price substantially in excess

1 of marginal cost.

2 Q. Did you calculate a Lerner Index for Endo for
3 Opana ER in this case?

4 A. Well, I both calculated it and I observed
5 calculations of it by people inside Endo.

6 Q. And what did those calculations show?

7 A. Depending on what you assume about what
8 marginal costs are, because it's not absolutely clear,
9 you get some number somewhere between .7 and .9 in
10 every year since the product has been on the market.

11 Q. Is that a high Lerner Index?

12 A. Yes. As I said before, the articles in the
13 peer-reviewed economics journals normally find
14 Lerner Indexes that are half or less of that.

15 Q. You had indicated, in addition to looking at
16 these price issues that you measured Lerner Index, that
17 the fact that a company could exclude competition also
18 tells you something about the presence of market power;
19 correct?

20 A. Yes.

21 Q. And what does that tell you?

22 A. Well, it's the same story. That is, the
23 mechanism that enables people to sustain high
24 Lerner Indexes for a substantial period of time is the
25 presence of the barriers to entry.

1 If the barriers to entry weren't there, nobody
2 would ever enter the drug industry because the fixed
3 costs of entry are too high. You would never pay
4 hundreds of millions of dollars to do research and
5 development and to get an NDA unless you expected that
6 you would have several years of essentially monopoly,
7 of a circumstance where you could exercise substantial
8 market power.

9 Q. So to summarize, what do you conclude about
10 Endo's market power in the relevant market based on
11 both the indirect and direct measures of market power?

12 A. That from the period right after Opana ER was
13 introduced until the end of the data that I have,
14 which is sometime within the last year -- I forget the
15 exact date -- there's always been -- it's always been
16 the case Endo has enjoyed substantial market power,
17 although it's less now than it was at its peak.

18 Q. Professor Noll, did you review Dr. Addanki's
19 arguments relating to market power?

20 A. Yes.

21 Q. What opinions have you reached about
22 Dr. Addanki's arguments about market power?

23 A. That it was confused.

24 Q. Can you elaborate a little more?

25 A. Yes. I mean, the problem is he -- he sort of

1 mushed together the issue of does a firm have market
2 power with the issue of whether the market power is
3 achieved by anticompetitive conduct.

4 And he seems to believe that only market power
5 that's achieved by anticompetitive conduct is really
6 market power or monopoly power, and that's just not
7 true, that you can have something called a natural
8 monopoly, where a firm has such great patent rights or
9 there's such strong economies of scale that the market
10 could never have anything more than one firm in it.

11 And that is a case in which the firm that is in
12 the market has what we call superior efficiency; that
13 is to say, it's so efficient because of economies of
14 scale that no one could ever succeed in competing
15 against it. That's monopoly power, but it's not
16 anticompetitive, because it wasn't achieved by
17 anticompetitive means.

18 And Dr. Addanki's expert report doesn't
19 actually make the distinction. He just says that
20 unless basically -- he defines market power in a way
21 that it somehow has to be achieved by anticompetitive
22 conduct. And then he actually cites a couple of other
23 articles in the literature that make the same mistake,
24 and so it's just not true that that's the right
25 definition of "market power" in economics.

1 Q. You've already touched on this, but in general,
2 what are the sources of market power that a firm may
3 enjoy?

4 A. The first category consists of superior
5 efficiency and foresight, which is another one of these
6 Supreme Court terms, that what it really means is that
7 one firm can produce at lower cost or produce a
8 superior product that nobody else can successfully
9 duplicate.

10 And that can be a source of market power
11 because it's related to the barriers to entry point;
12 that is, no one can enter against you successfully
13 because you're so good at what you do. That may be
14 backed up by a patent right or it may not, so a patent
15 right may be a source of superior efficiency and
16 foresight.

17 The other way to obtain market power is
18 anticompetitive conduct. The easiest example and the
19 least controversial example is -- would be merger to
20 monopoly or collusion among firms in an industry that
21 allowed them collectively to raise price.

22 Q. In your view, is there anything wrong with a
23 firm achieving monopoly or market power as a result of
24 a patent?

25 A. No.

1 Q. In your opinion, is there anything wrong with a
2 company achieving market or monopoly power through
3 superior foresight, skill and industry?

4 A. No.

5 Q. So what is your concern with Endo's market
6 power in this case?

7 A. It's -- it's either achieving it or sustaining
8 it through anticompetitive conduct. It has no
9 efficiency component to it. It's engaging in conduct
10 that reduces the intensity of competition that has no
11 offsetting competitive benefit.

12 Q. And you've used the term "anticompetitive
13 conduct" a number of times.

14 Can you just give me an industrial organization
15 economist's understanding of what anticompetitive
16 conduct is?

17 A. It is conduct that increases the market power
18 of a firm in a market that has no efficiency benefit of
19 the form of it was achieved because lower prices and
20 they drove everybody else out of the market, it was
21 achieved because they had intellectual property rights,
22 it was achieved because they had a better quality of
23 product.

24 In other words, it's -- there's -- there's none
25 of this other component of there was something nice

1 that they did that is the reason for their market
2 power.

3 Q. In your opinion, did Impax and Endo engage in
4 anticompetitive conduct when they settled their patent
5 litigation?

6 A. Yes.

7 Q. Can you elaborate on that a little bit?

8 A. The reason that it's anticompetitive is that
9 it extended the period of Endo's monopoly in the
10 market. It gave them insurance or protection against
11 the possibility of generic entry for two and a half
12 years.

13 Q. So, Professor Noll, let's move away from
14 talking about market definition and market power to
15 talk about your economic analysis of reverse payment
16 agreements.

17 A. Yes.

18 Q. First, what is a reverse payment agreement?

19 A. A reverse payment agreement of a patent, a
20 patent litigation, is an agreement in which on the --
21 the parties specify a date at which a competitor will
22 be allowed to enter the market, and the incumbent firm
23 whose patent has been allegedly infringed pays the
24 infringer as part of the agreement; that is to say, the
25 money goes in the wrong direction.

1 Normally we would expect that if somebody were
2 going to enter a market that was protected by a patent,
3 that they would pay royalties to the entity that owned
4 the patent, that held the patent, in order to obtain
5 the right to enter before the patent expires.

6 A reverse payment is one in which entry occurs
7 before the expiration of the patent, but instead of the
8 infringer paying a royalty to the patent holder, the
9 patent holder pays the infringer.

10 Q. Where does the term "reverse payment" come
11 from? Do you know?

12 A. It comes from observations of these results in
13 the drug industry that have been written about first of
14 all by economists and lawyers in antitrust economics
15 and law and economics.

16 Q. I think you've touched on this already, but
17 maybe go into it in just a little more detail.

18 What are the general features of a reverse
19 payment agreement?

20 A. I think -- just a reverse payment agreement,
21 I've already answered it. It's just that the payment
22 goes in the wrong direction, and there's an entry date
23 agreed upon that is before the expiration of the
24 patent.

25 Q. Okay.

1 A. It has no other features besides that, just to
2 characterize it.

3 Q. In your report, have you included a chart that
4 illustrates the parties', that is to say, the brand and
5 the generic companies' incentives to enter into a
6 reverse payment agreement?

7 A. Yes, I have prepared a chart. But that's a
8 chart about when reverse payments can be
9 anticompetitive.

10 Q. Okay. Ms. Durand, could you call up Appendix C
11 from Professor Noll's report.

12 Professor Noll, is that the chart that
13 illustrates --

14 A. Yes.

15 Q. -- parties' incentives?

16 A. It is.

17 Q. Can you give a brief explanation of what this
18 chart is intended to show?

19 A. What this chart shows is why both a generic
20 firm and a brand name firm have an incentive to engage
21 in an anticompetitive reverse payment agreement as
22 opposed to just any reverse payment agreement.

23 And it -- the three circles essentially
24 represent all of the potential welfare to be generated
25 from the market and on -- on the supply side, the drug

1 firm side, and what happens to that under three
2 circumstances.

3 Q. So taking the pie chart to the far left, the
4 fully red chart, what does that show?

5 A. That shows that prior to a generic entering
6 the market, the brand name firm has this big excess of
7 price over marginal cost, which means it has a big
8 positive operating profit; that is to say, a
9 substantial fraction, like 80 or 90 percent, of the
10 revenues from selling the drug are operating profit,
11 which is the result from the Lerner Index analysis.

12 So prior to any generic entry, there's this
13 big monopoly profit that is arising -- operating profit
14 that is arising from the monopoly power from having
15 only one firm in the market.

16 Q. So looking then at the pie in the middle, what
17 does that show?

18 A. This is what the picture looks like after
19 generic entry.

20 The key -- the key point here is that even if
21 there's only two firms in an industry, the price
22 competition, as weak as it is between only two firms,
23 still produces a total profit, total operating profit
24 for the industry, that's less than monopoly profit.
25 And that is divided between the part that's still

1 red-orange, which is kept by the brand name firm, the
2 part that's yellow, which is what goes to the generic,
3 and then the green part is captured by consumers in the
4 form of lower prices.

5 And so what happens when generic firms enter,
6 total profits go down and consumer welfare from the
7 drug go up.

8 Q. And then there's the last pie chart on the far
9 right.

10 What does that pie chart show?

11 A. An anticompetitive reverse payment settlement
12 of a patent infringement case is one which restores
13 the first picture, but the reverse payment is a
14 mechanism for dividing that profit between the brand
15 name firm and the generic firm, so what happens is the
16 generic firm agrees to a -- an entry date that is
17 sometime in the future and in return for that gets paid
18 a fraction of the monopoly profit that accrues between
19 the date of the settlement and the date the generic
20 firm enters -- enters.

21 And so you'll notice that during that period
22 before generic entry, before we can get to the middle
23 circle, we have to experience some period of the third
24 circle, when the generic firm is simply being paid to
25 stay off the market and they're being paid a fraction

1 of the monopoly profit.

2 Q. So what happened to the consumer savings in
3 the --

4 A. It goes into the -- the profits, the operating
5 profits. Most of it goes to the operating profit of
6 the brand name firm, but a big hunk of it goes to the
7 operating profit of the generic firm.

8 Q. Ms. Durand, you can take that down now.
9 Thank you.

10 In your opinion, is a reverse payment agreement
11 akin to a branded pharmaceutical company buying an
12 insurance policy?

13 A. I'm sorry. I didn't hear you. Can you speak
14 up?

15 Q. In your opinion, is a reverse payment agreement
16 akin to a branded pharmaceutical company buying an
17 insurance policy?

18 A. Yes.

19 Q. How?

20 A. It's -- what they're doing is they -- they
21 face uncertain prospects that a generic firm may enter
22 as soon as it gets approval from the FDA for its ANDA,
23 which usually comes roughly at the end of the
24 30-day (sic) stay in the Hatch-Waxman Act. And then
25 there's -- then it may win the patent infringement suit

1 and enter then.

2 There's a whole bunch of times it might enter.
3 And what happens is that the generic firm agrees that
4 it will not enter on any of those dates prior to the
5 date in the settlement in return for getting paid.

6 And that's essentially an insurance policy.
7 The payment to the generic is an insurance payment by
8 the brand name against the risk of competition
9 occurring prior to the date that's agreed in the
10 settlement.

11 Q. In giving that answer a moment ago -- I just
12 checked this on the realtime -- you said "the 30-day
13 stay."

14 Did you mean 30- --

15 A. 30-month. I'm sorry. I'm sorry. Thank you.
16 I mean 30-month.

17 Q. Okay. Has any economic research been
18 conducted on the settlement of patent infringement
19 litigation?

20 A. Oh, yes. There's a lot of economics research
21 on it.

22 Q. In forming your opinions in this case, did you
23 conduct a review of the economic literature on reverse
24 payment cases?

25 A. Yes. That's in my expert report.

1 Q. What are some of the main conclusions from the
2 economic literature concerning the brand company's
3 incentives to enter into reverse payment agreements?

4 A. The conclusions are basically the same as the
5 ones I just gave you, that -- that because of the --
6 the -- the structure of the Hatch-Waxman Act, which
7 creates this 180-day exclusivity period for the
8 generic first to file, that that firm has the ability
9 to block all generic entry, and so it has a really
10 valuable asset that it can sell to the brand name
11 firm, which is the ability to block further generic
12 entry, and that the -- that that incentive structure
13 that's created by Hatch-Waxman is the principal reason
14 we observe reverse payment settlements of patent
15 infringement cases in the drug industry.

16 Q. When you were helping the FDA with the
17 precursor to the Hatch-Waxman Act, is that something
18 you had anticipated?

19 A. No. I -- it completely -- I completely missed
20 it. I plead guilty. One of the worst pieces of policy
21 advice I ever gave.

22 Q. What else does the economics literature teach
23 about the incentives of parties to enter into reverse
24 payment agreements?

25 A. Well, the -- the economics literature itself

1 contains further -- further development of the concept
2 of how do you detect when a reverse payment settlement
3 falls into the anticompetitive category. And that's
4 the -- that is the literature that forms the basis for
5 the theoretical model that I put in my expert report,
6 which actually does develop some more implications from
7 that model than you can find in the literature, but
8 it's still the same basic model that's in the
9 literature.

10 Q. I'm going to ask you a little bit more about
11 your mathematical model in a moment, but before I do,
12 I want to finish talking about the economic
13 literature.

14 A. Sure.

15 Q. Are there any other conclusions from the
16 economic literature that you're aware of on the
17 brand's incentives to settle infringement litigation?

18 A. Well, the observations that appear in the
19 published literature are that brand name firms have a
20 strong incentive to defend patents even if they're
21 weak. And the reason they do is, first of all, the
22 act of defending them right off the bat gets you the
23 30-month delay of generic entry, so it's like getting
24 an extra 30 months of value out of a patent.

25 Even if you know that the patent is not -- is

1 not enforceable, it's invalid or it's not infringed,
2 even if you know that, you still have an incentive to
3 file an infringement suit.

4 And then secondly, once you -- that 30-day
5 period has expired, it's -- it's still in your
6 interest to get the brand -- the generic firm not to
7 enter by paying it.

8 And so those -- those results are in the
9 economic literature on reverse payment settlements.

10 Q. A moment ago you just said "30-day" again. You
11 meant 30-month?

12 A. Oh, I'm sorry. 30-month. I thought I said
13 30-month. I thought really hard about that.

14 Q. What does the economics literature teach about
15 the generic's incentives to enter into a reverse
16 payment settlement?

17 A. The generic firm always has substantially less
18 profit than the brand name firm if it enters, and it
19 has less profit for two reasons.

20 The first reason is it has less than a hundred
21 percent of the market as long as the brand name firm
22 stays in. And indeed, after 180 days, it may have to
23 share even the generic part of the market with other
24 generic firms, so its sales volume is going to be
25 substantially less than a brand name firm.

1 Secondly, the way the generic firm obtains
2 sales is through price competition. It's through
3 charging substantially lower prices. And indeed, the
4 research on generic entry finds that usually in the
5 range of a few months after generic entry occurs you
6 get price reductions of 30 to 50 percent, and then
7 after multiple generics enter after 180 days, you get
8 reductions in price up to 85-90 percent.

9 So what that means is that not only does the
10 generic firm, even the first-to-file firm have a
11 relatively small market share after the 180-day period,
12 they also have a much lower price.

13 Now, what that does is say it doesn't take
14 very much to buy off the generic first-to-file firm
15 because the potential profits in -- for a generic firm
16 to enter a market are far less than the monopoly
17 profits of the brand name firm if it retains the
18 monopoly.

19 So that means the -- the -- the price -- the
20 minimum price that a generic firm would be willing to
21 accept to delay its entry is much lower than the
22 maximum price that the brand name firm will be willing
23 to pay to preserve its entry, and that -- because
24 that's normally true, it's not always true, because
25 it's normally true, there usually is a potential at

1 least -- if anticompetitive reverse payment
2 settlements are allowed, then indeed there's almost
3 always a potential for a deal between the brand name
4 firm and the generic firm where the brand name firm
5 pays the generic firm more than it expected to earn by
6 being in the market and in return stays off the market
7 until near the end of the patent for the brand name
8 firm.

9 Q. In your expert report on pages 101 to 143, you
10 present a mathematical model of reverse payment
11 settlements; correct?

12 A. That's correct.

13 Q. And why do economists construct mathematical
14 models?

15 A. The reason you construct a mathematical model
16 is because the world is complex, and it's -- it's --
17 there's lots and lots of moving parts, lots of
18 variables and lots of equations. You can -- you can
19 get insights from the mathematical model that you
20 can't get from just trying to think through it on your
21 own, and that's the purpose of mathematical models, is
22 to generate insights you wouldn't otherwise have.

23 And a lot of the results are counterintuitive.
24 They're things that normal people, even normal
25 economists, if they're not doing the math, they're not

1 building a model, would not think of.

2 Q. Is mathematical modeling something you taught
3 as a professor at Stanford?

4 A. Oh, yes. I mean, you can't teach economics
5 without using mathematics. That's been true ever since
6 I was a graduate student.

7 Q. That's back to the '60s?

8 A. Yes.

9 Remember, my undergraduate degree is in
10 mathematics. And I spent part of my time as a graduate
11 student teaching the other graduate students
12 mathematics that hadn't had it in a sufficient quantity
13 to do economics.

14 Q. So why did you construct a mathematical model
15 in this case?

16 A. To see if it -- what I could learn about the
17 nature of the market and in particular the bargaining
18 relationship between the brand name and the generic
19 firm, you know, what insights could I get that I
20 wouldn't otherwise get that would be counterintuitive.

21 Q. Did you just make up this mathematical model
22 for your work in this case?

23 A. No. As I said before, it's basically the
24 model that economists have used to -- it starts with a
25 paper by Joe Farrell and Carl Shapiro, who used to be

1 the chief economists at the FTC and the Department of
2 Justice, called Probabilistic Patents, which is, the
3 way you think about patents is that whether they're
4 really a property right or not is probabilistic. They
5 may be good and they may be bad, and you don't know
6 that until you litigate them.

7 And then I -- then the people who have studied
8 reverse payment take that basic idea and apply it to
9 the context of the drug industry. And I took that
10 model and then just did more things with it in the
11 report.

12 Q. So your model is derived from published
13 peer-reviewed economic articles?

14 A. Yes. The basic structure of the model is
15 exactly the same as appears in several other articles.

16 Q. Does your mathematical model provide any useful
17 insights on the likely competitive effects of the
18 reverse payment agreements?

19 A. Yes.

20 Q. And does it provide any useful insights on the
21 likely competitive effects of the reverse payment
22 agreement in this case?

23 A. Yes.

24 Q. Let's talk a little bit about some of those
25 insights.

1 What insight does your mathematical model
2 reveal about the incentives of brand firms to settle?

3 A. Well, that part of the model is the same
4 results as I just described. It says that there is
5 this big incentive, but it has one additional result,
6 which is that given that any reverse payment settlement
7 is feasible, that is to say, there is at least one
8 circumstance in which the brand name firm and the
9 generic firm could agree to an anticompetitive reverse
10 payment settlement, if any such agreement is feasible,
11 then the incentives of both parties are to extend the
12 duration of the agreement, to delay the entry date as
13 far as possible, that is to say that the
14 profit-maximizing bargain for the brand name and the
15 generic firm is to delay entry as long as possible
16 and -- now, the thing that gets in the way, of course,
17 is the 180-day exclusivity period because that's really
18 valuable to the brand name firm, so -- and then in
19 addition to that, if a brand name firm sold its
20 exclusivity period entirely, so it never entered before
21 the expiration of the patent, that would be a red flag
22 for antitrust enforcement.

23 So, you know, you would never observe a
24 reverse payment settlement that actually allowed entry
25 the date of patent expiry, so you -- but you observe

1 them that are close to that, and that's the result in
2 this case.

3 Q. A moment ago, in giving that answer, you said
4 the 180-day period is very valuable to the brand
5 company.

6 A. Yes.

7 Q. Did you mean to the generic company?

8 A. The generic. The 180-day exclusivity period
9 for the generic company, yes.

10 Q. Thank you.

11 Does a brand's willingness to litigate the
12 patent reveal anything about the strength of its patent
13 case under the mathematical model?

14 A. No. And that's -- that's the point I made
15 earlier before. But I'll make a stronger statement
16 now because the model says something stronger than
17 that.

18 The earlier statement I made was that a brand
19 name firm is willing to defend even a really weak
20 patent because of these two opportunities, the 30-month
21 delay and then the possibility of a reverse payment
22 settlement that blocks entry for the first filer.

23 But then there's an additional result, which is
24 the actual incentive to engage in reverse payment
25 settlements does not depend on the probability that

1 the brand name firm is going to win the patent
2 infringement suit. As long as that probability is
3 substantially less than one, in other words, as long as
4 there's any chance at all they could lose it, they have
5 an incentive to engage in a reverse payment settlement
6 of the patent dispute. And it doesn't depend on how
7 big that probability is.

8 Q. What does your mathematical model reveal about
9 the incentives of the generic firm to settle if it
10 expects to win the patent litigation?

11 A. If they expect to win the patent infringement
12 case, there's no reason for them to allow entry before
13 the expiration of the patent. They can always get a
14 date at the expiration date.

15 The only incentive they have is that they can
16 save some litigation costs if they let the generic in
17 earlier, but those litigation costs are tiny compared
18 to the profitability of most brand name drugs, so that
19 would not be a sufficient incentive to settle an
20 antitrust case if you were certain or virtually certain
21 to win the antitrust case. You would simply wait it
22 out and let entry occur when the patent system allowed
23 it.

24 Q. If a generic firm would expect to win the
25 patent infringement case, would it settle without a

1 large reverse payment?

2 A. No. It would never -- the generic -- the
3 generic firm, if it's certain to lose the antitrust
4 suit, again wouldn't pay the cost of litigating it. It
5 would probably fold. But if it got a settlement, it
6 would have to be something where the entry date was
7 really close to the patent expiration date, because it
8 has no bargaining power over the brand name firm in
9 that case.

10 Q. Okay. So my question was actually whether, if
11 the generic firm expects to win --

12 A. Oh, I'm sorry.

13 Q. -- the patent --

14 A. I misheard you.

15 (Counsel and witness speaking at the same time
16 and cautioned by court reporter.)

17 BY MR. MEIER:

18 Q. Let me start the question over.

19 A. Yeah.

20 Q. What does your mathematical model reveal about
21 the incentives of a generic firm to settle if it
22 expects to win the patent litigation?

23 A. If it expects to win the patent litigation,
24 then it's going to want to enter at or soon after the
25 date of the -- at or very soon after the date that its

1 ANDA is approved by the FDA. It's not going to enter
2 later than that unless it's paid a great deal of
3 money, because it has to sacrifice the certainty of
4 earning generic profits after entry.

5 Now, that is a beautiful example,
6 incidentally, of a circumstance where a reverse
7 payment can be extremely harmful to consumers, because
8 the brand name firm still has the incentive to pay a
9 lot of money to the generic firm to delay entry, but
10 with certainty or near certainty, without that
11 settlement, entry would occur much sooner and consumers
12 would derive that big green benefit that was in my
13 picture.

14 Q. So now I'm going to reverse it and ask, what
15 does your mathematical model reveal about the
16 incentives of a generic firm to settle if it expects to
17 lose the patent litigation?

18 A. If it expects to lose the patent litigation,
19 then that's the point I've already -- that's the
20 question I answered that you didn't ask. It has no
21 bargaining strength, and it knows it has no bargaining
22 strength, so it -- if it gets anything other than the
23 date of patent expiry out of the settlement, that's a
24 benefit. And it doesn't need to be paid to stay off
25 the market until at or near the date of expiration of

1 the patent.

2 Q. What does your mathematical model reveal about
3 the relationship between the payments and the patent?

4 A. The relationship is that the weaker the patent,
5 the bigger the payment will be. But it doesn't
6 affect -- in the absence of antitrust, it doesn't
7 expect (sic) the profit-maximizing solution to the
8 bargaining game, which is always delay entry as long as
9 you can get away with, because you can -- the brand
10 name firm always has more profits than the generic
11 firm, so there's always an incentive, regardless of
12 that probability of the patent's validity, to settle as
13 late -- an entry date as late as possible.

14 Q. Does your mathematical model depend on knowing
15 the merits of the underlying patent litigation?

16 A. No. That's the -- that's the -- the great
17 insight from the economic theory of reverse payment
18 settlements is that the -- the -- you don't need to
19 know anything about the viability of the patent to
20 know that a reverse payment settlement is
21 anticompetitive. Instead, you have to know other
22 things that we haven't talked about yet.

23 Q. Well, why is that true?

24 A. Because what the probability does is tell you
25 how they're going to share the profits. And it

1 doesn't tell you anything about whether they have an
2 incentive to settle.

3 And the main incentive to settle here is not
4 avoided litigation costs, which in most civil disputes
5 the main reason you settle is because you can avoid
6 litigation costs that are significant. In this case,
7 in the case of patent infringement cases, that
8 incentive is really small in most circumstances
9 compared to the profitability of brand name drugs that
10 have a monopoly position, so that the dominant factor
11 in driving settlements in patent infringement cases in
12 the drug industry is just completely different than it
13 is in other patent infringement areas or in other kinds
14 of civil litigation.

15 In most kinds of civil litigation, settlement
16 is a good thing because it saves litigation costs. In
17 this case, the saved litigation costs are tiny
18 compared to the profitability of the drug companies and
19 the amount of consumer welfare at stake in the
20 settlement.

21 Q. Are there any published papers in the economics
22 literature that argue that reverse payment agreements
23 can be procompetitive?

24 A. Yes.

25 Q. And what is your opinion of these arguments?

1 A. Well, there's a -- again, the -- there's a --
2 the papers themselves are correct in what they state,
3 but they're not statements about whether a reverse
4 payment settlement will be or is procompetitive.
5 They're statements about -- there's an existence
6 there -- they're -- they're a statement that is --
7 there are circumstances in which the only way you can
8 get a procompetitive reverse payment settlement -- a
9 procompetitive settlement -- excuse me -- that is a
10 settlement that avoids litigation costs and occurs on
11 the date that entry would otherwise be expected to
12 occur anyway, all right, that there are circumstances
13 where you could only get that with a reverse payment.

14 What they do not say is that will actually be
15 the outcome. All right. They just say it's -- that
16 such a settlement in principle could happen or it
17 could -- you know, that it could be the case you can't
18 achieve a settlement at -- at approximately the
19 expected date of generic entry without a reverse
20 payment.

21 Q. As part of your work in this case, have you
22 read the Supreme Court's Actavis decision?

23 A. Yes.

24 Q. Why?

25 A. First of all, as I said earlier, in teaching

1 antitrust and regulation, I need to teach cases. And
2 the whole history of Hatch-Waxman litigation is really
3 interesting. It's one of the more important areas of
4 antitrust in the last 30 or 40 years. It's right up
5 there in the hall of fame of antitrust issues, so it
6 would be impossible to teach an antitrust course of --
7 a good, high-quality antitrust course and ignore it.

8 So that's the first reason.

9 The second reason is that we economists, just
10 like you lawyers, like reading Supreme Court
11 decisions, but in our case, the reason we read them is
12 to see if they got the economics right or to interpret
13 what the economics implications of the decisions are.

14 And indeed, a lot of people have written
15 articles -- a very large number of people have written
16 articles in the last couple of years about what is the
17 proper economic interpretation of the Actavis
18 decision.

19 Q. Does the economic analysis you did in this
20 case address the economic issues the Supreme Court
21 identified as relevant to determining the circumstances
22 under which a reverse payment agreement can harm
23 competition?

24 JUDGE CHAPPELL: His opinion on what the
25 Supreme Court has to say legally in Actavis is not

1 relevant in this case. Rephrase your question.

2 MR. MEIER: Your Honor, if I may --

3 JUDGE CHAPPELL: Not relevant, not acceptable
4 and won't be heard.

5 MR. MEIER: I did not ask --

6 JUDGE CHAPPELL: Then rephrase.

7 MR. MEIER: My question was about the economic
8 issues the Supreme Court identified. I'll try the
9 question again.

10 BY MR. MEIER:

11 Q. Does your economic analysis address the
12 economic issues the Supreme Court identified as
13 relevant to determining the circumstances under which a
14 reverse payment agreement can harm competition?

15 A. Yes. It does -- it addresses exactly the same
16 issues. My -- the conditions I conclude are the
17 conditions to identify an anticompetitive reverse
18 payment settlement. The economic conditions are
19 exactly the same issues.

20 Q. So let's now turn to your application of these
21 economic analyses to the facts of the Impax-Endo
22 agreement.

23 In your opinion, what are the key issues to
24 consider in applying economic analysis to the facts in
25 this case?

1 A. The key issues are: one, were there plausible
2 possible entry dates before the date that's in the
3 settlement agreement; number two, was there a reverse
4 payment; number three, was that reverse payment large
5 and unjustified, where "large" means bigger than the
6 saved costs of litigation and "unjustified" means it
7 was not a transaction involving the exchange of some
8 other services or assets or products that were obtained
9 by the brand name firm from payments to the generic
10 firm.

11 Q. All right. We're going to break that down a
12 little more by looking at the market for Opana ER
13 before the settlement agreement.

14 What did the market for Opana ER look like
15 before the settlement agreement with Impax?

16 A. At that time there was nobody in it except
17 Endo, that neither Impax nor Actavis had entered, so
18 they had complete monopoly.

19 Q. Was Endo, in your opinion, concerned about the
20 possibility of Impax' generic entry?

21 A. Yes. The discovery information, the discovery
22 documents show that they not only expressed concern,
23 but they actually did financial modeling of what the
24 effect on them would be from various entry dates of
25 the generics of Impax in particular, starting with an

1 entry date soon after the FDA approved the NDA through
2 entry dates that would be a little bit more than a
3 year later when the court of appeals decision would
4 have been decided. You know, the intermediate there is
5 the district court patent infringement decision and
6 then there's the court of appeals.

7 So they looked at scenarios where Impax might
8 enter in June of 2010 all the way to Impax might enter
9 at the end of the summer of 2011.

10 Q. In giving that answer a moment ago, you said
11 "starting with an entry date soon after the" --

12 A. I'm sorry. I'm not hearing you. I'm sorry.

13 Q. In giving that answer a moment ago, you said
14 that "starting with an entry date soon after the FDA
15 approved the NDA." Did you mean --

16 A. ANDA.

17 Q. -- ANDA?

18 A. I thought I said ANDA. I may have slurred it
19 together. I'm sorry. I apologize.

20 Q. That's all right. I just wanted to make sure
21 the record is clear.

22 A. Okay.

23 Q. Based on your review of the discovery materials
24 in this case, what were Endo's plans for dealing with
25 its concern about Impax' generic entry?

1 A. The -- the -- the discovery documents show two
2 different strategies. All right. The first
3 strategy --

4 JUDGE CHAPPELL: Are you asking him for an
5 opinion, because he's not a fact witness? Let's make
6 that very clear. He's talking about this like he's a
7 fact witness, like he was there, so let's be real clear
8 for the record these are opinions.

9 MR. MEIER: Absolutely, Your Honor.

10 BY MR. MEIER:

11 Q. Based on your review of the discovery
12 materials, in your opinion, what were Endo's plans for
13 dealing with its concerns about Impax' generic entry?

14 A. They had two contingency plans.

15 The first was to develop and introduce a
16 reformulated version of Opana ER that would mitigate to
17 some significant effect the impact of generic entry.

18 And the second was, if they failed to introduce
19 the reformulated product, to introduce an authorized
20 generic, which would save them roughly one-third of the
21 profit loss that they would experience from the entry
22 of Impax.

23 Q. In your opinion, was the timing important to
24 Endo's plans for launching its reformulated Opana ER
25 product?

1 A. Exactly -- it was extremely important, because
2 it would determine which of those two strategies would
3 have to be implemented, because the reformulated
4 product had not yet been fully developed and approved
5 by the FDA, and that -- so the date at which they could
6 enter was uncertain.

7 The longer they delayed entry, the more likely
8 it was that they were going to have a reformulated
9 product on the market and thereby reduce the impact of
10 generic entry.

11 Q. Professor Noll, the FTC and Impax' counsel have
12 entered certain factual stipulations in this case, and
13 Judge Chappell has admitted those stipulations as
14 Joint Exhibit Number 1.

15 And stipulation number 19 states as follows:

16 "On June 8, 2010, Impax and Endo entered into
17 the Settlement and License Agreement."

18 So you can take that fact as a given.

19 A. Okay.

20 Q. Do you understand that?

21 A. Yes.

22 Q. In your opinion, what did Impax get from its
23 June 8, 2010 settlement agreement with Endo?

24 A. It got three things -- well, it got four things
25 actually.

1 It got, first of all, the guarantee of an
2 entry date of -- in January of 2013 instead of facing
3 the same uncertainty that Endo faced about when
4 generics would actually enter and who would win various
5 patent infringement cases, et cetera, et cetera. All
6 the stuff involving patent litigation, that
7 uncertainty, is resolved.

8 Secondly, it got a \$10 million payment for
9 co-development and co-promotion of a drug that was
10 under development.

11 Third, it got the guarantee that Endo would
12 not enter with an authorized generic during the
13 180-day exclusivity period for Impax, which is
14 relevant if Impax enters before the reformulated
15 product is on the market.

16 And last, it got this formulaic-determined
17 payment. If the reformulated product did enter and/or
18 for some other reason the market for the original
19 formulation of Opana ER substantially deteriorated,
20 fell by more than half, they would get a payment to
21 compensate them for the loss of sales below what would
22 have occurred had the original version of Opana ER
23 retained 50 percent of its peak sales between the
24 signing of the agreement and the date of entry of the
25 generic version that Impax was going to produce.

1 Q. So I want to talk a little bit more about --

2 JUDGE CHAPPELL: Hold on a second.

3 Are you reading from something there?

4 THE WITNESS: No.

5 JUDGE CHAPPELL: All right. I just saw you
6 looking down.

7 THE WITNESS: You just saw me looking to try to
8 remember things. That's all. I'm not reading
9 anything.

10 JUDGE CHAPPELL: For the record, I'm just
11 trying to figure out, did you just have the witness
12 give us his opinion on what the contract gave to
13 respondent? Is that what I just heard?

14 MR. MEIER: I asked -- yes, I did essentially
15 ask that.

16 JUDGE CHAPPELL: Do we need expert opinion on
17 what the contract gives to one side or the other? We
18 can read the contract.

19 MR. MEIER: That's right. But I wanted his
20 understanding. It's a setup. It's basically a
21 foundation for me to go and now explore each of those
22 elements, Your Honor. I just wanted to recite what
23 the elements were, and now we're going to go march
24 through them and get his opinions on the value of
25 those.

1 BY MR. MEIER:

2 Q. Taking the no-authorized-generic provision
3 first, in your opinion, was the no-authorized-generic
4 provision valuable to Impax?

5 A. Yes. It was -- it was extremely valuable if --
6 under the condition that you thought you were going to
7 enter competing against the original formulation of
8 Opana ER, so it's a conditional value, but it's a
9 value.

10 Q. Are you opining that Endo would have launched
11 an authorized generic in competition with Impax if it
12 had not introduced reformulated Opana ER before generic
13 oxymorphone entered?

14 A. No. I'm not making a prediction about what
15 Endo would do, no.

16 Q. Did you see anything in Endo's discovery
17 materials that shed any light on that issue?

18 A. Yes.

19 Q. And is that relevant to your opinions in this
20 case?

21 A. Yes.

22 Q. And what is that that you saw?

23 A. That in the case where the reformulated
24 product was not introduced, then Endo had made plans
25 to enter with an authorized generic. And its own

1 financial statement is consistent with the results in
2 the economics research literature, which is that a
3 substantial fraction of the profit impact of generic
4 entry can be avoided by entering with an authorized
5 generic at the same time the generic enters.

6 So what I conclude from that is that, A, Endo
7 had the same incentives most all brand name drug
8 companies do, which is to enter with an authorized
9 generic; and number two, they knew that, and they had
10 made plans to do it. It doesn't mean they would
11 actually do it, but it means it was credible and
12 plausible that they would do it.

13 Q. In your opinion, did the no-authorized-generic
14 provision have value to Impax even if there was
15 uncertainty about whether Endo would have launched an
16 authorized generic?

17 A. Right. Of course. Because you're trading the
18 possibility for the certainty of no entry, and this
19 was -- based on the record of other circumstances,
20 similar circumstances, authorized generics are
21 extremely common, so this was a valuable property to
22 Impax to be guaranteed that if it did enter in
23 competition against the original formulation of
24 Opana ER that it in fact would not face generic
25 competition from the brand name firm.

1 But you -- typically the authorized generic
2 gets more than half of the generic market during that
3 180-day exclusive period, so this is a very big deal
4 for a generic company to keep the authorized generic
5 off the market.

6 Q. In your opinion, was the Endo credit valuable
7 to Impax?

8 A. Yes.

9 Q. Based on your review of the discovery
10 materials, what, in your opinion, did those materials
11 reveal about the purpose of the Endo credit?

12 A. The purpose of the Endo credit was to protect
13 Impax against a consequence of agreeing to a late --
14 this late entry date relative to all the possible
15 entry dates that were available to them, that -- that
16 if it should be the case that they waited so long that
17 the market for the original formulation of Opana ER had
18 disappeared, they would be compensated for it.

19 Q. Did you see any discovery materials showing
20 whether Endo calculated the potential payment to Impax
21 under the final version of the settlement agreement?

22 A. Yes. They did make some calculations about
23 what that value was.

24 Q. What, in your opinion, do these calculations
25 show about what Endo thought at the time of the

1 June 2010 settlement?

2 A. That -- that the -- the -- if -- if the
3 reformulated product were introduced substantially
4 before January of 2013 that they would owe a
5 substantial amount of money.

6 But of course, how much they would owe is
7 uncertain because you don't know what the peak sales
8 of the original formulation are going to be. And the
9 reason you don't know that is partly because you don't
10 know for certain what the market is going to -- how
11 it's going to grow. But more importantly, you don't
12 know when you're going to be able to enter with your
13 reformulated product.

14 And the longer the reformulated product is
15 delayed, the bigger the peak sales date is going to be
16 for the original formulation of Opana ER, and so their
17 liability kept growing as the date of entry of the
18 reformulated product get pushed -- kept getting pushed
19 into the future.

20 Q. You used the term "peak sales" a couple times
21 in that answer.

22 Is peak -- is your understanding that peak
23 sales is part of the formula for calculating the Endo
24 credit?

25 A. Yeah. The Endo credit is based on 50 percent

1 of peak sales in the -- in the period from
2 June of 2010 until January of 2013.

3 The calculation is, if sales fall below
4 50 percent of peak sales, then there's going to be a
5 compensation paid to Impax based upon how far below
6 50 percent they went.

7 Q. What conclusions have you reached about the
8 drift terms in the settlement agreement?

9 A. That the value of the -- these provisions we've
10 been discussing was -- to -- to Endo were large and
11 unjustified, that is, unexplained by exchange of other
12 goods, services and assets, and so as a consequence
13 were anticompetitive.

14 Q. Do you have an opinion on the value of the
15 development and co-promotion agreement to Impax?

16 A. No.

17 I just know what the magnitude was. It was
18 \$10 million. But how much that was actually worth in
19 terms of an asset transaction, that wasn't part of my
20 responsibility.

21 Q. Let's turn now to the January 1, 20- -- let's
22 turn now to the January 1, 2013 entry term in the
23 settlement agreement.

24 In your opinion, what was the effect of the
25 January 2013 entry term?

1 A. It eliminated from possibility any of the
2 entry dates that could have occurred between
3 January 8 and -- 2010 and -- excuse me --
4 June 8, 2010 and January 1, 2013. Those are now off
5 the table as possibilities.

6 And secondly, that means that not only would
7 Impax not enter but also that whatever the consumer
8 benefits were from having earlier generic entry occur
9 would never happen. Instead of being a possibility,
10 they became a nullity. They couldn't happen.

11 Q. In your opinion, was the January 2013 entry
12 term valuable to Endo?

13 A. It was extremely valuable to Endo because it
14 guaranteed that they would not lose their -- that big
15 red-orange ball for that two and a half years between
16 the date of the settlement until January 1, 2013, that
17 that big ball would continue to flow, minus the
18 liability they had to Impax from the settlement.

19 Q. "That big red-orange ball" is referring back to
20 the pie charts we looked at earlier?

21 A. Exactly.

22 Q. Based on your review of the discovery materials
23 in this case, can you tell the court whether you
24 actually identified other possible earlier entry dates
25 for Impax' generic entry?

1 A. Yes.

2 Q. And what were some of those other possible
3 entry dates?

4 A. These were the same ones that are analyzed in
5 the -- in the various discovery documents, that the
6 big -- the big-ticket dates are the date of the
7 approval of the ANDA, which is June 10, and then the
8 next big date is when the district court would have
9 decided the patent infringement case because -- and
10 then the -- which is probably sometime in the late
11 summer of 2010.

12 And then the next big date is when the court of
13 appeals decision would have come down reviewing the
14 district court decision, which was sometime in the
15 second half of 2011. We can't be real precise about
16 when it would be, and there's some quibbling among the
17 experts about when it would be, but it's sometime in
18 that period.

19 And then, you know, there could be a later
20 date if what the district -- if the appeals court
21 decision was not definitive, if it said, oh, you got to
22 redo the following elements, some sort of remand.

23 So there's various possible dates. Each date
24 has a different profile in terms of how risky it is for
25 Impax to enter on that date, and so the -- they

1 represent important changes in the information that
2 Impax would have that would -- might affect its
3 decision whether to enter.

4 Q. When you said "June 10" in that last answer,
5 did you mean June 10 of 2010?

6 A. I thought that's what I said. What did I say?

7 Q. It just says "June 10." And I think you meant
8 June 2010.

9 A. I said June -- I thought I said June -- I
10 started to say January, and then I thought I corrected
11 it to June 10.

12 Q. Are you opining in this case that Impax would
13 have launched generic Opana ER at risk?

14 A. No. I'm -- what I'm opining on is that these
15 were possibilities that were considered by both firms
16 as sufficiently plausible that they actually did
17 financial planning on the basis of those events
18 actually occurring.

19 Q. Do you have an opinion in this case as to
20 whether the payments from Endo to Impax in the form of
21 the no-AG agreement, the Endo credit and the
22 co-promotion and development deal were large?

23 A. Yes.

24 Q. What is that opinion?

25 A. That the combined value of all of these things

1 is substantially in excess of the costs of completing
2 the patent infringement litigation.

3 Remember that this -- when the settlement was
4 made, they were already into the trial, so most of the
5 costs of the litigation had already been spent, so the
6 amount they had to save was relatively small. And so
7 it doesn't take much of a value for these things to
8 exceed saved litigation costs.

9 Q. Is saved litigation cost a benchmark you used
10 to determine whether the payment was large?

11 A. The economic model in my first expert report
12 holds out the sum of the saved litigation costs as a
13 benchmark for whether a reverse payment settlement is
14 large.

15 And if the -- because those saved litigation
16 costs represent the resources that society would have
17 to devote to resolving the patent case. And if you
18 could save those, those are resources that otherwise
19 wouldn't have to be used.

20 And the amount of the reverse payment is a
21 lower bound on the loss of consumer welfare arising
22 from the reverse payment settlement, so if the reverse
23 payment settlement is less than the saved litigation
24 costs, then you have a prima facie case that the cost
25 to consumers of the settlement are less than the saved

1 litigation costs or at least comparable to the saved
2 litigation costs, so my conclusion is those wouldn't be
3 regarded as anticompetitive. As an economist, I
4 wouldn't regard them as anticompetitive.

5 But if the reverse payment was in excess of
6 the summation of the saved litigation costs, then the
7 costs imposed on consumers would in fact be greater
8 than the resources saved in completing litigation, and
9 that would make the settlement anticompetitive.

10 Q. Why?

11 JUDGE CHAPPELL: Hang on a second.

12 I just heard you refer to your first expert
13 report and I've heard you refer earlier at least once
14 to something you call your original expert report.

15 Just so the record is clear, how many expert
16 reports do you have in this case?

17 THE WITNESS: There are two in this -- I
18 have -- I have an original -- oh, oh, wait a minute.
19 You're right. Corrected -- there's the original
20 liability report which is full of typos, then there's
21 the corrected report, and then there's the rebuttal
22 report. By "the first original report" I mean the
23 corrected one and by "the second report" I mean the
24 rebuttal report.

25 JUDGE CHAPPELL: I don't think I've heard you

1 refer to a second one, but I've heard you say
2 "the first" and "original."

3 THE WITNESS: Yeah. The first one will
4 actually be the second because it would be the
5 corrected report.

6 JUDGE CHAPPELL: Which report is a part of
7 JX that's submitted in this case?

8 MR. MEIER: We submitted both his original or
9 what he called the first report and the rebuttal
10 report, and they're both in. The first report --

11 JUDGE CHAPPELL: The one he calls corrected.

12 MR. MEIER: -- is the corrected version. It's
13 a -- as Professor Noll explained, there was a lot of
14 typos, and we cleaned that up and resubmitted it as a
15 corrected report. That's the report that
16 Professor Noll was deposed on at his deposition, the
17 corrected report, and the rebuttal report.

18 BY MR. MEIER:

19 Q. Why as a matter of economics is saved
20 litigation costs an appropriate benchmark to use in
21 determining whether a payment is large?

22 A. Because litigation costs are a real cost not
23 only to the companies but to society. Where lawyers
24 see income economists see costs, and if you can save
25 those costs, that's a good thing.

1 Q. Based on your review of the discovery materials
2 and in your opinion, what were Endo's and Impax' saved
3 litigation costs?

4 A. The -- on the order of \$5 million, something
5 like that.

6 Q. That's for both companies together?

7 A. Both companies together.

8 Q. And that would have been the cost of continuing
9 the litigation rather than settling it?

10 A. That would have been continuing the trial to
11 conclusion and then doing the appeal.

12 Q. In your opinion, how do the saved litigation
13 costs in this case compare to the payments in this
14 case?

15 A. Well, obviously the payments that were
16 actually made are huge compared to the saved
17 litigation costs, but that's not the right comparison.
18 The right comparison is what is the full range of the
19 costs that might have come about.

20 And I've also calculated what those payments
21 could have been under various scenarios, and no matter
22 how I do it, it -- the saved litigation costs are
23 always smaller than the benefits to Endo and the
24 payments to Impax of the settlement.

25 Q. Let's talk a little bit about some of the

1 other benchmarks you used beyond the saved litigation
2 costs.

3 JUDGE CHAPPELL: I have a quick question.

4 You predict -- you projected or predicted what
5 litigation would cost; is that correct?

6 THE WITNESS: Yes.

7 JUDGE CHAPPELL: What did you refer to for
8 hourly rates?

9 THE WITNESS: The -- there's two sources of
10 information.

11 The first is the annual study that's done on
12 what patent infringement litigation costs cost, and I
13 took the number for the maximum value of litigation,
14 patent infringement litigation.

15 And the second was the discovery information
16 from the parties about how much they had already spent
17 and expected to spend on litigation.

18 JUDGE CHAPPELL: Did you look at any recent
19 numbers, for example, what attorneys who specialize in
20 patent litigation charge per hour in trial?

21 THE WITNESS: I haven't looked at the per-hour
22 charges, but I've looked at them all -- outside --

23 JUDGE CHAPPELL: Those hours matter.

24 THE WITNESS: Huh?

25 JUDGE CHAPPELL: Those hours matter.

1 THE WITNESS: Oh, of course they matter. They
2 go into the survey results about the total costs and
3 they go into data of how much they actually paid.

4 The financial records of the companies show
5 how much they had spent on litigation up to the point
6 at which the trial ended, and then they have
7 projections of how much -- Endo has projections of how
8 much they expected to spend afterwards, so -- and then
9 the surveys that are done are basically of this.
10 They're not about, you know, what's the hourly rate or
11 billable hours. They're about how much do you spend,
12 and they get, you know -- I don't -- a lot of -- these
13 are used, commonly used, in research papers about the
14 costs of patent infringement litigation.

15 JUDGE CHAPPELL: What are these surveys? Who
16 does these surveys?

17 THE WITNESS: I -- I -- what is the name -- I
18 forgot the name. It's in my -- it's referenced in my
19 expert report. I've just forgotten the name.

20 BY MR. MEIER:

21 Q. Professor Bazerman, what are --

22 A. Pardon?

23 Q. Sorry. Bazerman. I'm sorry. I'm getting
24 tired myself.

25 Professor Noll, when you talk about the survey

1 results, you're talking about results that are surveyed
2 by the American Intellectual Property Lawyers
3 Association?

4 A. Yes.

5 Q. And this is an annual survey that they do?

6 A. I'm not sure it's done every year. I wouldn't
7 want to swear to that. But I know it's done
8 periodically.

9 Q. And so these are surveys done specifically of
10 patent litigation?

11 A. Not only surveys of patent litigation, but they
12 break them down to how much was at stake in the
13 litigation, because, obviously, the more valuable the
14 case, the more parties tend to spend on it.

15 Q. So I was starting to ask you a question about
16 whether you used other benchmarks other than saved
17 litigation costs in coming to your conclusion that the
18 payments in this case were large.

19 Did you use other benchmarks?

20 A. I'm sorry. I didn't fully -- I must have
21 missed something in the question. I didn't hear.

22 Q. All right. I'll try again.

23 Did you use any other benchmarks --

24 A. Oh.

25 Q. -- in reaching your conclusion that the

1 payments from Endo to Impax were large?

2 A. Yes.

3 Q. And can you tell us what some of those other
4 benchmarks were.

5 A. How they compared to Impax' actual profits from
6 both, you know, overall and the anticipated profits
7 they expected from generic entry.

8 Q. Do you recall using any other benchmarks to
9 determine whether the payment was large?

10 A. Other than saved litigation costs and the
11 profitability of the firms, I don't recall any others.

12 Q. Do you recall looking at the -- whether it was
13 large in relation to the total annual revenues for
14 Impax?

15 A. Oh. But that -- I meant -- when I said "the
16 profits," I meant -- since revenues and profits are
17 almost the same thing in the drug industry, it's not
18 much of a difference.

19 Q. So in your opinion, under the settlement
20 agreement, was it possible that Impax could make more
21 money by settling the litigation than by actually
22 entering with its generic product?

23 A. It is the case that the information we have on
24 the -- both the projections and the actual experience
25 of Impax, that the magnitude that they received in the

1 payment was larger than the stakes they had in actually
2 entering the market.

3 JUDGE CHAPPELL: How much more time do you
4 think you need for direct?

5 MR. MEIER: I have what looks based on so far
6 about 20 minutes, 25 minutes.

7 JUDGE CHAPPELL: Go ahead.

8 MR. MEIER: I'd be happy to take a break now,
9 Your Honor, if it --

10 JUDGE CHAPPELL: Would it elongate or shorten
11 your questions?

12 MR. MEIER: Excuse me, Your Honor?

13 JUDGE CHAPPELL: Would your questions become
14 longer or shorter?

15 MR. MEIER: After the break, I think they'd
16 probably be a little shorter.

17 JUDGE CHAPPELL: I'll buy that. Be it true or
18 not, I'll buy it. Sometimes during a break these
19 things expand like monsters.

20 MR. MEIER: Actually, I'd try to shrink it.

21 JUDGE CHAPPELL: We'll reconvene at 4:15.

22 We're in recess.

23 (Recess)

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

25 Next question.

1 BY MR. MEIER:

2 Q. Professor Noll, before we took the break, we
3 were talking about whether the payments in this case
4 were large, and I'd like to pick that up again.

5 In forming your opinion that the payment was
6 large, did you review Endo's and Impax' contemporaneous
7 plans and forecasts about the payment?

8 A. Yes, I did.

9 Q. Did you find any plans or forecasts by either
10 Endo or Impax projecting that Impax would not receive
11 any payment from Endo?

12 A. Only in the case where the reformulated
13 product never entered. Then the AG -- no-AG provision
14 would be the factor that would be providing benefit to
15 Impax.

16 There's no -- there's no example in the
17 financial projections in which the reformulated product
18 is introduced and the Endo credit is not paid, nothing
19 is paid from the Endo credit.

20 Q. Have you prepared a table in your report that
21 illustrates the approximate value of the no-AG and Endo
22 credit at the time of the settlement?

23 A. Yes.

24 Q. Ms. Durand, could you please call up Appendix F
25 from Professor Noll's original report. Thank you.

1 Before we get into -- can you see that very
2 well?

3 A. Yeah. I can sort of see it. That's fine.

4 Q. Maybe we can blow that up just a little bit.

5 A. Oh, much better.

6 Q. Before we get into the details of this chart,
7 can you explain generally what it's intended to show?

8 A. Yes.

9 This shows the calculation of the payment or
10 the no-AG provision under various assumptions about
11 what happens at the more -- you know, what happens in
12 the intervening period and what the state of the world
13 is at the date of entry by Impax.

14 Q. So looking at the top row, when it says
15 "Scenario," what does "Scenario" mean?

16 A. "Scenario" means a condition of the market at
17 the time of Impax entry.

18 And the major condition of concern here is what
19 the status of the reformulated product is, is it on yet
20 or not.

21 Q. Okay. And then moving at the top row across to
22 the right where it says "Form of Payment," what does
23 that mean?

24 A. That means the provision of the settlement
25 agreement that would be in force if that scenario

1 occurred.

2 In three of the four examples here in this
3 illustrative example, it's the no-AG provision that is
4 the component of the settlement agreement that is
5 actually operative as opposed to the Endo credit
6 provision.

7 Q. And then continuing to the far right at the
8 top row, it says "Approximate Value," and what was
9 that?

10 A. Well, that's two things.

11 First of all, it's a calculation of what the
12 payment would actually be under the assumptions by --
13 next to the Scenario and the -- then the discounted
14 present value of that to the date of the settlement
15 agreement.

16 Q. Yeah, what does -- what does the discounted
17 present value mean?

18 A. The discounted present value is a procedure
19 that actually both companies used to represent a
20 future stream of income in present dollars, that is to
21 say, how much would you -- if you're going to get a
22 hundred million dollars five years from now, how much
23 is that worth today, what's the amount you'd be happy
24 to be paid today to be indifferent between a
25 hundred million dollars five years from now and X

1 dollars today, what's the value of X that makes that
2 equality.

3 Q. So does the present value reflect the fact that
4 the settlement was entered in 2010, but the payment
5 might not come till sometime later?

6 A. The payments actually came I think in April of
7 2014 -- 2013, so you would take -- it's almost three
8 years of discounting you -- and I used a rate that's
9 higher than either company uses. I used 15 percent.

10 Q. Is that a rate that's essentially more
11 conservative in the favor of the companies?

12 A. Yes. It assumes that you are more impatient,
13 that you value the future less than either company
14 actually values it.

15 Q. And did you actually do the mathematical
16 calculations that are reflected in the
17 Approximate Value column of this exhibit?

18 A. Yes. And then they were checked by one of my
19 economist colleagues at the FTC.

20 Q. But you did the original calculations?

21 A. I did the calculations.

22 Q. And is the work that you did, the calculation
23 work, detailed in your report?

24 A. Yes. It's how -- how I did it is in the
25 report, and the actual mechanical part of the how is I

1 just did it on my computer with a calculator that's
2 built into my computer and just wrote down into the
3 report what the numbers were after I did them. I don't
4 have any intermediate product.

5 Q. So let's take a look at the first scenario at
6 the very top.

7 What's that, basically the facts of that
8 scenario?

9 A. This is basically under various scenarios
10 about when the original formulation of Opana ER would
11 be withdrawn and when the new formulation would come
12 on the market.

13 We know what the actual payment was, which was
14 a date of entry, you know, in 2012, but there are some
15 other dates in the documents, in the Endo documents,
16 that are earlier in that. And of course, the earlier
17 that the reformulated product enters the market, then
18 the lower the peak sales are for original Opana ER, and
19 so the magnitude of the Endo credit goes down.

20 And of all the entry dates I considered, the
21 lowest one was a \$62 million payment in April of -- or
22 whenever the right date is -- I think it's April -- of
23 2013, which has a -- the -- you know, the discounted
24 present value of 33 million.

25 And then there's a bunch of other values that

1 are higher and higher. As the date of entry of the
2 reformulated product gets later and later and later,
3 that number -- both the amount paid and the discounted
4 present value keep growing.

5 Q. So as we know, the actual payment that ended up
6 in this case was greater than this.

7 A. Yes. Because I -- this is to cover all the
8 possible eventualities.

9 Remember I said earlier that the -- that one
10 of the sources of uncertainty is when the reformulated
11 product would be brought on the market. And Endo's
12 original plans were to bring it on the market much
13 sooner than it actually came on the market, so -- and
14 those plans were never realized because of the delay in
15 getting approval from the FDA.

16 Q. The bullet point in the first scenario, the
17 second bullet point that says "Lowest possible payment
18 under the Endo credit," how did you arrive at that?

19 A. That's the earliest entry date that was in the
20 documents, and so you use the loss of half of the sales
21 from what would have been the peak sales of original
22 Opana ER had that earlier date transpired.

23 Q. Is this lowest possible payment under the Endo
24 credit something the companies would have known at the
25 time of the settlement?

1 A. Well, it knows what the -- it knows the
2 formula because it negotiated it, and it knows what its
3 own sales were, and it knows what half of those sales
4 were, so it has all of -- it knows for certain every
5 single element that goes into the formula.

6 Whether they actually calculated this number or
7 not I don't know. They calculated some of them, but
8 they didn't calculate all of them.

9 Q. Looking at the approximate value for the first
10 scenario where it says 62 million and 33 million
11 present value, in your opinion, is that a large
12 payment?

13 A. Well, of course. It's substantially larger
14 than the saved litigation costs of the settlement.

15 Q. Looking at the second scenario just generally,
16 what's -- what does that scenario reflect?

17 A. Okay. This one is the circumstance in which
18 Endo does not withdraw Opana ER from the market, and
19 there's no growth at all after the settlement agreement
20 in the revenues from Opana ER, so all you're getting
21 here is the benefit of no AG if the sales at the time
22 of entry are the same as they were in the quarter the
23 settlement agreement was signed.

24 Q. And then for the approximate value for the
25 second scenario, you said 33 million and 22 million

1 present value?

2 A. Yes.

3 Q. Just in your opinion, was that a large
4 opinion?

5 A. Well, again, it's -- it would be a large
6 payment because it's substantially larger than the
7 saved litigation costs.

8 Q. Taking a quick look at the third scenario,
9 what does that scenario -- what's the significance of
10 that scenario?

11 A. This one is -- is based on Endo's -- you know,
12 the original Opana ER continuing to grow and the --
13 the value of the no-AG provision is based upon the
14 sales of original Opana ER at the very end of the
15 period when -- you know, what those sales would have
16 been in the first quarter of 2013, which is the
17 quarter when you would get the benefit of the no-AG
18 provision, assuming continued growth of the sales of
19 Opana ER.

20 Q. And you estimated the approximate value of that
21 scenario to be 53 million or 35 million in present
22 value; correct?

23 A. That's correct.

24 Q. And in your opinion, is that a large payment?

25 A. Again, the same story. It's bigger than

1 \$5 million, which is the saved litigation costs.

2 Q. And then there's the fourth scenario.

3 Can you give us the gist of what that scenario
4 reflects.

5 A. Again, it assumes that the original
6 formulation is not withdrawn. It assumes that there
7 is a 50 percent decline in sales so that the maximum
8 possible reduction in sales of original Opana ER
9 occurs, but not because of the reformulation but
10 because simply something bad happens in the market for
11 oxymorphone ER.

12 And so this -- this is the worst possible
13 result in terms of the value of the no-AG provision
14 without triggering the Endo credit.

15 Q. And your approximate value there is
16 16.5 million or 11 million in present value?

17 A. Yes.

18 Q. And again, in your opinion, is that a large
19 payment?

20 A. Yes. Because again it exceeds five million.

21 Q. And in going back to the scenario, the fourth
22 bullet point says "Lower bound on benefit to Impax."

23 What does that mean?

24 A. This is -- this is as bad as it could get for
25 Impax from the agreement, well, under the circumstance

1 where the reformulated product is never introduced.

2 Q. Why didn't you include a scenario in which
3 Impax didn't receive any payment from Endo?

4 A. Again, remember that these are all based upon
5 circumstances they actually considered, and so I
6 didn't consider one like the scenario imagined by
7 Dr. Addanki in his report because the first time I'd
8 ever heard about that scenario in any kind of detailed
9 way was when I read his report.

10 Q. Okay. We're going to get back to that in a
11 moment.

12 A. Uh-huh.

13 Q. Did you calculate an expected value of the
14 payments to Impax incorporating all possible
15 scenarios?

16 A. I didn't create an expected value because I
17 don't know how to assign probabilities to all of these
18 events.

19 An expected value is the probability-weighted
20 sum of every conceivable event. That means you
21 multiply the probability that event will occur times
22 the present value of that number. And you can't do
23 that without making an assumption about what the
24 probabilities are.

25 I did do a calculation about what the

1 probability of the event that Dr. Addanki describes,
2 the one you just asked me about, what that would have
3 to be in order for the value of the settlement
4 agreement to Impax to be small, not to be large.

5 Q. What would the probability of the scenario in
6 which the value of the settlement to Impax was zero
7 have to be for the total expected value of the
8 payments in this case to no longer be considered
9 large?

10 A. The event in question, just to clarify, is
11 that reformulated Opana ER has to be introduced in
12 such a way that in the fourth quarter of 2012 sales
13 exceed 50 percent of the peak, and then they go to
14 zero, so that by the time January 1, 2013 comes, there
15 is zero sales, so that you get the maximum possible
16 effect of the fact that the generic is not an AB-rated
17 therapeutic substitute and the generic substitution
18 laws come in.

19 So you have to -- it has to be an extremely
20 precise timing of when the reformulated product is
21 introduced. And that creates the circumstance in
22 which there's a zero -- where the value of the no-AG is
23 zero and the value of the Endo credit is zero.

24 The probability of that event happening has to
25 be over 90 percent to get the expected value of the

1 agreement to Impax to be less than the saved litigation
2 costs.

3 Q. What does that mean, that the probability would
4 have to be over 90 percent?

5 A. That means an event that does not appear in
6 any of the financial planning of either party has to
7 be by far the most likely event and that the event
8 that actually did occur has to have almost zero
9 probability assigned to it. It has to be like one
10 one-hundredth of 1 percent likely to happen.

11 Q. What assumptions did Dr. Addanki have to make
12 in order to find that the payment wasn't large?

13 A. He had to -- he had to assume that the timing
14 of the entry was so precise that you -- there was not
15 enough of a decline in sales in the fourth quarter of
16 2012 to trigger the Endo credit and that the sales of
17 the original formulation of Opana ER in the first
18 quarter of 2013 were essentially zero so that you got
19 no benefit to Impax from generic substitution laws.
20 That has to be the assumption.

21 So that means you get no Endo credit and you
22 get no value from the generic substitution laws and you
23 get no value from the no-AG provision. All right.
24 That -- and in order to do that, you'd have to have a
25 very precise date at which you introduced the -- the

1 Opana ER.

2 And I don't know what that date would be. It
3 would probably be sometime around the 1st of November
4 or the middle of November or something, because you'd
5 have to -- in 2012, because you'd have to have enough
6 sales in the first part of the period that you kept
7 total sales for the quarter above the 50 percent
8 threshold, and then when the crash came, it would have
9 to be sufficiently late that -- you know, that you
10 would then have -- you'd stay above the 50 percent
11 threshold for the quarter, but you'd be into the zero
12 territory in the first quarter of 2013.

13 Q. To summarize then, what do you think of
14 Dr. Addanki's argument that Endo's \$102 million to
15 Impax was not large?

16 A. I think it's -- it's extremely implausible
17 because I don't think it's possible to time the entry
18 of -- of a generic -- of a -- of the reformulated
19 product that precisely, that we know from the
20 experience that Endo actually had that its ability to
21 plan for its launch date was highly uncertain because
22 of all kinds of things.

23 They had -- they -- a -- they differed -- that
24 the assumed launch date of reformulated Opana ER in
25 the various financial forecasts varies by more than a

1 year, and so the differences that occur are because of
2 differences in events that were -- that occurred that
3 they couldn't really predict with complete certainty.

4 So it seems to me highly unlikely that Endo
5 would have been able to time everything so precisely to
6 meet that target, but you have to be able to assume
7 that their ability to do that was so precise that it
8 was the -- by far the most likely outcome and -- in
9 order to get the value of the entire settlement
10 agreement to Impax to get down to the saved litigation
11 costs.

12 And I might add that even if you do this, you
13 still haven't dealt with the \$10 million. All right.
14 That is to say --

15 Q. What \$10 million?

16 A. -- even if you could assume this thing went to
17 zero, you still have the \$10 million payment for the
18 co-development and co-promotion agreement.

19 So even if that's all there, you have to make
20 the additional argument that you have to knock off at
21 least half of that as payment for something of value in
22 order to get the entire value of the agreement to go
23 below saved litigation costs.

24 Q. Shifting gears now, have you reached an
25 opinion on whether Impax' agreement with Endo was

1 justified?

2 A. Yes. There's -- I have reached an opinion on
3 that.

4 Q. And what is your opinion?

5 A. My opinion is it was not justified.

6 Q. And what is the basis for that opinion that
7 Endo's payment to Impax lacks a justification?

8 A. That there was -- there was no goods, service
9 or assets acquired by Endo that were compensation for
10 the money that was or the value that they delivered to
11 Impax in the agreement.

12 Q. In giving that answer, did you say there were
13 no goods, services or assets?

14 A. Yes.

15 Q. Have you been able to identify any plausible
16 procompetitive justification for Endo's payments to
17 Impax?

18 A. I don't believe there are any, but I can recite
19 what I believe they're asserted to be.

20 Q. Has the parties made -- has Impax made or
21 asserted some procompetitive justifications?

22 A. Dr. Addanki has. That's the only person I can
23 talk about. I can talk about him.

24 Q. What is your opinion of Dr. Addanki's asserted
25 procompetitive justifications for Endo's payments to

1 Impax?

2 A. That it's -- it's -- it has no basis in reality
3 basically.

4 Q. Are you opining that Impax would have entered
5 earlier than January 2013 if it had not received a
6 large, unjustified payment from Endo?

7 A. I'm not opining anything about the likelihood
8 of Impax entering at any date.

9 That -- the -- the -- the economic model and
10 analysis of reverse payment settlements that's in the
11 literature and that's in my report says you don't need
12 to know that. All right.

13 That's the crucial fact. You don't need to
14 know what the probability of entry was on any given
15 day. You don't have to re- -- you don't have to
16 litigate every conceivable patent infringement case.
17 You don't have to evaluate at the value of at-risk
18 launch.

19 All these contingencies that are mentioned in
20 Dr. Addanki's report and Mr. Figg's report, you don't
21 have to deal with them, because the reverse payment
22 itself embodies the value of all those things. It's a
23 number. It tells you what the -- what the -- what in
24 fact was being purchased, the value of what was being
25 purchased. And it's the sum of the values that Endo

1 perceived from being guaranteed that none of these
2 potential entry scenarios would actually happen before
3 January 1, 2013.

4 Q. Are you opining that the only way a brand and a
5 generic pharmaceutical company can settle their patent
6 litigation without running afoul of antitrust law is
7 through a pure time-split settlement?

8 A. No, I'm not opining that.

9 But I am opining that the -- the rule of
10 reason test here says that if there's no exchange of
11 goods and services and assets and nothing being
12 acquired of value, then a reverse payment that is
13 larger than saved litigation costs combined with the
14 plausibility of entry prior to that date is sufficient
15 for the settlement to be anticompetitive.

16 MR. HASSI: Your Honor, I have an objection to
17 the witness testifying about the rule of reason test.

18 JUDGE CHAPPELL: He did so like he was trying
19 to sneak a legal opinion in there on us.

20 To the extent that's a legal conclusion or
21 opinion, you're sustained.

22 MR. HASSI: Thank you, Your Honor.

23 Move to strike?

24 MR. MEIER: Your Honor, may I be heard?

25 JUDGE CHAPPELL: I will strike that answer if

1 the witness doesn't clarify that he's not intending to
2 give a legal opinion. Then you may be heard.

3 BY MR. MEIER:

4 Q. Professor Noll, were you intending to give a
5 legal opinion?

6 A. No. I'm talking about the antitrust economics
7 of rule of reason. I'm not talking about law. I'm
8 talking about what the test is for anticompetitive
9 harm to have occurred as economists do a rule of
10 reason test. Whether the legal system wants to pay
11 attention to that is up to the legal system to decide.

12 Q. Thank you.

13 What are some examples of patent settlements
14 pharmaceutical companies could enter into that in your
15 opinion wouldn't be anticompetitive?

16 A. If in the course of negotiating a settlement
17 they did identify a product they would like to develop
18 together and they in fact did in good faith try to
19 develop that product and it had an expected value that
20 exceeded the development costs, then in fact that
21 would be a perfectly reasonable justification for a
22 payment that was associated with a settlement.

23 Likewise, if the reverse payment were less than
24 the saved litigation costs, that would be fine.

25 Q. What if the payment ran from the generic firm

1 to the brand firm?

2 A. Oh, of course. That's like a royalty.

3 That's -- that's not a reverse payment. That's --
4 that's what we would expect in a -- what one -- one
5 common outcome of patent infringement cases is that the
6 infringer says, Okay, you know, what if I pay you a
7 license fee and you let me compete. And that's a
8 perfectly legitimate outcome of a patent settlement
9 negotiation.

10 Q. Professor Noll, does your analysis in this case
11 ignore what happened in the real world?

12 A. No. It considers what happened in the real
13 world and all the possible real-world events that the
14 parties considered not only at the time of the
15 settlement agreement but in the year or so
16 afterwards.

17 Q. I'd like to now turn to something that you
18 identified in your rebuttal expert report as the
19 elephant in the room.

20 A. Yes.

21 Q. Professor Noll, in your opinion, what is the
22 elephant in the room?

23 A. The elephant in the room is in reference to the
24 conclusions expressed by Mr. Figg and Dr. Addanki,
25 which is that the -- remember I said there was an

1 alleged procompetitive benefit.

2 The alleged procompetitive benefit is that
3 Impax actually got to enter earlier than it otherwise
4 would have been allowed to enter because it would have
5 lost not only the patent infringement suit at issue at
6 the time of the settlement, but it would have lost a
7 whole bunch of other patent infringement settlements,
8 and it would never have been able to enter.

9 So the elephant in the room is, Endo signed an
10 agreement in which it ended up paying 120 --
11 \$112 million to Impax and gave them the right to enter
12 earlier than they would have entered had nothing
13 happened, and so the question is why did Endo make a
14 \$112 charitable contribution to Impax to achieve a
15 worse result from it than it could have achieved by
16 just doing nothing.

17 MR. MEIER: Your Honor, if I may consult with
18 counsel briefly?

19 JUDGE CHAPPELL: Go ahead.

20 (Pause in the proceedings.)

21 MR. MEIER: I have no further questions,
22 Your Honor, at this time

23 JUDGE CHAPPELL: Cross?

24 MR. HASSI: Yes, Your Honor.

25 - - - - -

1 CROSS-EXAMINATION

2 BY MR. HASSI:

3 Q. Good afternoon, Professor Noll.

4 A. Good afternoon.

5 Q. Sir, you -- I want to go back to your
6 experience which you talked about late this morning,
7 early this afternoon.

8 You retired 11 years ago; is that right?

9 A. 2006. Yes.

10 Q. When was the last time you taught a course in
11 antitrust and regulation?

12 A. Three or four years ago. I co-taught a
13 course. It was the person who replaced me teaching the
14 course.

15 Q. And you currently teach one course in economics
16 each year, a course on fun for profit and sports and
17 entertainment; is that correct?

18 A. I don't teach it every year, but I taught it
19 this year. And I don't know whether I'll teach it
20 again next year. It depends on the demand, how many
21 students want to take it.

22 Q. And you mentioned doing some work for
23 GlaxoSmithKline; is that right?

24 A. Yes.

25 Q. And what kind of case was that?

1 You were an expert economist in that case?

2 A. Yes.

3 Q. What kind of case was that?

4 A. It was an antitrust case involving conduct by
5 Abbott that inhibited the ability of GlaxoSmithKline
6 and another company to introduce a protease inhibitor
7 for HIV/AIDS treatment that competed with a protease
8 inhibitor that was being sold by Abbott.

9 Q. It was not a reverse settlement case I take
10 it?

11 A. No, it was not -- it was not about patents at
12 all. It was about -- it actually was -- had to do
13 with the contract between GlaxoSmithKline and Abbott
14 regarding a license to promote their drug in
15 combination with another drug that was produced by
16 Abbott and how that contract -- whether -- the issue
17 was whether that contract was legitimately adhered to
18 or not.

19 JUDGE CHAPPELL: Was it private litigation or
20 was the government a party?

21 THE WITNESS: There's no -- the government was
22 not involved at all.

23 BY MR. HASSI:

24 Q. Sir, other than that one case for
25 GlaxoSmithKline and the work you've done for the

1 Federal Trade Commission, have you done any other work
2 in the pharmaceutical industry?

3 A. I've never done any consulting, litigation
4 consulting. No.

5 Q. And you've never worked for a pharmaceutical
6 company.

7 A. I've never been employed by a pharmaceutical
8 company in any capacity ever.

9 Q. You've done a lot of reading of Impax
10 documents, for example, in this case.

11 You've never worked for Impax, have you, sir?

12 A. No.

13 Q. And you've read a lot of Endo documents.

14 You never worked for Endo, did you, sir?

15 A. I've never worked for Endo.

16 And I've never worked for Actavis either.

17 Q. You were involved in -- well, strike that.

18 What was your involvement in the original
19 effort of what later became Hatch-Waxman?

20 A. Became what?

21 Q. Became Hatch-Waxman.

22 You're familiar with Hatch-Waxman?

23 A. Oh. Of course, I'm familiar with
24 Hatch-Waxman. It just -- the words didn't compute.

25 Okay?

1 I was not involved with Hatch-Waxman per se.
2 I was involved in the original proposal for ANDAs
3 for -- as a way to facilitate speedy generic entry,
4 that proposal that came out of -- that came from
5 Don Kennedy in the late 1970s. And then I -- A, I
6 helped them with the design of what that proposal was,
7 and then I testified before Congress to support it.
8 And I don't remember the precise date, but it was
9 probably '79 or something like that.

10 Q. Did that proposal get incorporated into the
11 Hatch-Waxman bill?

12 A. No. It kept getting amended and amended and
13 amended until the final version that was passed years
14 later was much more complicated than what we were
15 proposing.

16 JUDGE CHAPPELL: Did that proposal allow a
17 generic in the market without safety or efficacy
18 studies?

19 THE WITNESS: It -- that was the crucial fact.
20 The crucial fact was the demonstration of
21 bioequivalency and that the ANDA would not have the
22 safety and efficacy requirement, that demonstration of
23 bioequivalence would be sufficient. That was the --
24 and then there were some timing proposals as well, but
25 they were not the ones that ended up in Hatch-Waxman.

1 JUDGE CHAPPELL: To avoid all the clinical
2 trials and skip that --

3 THE WITNESS: Yeah.

4 JUDGE CHAPPELL: -- monetary burden.

5 THE WITNESS: The skipping of the clinical
6 trials was the crucial part.

7 BY MR. HASSI:

8 Q. In your opinion, did Congress make some errors
9 in drafting the Hatch-Waxman Act?

10 A. I -- well, we know that they've amended it
11 since, so they thought they did.

12 Again, I think I answered this question. I
13 didn't see it coming. I didn't see the problems with
14 Hatch-Waxman coming.

15 Moreover, it took more than ten years for
16 these problems to appear, so I think it's fair to say
17 that no one, the drug companies, the advocates for the
18 bill, the members of Congress, the FDA, my -- you know,
19 anybody else providing economic advice to the
20 government, I don't think anybody foresaw what started
21 to emerge 15 years later as the problems arising from
22 Hatch-Waxman.

23 Q. And can you be specific as to what you're
24 referring to when you say the problems with
25 Hatch-Waxman?

1 A. Reverse payment settlements and excessive
2 litigation with respect to patent infringement.

3 JUDGE CHAPPELL: Hold on a second.

4 (Pause in the proceedings.)

5 Go ahead.

6 BY MR. HASSI:

7 Q. Sir, you don't have a degree in medicine, do
8 you?

9 A. No.

10 Q. You don't have a degree in pharmacology?

11 A. No.

12 Q. You don't have a degree in pharmacy?

13 A. No.

14 Q. You're not an expert in the therapeutic
15 differences between long-acting opioids, are you?

16 A. I wouldn't be in a position to try to match
17 therapeutic differences to patient conditions, but I
18 do know what they are and -- and from -- I'm able to
19 interpret them in an economic context, but not in a
20 medical context.

21 Q. And with respect to those therapeutic
22 differences, would you defer to the physicians that are
23 testifying in this trial?

24 A. I'm sorry. I can't hear you.

25 Q. With respect to the therapeutic differences

1 between long-acting opioids, if any, would you defer to
2 the physicians who are testifying in this trial?

3 A. Yes.

4 Q. You worked with the Federal Trade Commission in
5 the Cephalon case; is that right?

6 A. That's correct.

7 Q. And the opinions that you offered in the
8 Cephalon case are similar to the opinions you're
9 offering in this case; is that right?

10 A. That's correct.

11 Q. And the work you did in the Cephalon case, that
12 was before the Supreme Court's Actavis decision; is
13 that right?

14 A. Yes, it was.

15 Q. And in the Cephalon case, you offered the same
16 three-part test that you've explained this afternoon?

17 A. Yes. It's basically the same, although I used
18 the words a little differently because I -- as you may
19 notice, there was some further elaborations of the
20 model between the two, so there are some small
21 differences, but yes, it's basically the same
22 conclusion.

23 Q. You talked this afternoon about a mathematical
24 model in your report. Do you recall that?

25 A. I do.

1 Q. And you derived that mathematical model from
2 the work of other economists?

3 A. The model is built upon the published research
4 and literature. Yes.

5 Q. Have you published your model?

6 A. No. I've -- something very close to mine has
7 been published by Einer Elhague, who was another expert
8 in the Cephalon case, but the full-blown stuff in my
9 own, I haven't gotten around to writing it yet, and I
10 intend to, but I haven't done it yet.

11 Q. So your model hasn't been peer-reviewed; is
12 that right?

13 A. That's correct.

14 Q. You talked a little bit this afternoon about
15 patent cases.

16 You've never litigated a patent case; right?

17 A. I'm sorry. I can't hear you again.

18 Q. You have never litigated a patent case; is that
19 right, sir?

20 A. I have never been an expert witness in a patent
21 infringement case, yes.

22 Q. And you're not an expert in patent law, are
23 you?

24 A. I don't hold myself to be an expert in any
25 kind of law notwithstanding my articles in law

1 reviews.

2 Q. You're not an expert in evaluating the
3 strength of a patent case; correct?

4 A. Well, actually I have testified in evaluating
5 intellectual property, just not patents. I've
6 testified in evaluating copyrights.

7 Q. But not patents; right?

8 A. Not patents.

9 Q. You've been thinking about the three-part test
10 that you talked about this afternoon since the
11 Schering-Plough case was decided; is that right?

12 A. Yeah. I've been -- I've been thinking about
13 what's the right way to think about these things since
14 Schering-Plough. The details of the three-part test
15 didn't come about instantaneously, but they were -- the
16 thought process that led to it was the Schering-Plough
17 decision.

18 JUDGE CHAPPELL: What do you mean, since
19 Schering-Plough? Do you mean the initial decision,
20 the commission's reversal, the appeals court's
21 reversal of the commission, the Supreme Court not
22 taking the case and leaving the appeals court decision
23 in place?

24 THE WITNESS: The appeals court. The crucial
25 case to me and the one that got on my radar screen was

1 the appeals court decision.

2 BY MR. HASSI:

3 Q. You believe the appeals court decision was
4 incorrect as a matter of economics?

5 A. Yes, I do.

6 Q. And your colleague at Stanford, Tim Bresnahan,
7 Professor Tim Bresnahan, testified for the FTC in the
8 original Schering-Plough case?

9 A. Yes, sir.

10 Q. And you and he discussed this three-part model
11 that has evolved since then?

12 A. We discussed the decision in the case. The --
13 I don't know that the term "three-part model" or
14 "three-part test" was ever used, but yes, the basic
15 contours of how you think about it, we did discuss it
16 after the Schering-Plough decision and before I had any
17 involvement with the FTC.

18 Q. And that was at least ten years ago?

19 A. I don't know -- I think so, and I don't know
20 precise -- I don't have the exact dates in my head, but
21 it's something on that order. Yes.

22 Q. This afternoon, you gave an explanation of a
23 demonstrative from your report in Exhibit F with three
24 circles --

25 A. Yes.

1 Q. -- one red and one red and orange.

2 Is that something you created?

3 A. The picture itself, no. The picture itself was
4 done by one of the staff people at the FTC. The
5 concept behind it was mine.

6 Q. The concept behind that picture was yours; is
7 that right?

8 A. That's right.

9 Q. Do you know whether that demonstrative was used
10 in the Schering-Plough case 15 years ago?

11 A. I have no idea. All I did was talk to them
12 about what it -- what -- what my views were about what
13 the three circumstances were. And if they've used it
14 before, that's news to me.

15 Q. So you conceived of that Exhibit F in the
16 context of your work on this case; is that right?

17 A. A verbal description of what that picture says
18 was in my original report, and they asked me if it was
19 okay to draw a picture of it. I said yes. And if
20 they'd already drawn the picture in the past, that's --
21 that's news to me. I didn't know about it.

22 JUDGE CHAPPELL: Was that exhibit your opinion
23 or an opinion you adopted that was handed to you?

24 THE WITNESS: No. It's mine because the --
25 notice the picture has notation from my mathematical

1 model, so I think the proposition that this was used in
2 Schering-Plough is probably technically incorrect
3 because my notation for what the profitability of the
4 generic company and the brand name company are are
5 actually on the picture.

6 But I accept I think, you know, that the -- the
7 assertion that maybe that was used before with somewhat
8 different words and somewhat different notation, that's
9 possible.

10 I mean, one of the nice things about economics
11 is that everybody who studies it and does it in an
12 objective fashion is going to reach the same
13 conclusion, which is that the representation of what
14 happens to the profits of the brand name firm under two
15 different scenarios is going to look like that.

16 So, you know, it's not surprising to me that
17 other people would have made a similar diagram to the
18 one that is in my report.

19 BY MR. HASSI:

20 Q. I think you said this morning, or maybe it was
21 this afternoon, you've written over 400 articles and
22 papers; is that right?

23 A. I said nearly 400. I'm -- my CV does keep
24 growing, even though I'm as old as I am.

25 Q. And am I correct that none of those nearly

1 400 articles and papers addresses reverse patent
2 settlements?

3 A. That's correct. I haven't written that paper
4 yet.

5 Q. And so, for example, the three-part test that
6 you described this afternoon, you've not written about
7 that.

8 A. I personally haven't, but others have. It's in
9 the paper by Einer Elhague.

10 Q. You've read the Supreme Court's Actavis
11 decision?

12 A. I have read the Supreme Court decision, yes.

13 Q. And the Supreme Court's Actavis decision
14 didn't change your formulation of the three-part test,
15 just changed some of the nomenclature; is that right?

16 A. Yeah. I -- well, it's not the right way to
17 describe it. I actually -- the reason for the change
18 in wording is because of extensions of the model, but
19 yes, I did -- I did relate what the conclusions of the
20 model were to the words that were used in the Actavis
21 decision, because they didn't use exactly the same
22 words that I did.

23 Q. And you believe your three-part test is
24 consistent with the FTC's litigation strategy for these
25 cases; is that right?

1 A. I don't know. I -- I actually never even have
2 thought about that question. You know, what their
3 litigation strategy is I don't know about or care.

4 Q. Well, did you testify a couple of weeks ago
5 that you thought it was consistent with your three-part
6 test?

7 A. I thought that the complaint, you know, if you
8 want to say what's the complaint in the case, I think
9 that what I've done is consistent with the complaint,
10 yes.

11 But that's different than litigation strategy.
12 I think -- when I think of litigation strategy, I
13 don't -- I wasn't -- I thought you meant what goes on
14 in the trial and what goes on in terms of legal
15 arguments that are presented to a judge, and I don't
16 know that, anything about that.

17 Q. Maybe you could look at your deposition, which
18 is in the binder the FTC gave you --

19 A. Sure.

20 Q. -- at page 20 and specifically the lines 16 to
21 25, which is the end of the page.

22 (Document review.)

23 A. Okay. I see I used the term "litigation
24 strategy."

25 But I'm not using it in the same term here --

1 way here I just had in the answer to you.

2 Q. Sir, does that refresh your recollection that
3 you view your test from your perspective as consistent
4 with the FTC's litigation strategy?

5 A. Yeah. Only I shouldn't have used the word
6 "litigation strategy." The test -- you're absolutely
7 right about the test.

8 I didn't interpret the word "litigation
9 strategy" as you used it as being the test. I agree
10 that the test is consistent with the test they're
11 using, and I agree that I've talked to them about this
12 for years, and there is a commonality of how they think
13 about what the appropriate test is and what I think the
14 appropriate test is. I just didn't interpret
15 "litigation strategy" as being about the test.

16 Q. Thank you. You can set that aside. Thank you.

17 I want to talk about some of the bases for your
18 opinions.

19 Is it fair to say that in your expert report
20 you relied upon the opinions of Dr. Seddon Savage for
21 clinical information?

22 A. Yes. In the original report, the corrected
23 liability report, my -- I relied upon her.

24 Q. And I'm sorry. The corrected report, that's
25 the first report as corrected for typos that you issued

1 in this case?

2 A. That's correct.

3 Q. And you would agree that prescribers can choose
4 among long-acting opioids when deciding what to
5 prescribe a patient who has chronic pain?

6 A. I'm sorry. I didn't hear all --

7 Q. You would agree, sir, that a physician can
8 choose among the various long-acting opioids when
9 deciding what to prescribe a patient with chronic pain;
10 correct?

11 A. Of course.

12 Q. And you would agree that no one long-acting
13 opioid is superior for a particular new patient.

14 A. I don't -- I don't have knowledge to know
15 whether any particular patient has a superior
16 long-acting opioid -- I wouldn't be anyone -- I
17 couldn't decide that. If somebody says that's true,
18 okay. But I'm not someone to say what's the superior
19 long-acting opioid for this particular patient.

20 Q. And if Dr. Savage says she can't tell you which
21 long-acting opioid is superior for a patient with no
22 history of opioid use, you have no reason to doubt
23 that; right?

24 A. Well, I think that's absolutely right. In the
25 abstract, without more information, I don't think even

1 a doctor knows what the superior prescription is.

2 Q. In other words, there are a variety of
3 long-acting opioids that a doctor could choose from for
4 a new patient and test for that patient; right?

5 A. Yes. But that's -- the question of whether in
6 principle with perfect knowledge there is a superior
7 one is different from without any further information
8 could you know, could you identify what the superior
9 one was. I don't see any way to identify it just on
10 basic principles, first principles.

11 My understanding of how doctors behave is they
12 try to match the drug to the conditions of the patient,
13 but again, I'm not a doctor and I'm not going to
14 perform that match.

15 Q. Do you understand that no particular opioid is
16 a priori any better for any particular condition?

17 A. I don't have an expert opinion about that.
18 That's not -- I would rely upon Dr. Michna or
19 Dr. Savage to be the one who said for any given set of
20 conditions of a patient is there a single best
21 prescription or not. And I don't know the answer to
22 that in any kind of an expert capacity, and I don't
23 need to know it for anything I do.

24 Q. And you understand that physicians, in
25 choosing a long-acting opioid for any particular

1 patient, may make decisions based on formulary tiering
2 and prices.

3 A. Among other things, yes. They make it on the
4 basis of a long list of things of which those are one.

5 Now, a lot of them don't make it on the basis
6 of formularies because their patients are not in
7 formularies, so that would only be true for someone
8 who has insurance that covers drugs that has a
9 formulary.

10 Q. Do you know what percentage of patients in this
11 country have insurance that covers drugs on
12 formularies?

13 A. If you -- the fraction of patients on private
14 insurance is 55-60 percent. The rest are paid for by
15 the federal government in one form or another.

16 Q. So the majority of patients have private
17 insurance; right, 55 to 60 percent?

18 A. Something on that order. I don't remember the
19 precise numbers because you're asking me fact
20 questions, but that's roughly -- roughly right. It's
21 somewhat less than half are paid by one or another
22 federal program.

23 JUDGE CHAPPELL: But -- hang on a second.

24 But just because the federal government pays it
25 doesn't mean it's not insurance; correct?

1 THE WITNESS: Oh, it doesn't mean it's not
2 insurance. But the mechanism by which drug choice and
3 drug prices are controlled is different in federal
4 programs than it is in private insurance programs.

5 BY MR. HASSI:

6 Q. Does sometimes the federal government pay for
7 private programs such as Medicare Part D?

8 A. That's right.

9 There's -- there's an array of federal
10 programs, and Medicare Part D is one which may involve,
11 but is not mandatory, you know, the use of private
12 insurance. And then there -- and there are people who
13 don't have Medicare Part D, like me. And then there's
14 people under Medicaid. And then there's veterans.
15 Then there's people who are in other smaller federal
16 programs than those two.

17 Veterans and Medicaid are very big, so -- and
18 each one of those is treated differently. The whole
19 mechanism for doing drugs is different in almost every
20 one.

21 Q. Do they have formularies for veterans
22 programs?

23 A. Not of the form we think about for private
24 insurance companies. They have approved drugs, but it
25 works differently. It's a different system than the

1 formulary system in private insurance.

2 Q. Do you know whether drug companies compete to
3 be on the formulary, for example, that the VA
4 provides?

5 A. To some degree, yes. But the prices they can
6 charge in VA and Medicaid are governed by formulas for
7 price discounts, and so -- but they don't apply in the
8 private cases.

9 Q. Sir, you didn't assess the duration of therapy
10 for the average Opana patient; is that correct?

11 A. I'm sorry. I can't hear you again.

12 Q. You did not assess the duration of therapy for
13 the average Opana patient; correct?

14 A. I made no attempt to assess it. I knew it at
15 some point and I know -- remember you examined me about
16 it at my deposition, but it's -- I don't remember what
17 I learned from that process, no.

18 Q. You don't know it as you sit here today.

19 A. I don't recall -- again, it's asking me a fact
20 question, and I don't remember what the right fact is,
21 that -- there's a reasonably high turnover rate in the
22 use of long-acting opioids, but I don't remember
23 precisely what it is.

24 Q. Sir, you're not aware of any identifiable group
25 of patients for whom oxymorphone is the only safe and

1 effective long-acting opioid; correct?

2 A. I'm not aware of any patient in particular who
3 can only use any particular LAO, oxymorphone or
4 anything else.

5 Q. And you acknowledge that a given drug, such as
6 oxymorphone, may be listed differently on different
7 formularies or even not listed at all on a formulary;
8 correct?

9 A. Well, there's explicit examples of that in my
10 expert report. Yes.

11 Q. And you did not attempt to determine whether
12 oxymorphone is listed differently on different
13 formularies due to economic or therapeutic differences;
14 correct?

15 A. I -- what I did is say that all these things go
16 into it, and then I gave examples of how the same facts
17 about different drugs lead to different formulary
18 placement, and I made a comparison between the two
19 largest private insurance companies, so I -- you know,
20 that -- it's in there, and I did it, and it speaks for
21 itself.

22 Q. Sir, you've not considered the extent to which
23 the demand for oxymorphone is in fact price-elastic;
24 correct?

25 A. I did not attempt to estimate the elasticity of

1 the demand curve for any drug. I just inferred it from
2 facts about market events.

3 Q. And you would agree that physicians pay
4 attention to price and insurance coverage when
5 prescribing particular drugs; correct?

6 A. Sometimes. Some do and some don't. Yes.

7 In general, the reason that formularies work is
8 because they can impose some consideration of price on
9 physicians who otherwise don't have much of an
10 incentive to consider it.

11 Q. And your opinion that there's no significant
12 competition between brand name drugs with different
13 active ingredients is not based on your review of
14 either Endo or Impax documents; correct?

15 A. I'm -- I've -- most -- no. I mean, it -- I did
16 consider the documents in the sense, but I didn't find
17 much in them with respect to price sensitivity, that
18 the degree to which formularies affect price.

19 They contain documents about not only what
20 price changes they're considering in list price but
21 what the implications of those price changes are for
22 their actual net revenues. And the -- the actual net
23 revenues would take into account the discounts that
24 they give to formularies, and so when they -- when you
25 read a pricing document from Endo that says we're

1 going to increase the list price by X percent, then
2 they will follow that with, well, this will lead to an
3 increase in revenues of Y percent.

4 And Y is usually quite a bit less than X. And
5 it's less than it for two reasons. One is there's some
6 elasticity of the demand curve. And two, they're
7 actually giving discounts.

8 So you can -- you don't know precisely what
9 the discount is to any particular formulary, but you
10 know what the -- what their estimate of the net
11 revenue impact is that takes into account the
12 discounts to the formularies. And they actually talk
13 about that in their documents, but they don't quantify
14 it. They don't -- they just talk about it in a
15 qualitative sense.

16 Q. And is that a way of saying you couldn't tell
17 actual prices from looking at the Endo documents,
18 only --

19 A. When --

20 (Counsel and witness speaking at the same time
21 and cautioned by court reporter.)

22 THE WITNESS: When they tell you --

23 BY MR. HASSI:

24 Q. She didn't get my question, sir.

25 A. I'm sorry. I thought she was -- I stepped on

1 you. I'm sorry.

2 Q. Sir, is that a way of saying you couldn't tell
3 the actual prices Endo was charging its customers from
4 Endo's documents?

5 A. You could not tell the specific price to a
6 specific customer from the estimates of overall
7 revenue effects. All you can tell is what happened to
8 average price and sales. You can't tell what the
9 specific price to any specific customer was.

10 Q. You would agree, based on your review of Endo's
11 documents, that it regards Opana ER as competing with
12 other long-acting opioids, not just generic
13 oxymorphone; correct?

14 A. I said that in my direct testimony. Of course,
15 it regards itself as competing with other LAOs.

16 Q. And you're aware that Endo measures itself as
17 having a less than 10 percent share of the long-acting
18 opioid market; is that right, sir?

19 A. I wouldn't put it that way because I don't
20 think it's a market, but I agree that their total
21 sales are less than 10 percent of the total sales of
22 all LAOs.

23 Q. And you've seen internal Endo documents where
24 they did calculate a share, their share, of the
25 long-acting opioid market; correct, sir?

1 A. They -- they col- -- yes. They calculated
2 their own share, but their use of the term "market" is
3 not the same as it is in antitrust economics. They're
4 just --

5 Q. And when they calculate --

6 JUDGE CHAPPELL: Hold it, hold it. He wasn't
7 finished.

8 THE WITNESS: They're using the term "market"
9 to refer to sales of all long-acting opioids without
10 actually doing any test as to whether that is a
11 relevant market from the point of view of antitrust
12 economics.

13 BY MR. HASSI:

14 Q. So you disagree with Endo about what the
15 definition of the relevant market is; is that right?

16 A. They don't define the relevant market. They're
17 using the term "market" in a common parlance way, and
18 I'm using it in a -- in the detailed way that it's used
19 in economics. And neither one of us is wrong. We just
20 are using the term in a different way.

21 Q. And you would agree when they use -- when they
22 calculate their share of the long-acting opioid market,
23 whether it's the market as you define it or the market
24 as they define it, they compute that their share is
25 less than 10 percent; right?

1 A. Yeah. But that's not the way I would define
2 it, so you -- if you wouldn't have qualified it by
3 saying as I would define it, then I would agree with
4 you, but I didn't define the market that way, and
5 that's not a relevant antitrust market.

6 Q. Sir, in defining the market, you did not
7 conduct a SSNIP test; is that right?

8 A. No. I had to infer it from observed sales
9 behavior from changes that -- in market conditions that
10 I knew were related to price.

11 Q. And you made some criticism of Dr. Addanki's
12 report, but you would agree that all the types of
13 evidence that Dr. Addanki uses are part of the standard
14 approach to market definition in antitrust economics;
15 correct?

16 A. No, I would not agree that all the things he
17 uses are relevant, that are application -- are uses of
18 standard measures that are used in antitrust
19 economics.

20 Q. Sir, that wasn't my question.

21 My question was, would you agree that all of
22 the types of evidence that Dr. Addanki uses are part of
23 the standard approach to market definition in antitrust
24 economics?

25 A. No.

1 Q. Yes or no?

2 A. I would not agree that all the things he
3 uses -- some of them are but not all of them.

4 Q. Okay. Could you look at your report, your
5 rebuttal report -- that's the second report you filed
6 in this case -- at paragraph 24.

7 A. Sure.

8 (Document review.)

9 Okay. I'm there.

10 Q. So, sir, would you agree with me that you wrote
11 in your report -- and I'm referring to the first full
12 sentence on page 12, paragraph --

13 A. I thought you said page 24.

14 Q. Paragraph 24. It carries over --

15 A. Oh, paragraph. I turned the page. I'm sorry.

16 (Document review.)

17 Yeah, it identifies other sources of
18 information that are useful to ascertain, yes.

19 Q. And sir, did you or did you not write in your
20 rebuttal report -- and again, this is paragraph 24,
21 page 12, the first full sentence -- "Thus, all of the
22 types of evidence that Dr. Addanki uses are part of the
23 standard approach to market definition in antitrust
24 economics"?

25 Did you write that, sir?

1 A. I -- you said paragraph 24?

2 Q. Yes, paragraph 24.

3 A. The first sentence as I'm reading it is: "The
4 Addanki Report identifies other sources of information
5 that are useful to ascertain the extent of competition
6 amongst pharmaceuticals."

7 Q. That's the paragraph, sir. And if you go over
8 to page 12 --

9 A. Oh, you --

10 Q. It's a lengthy paragraph.

11 A. Oh, it's the end of it.

12 "Thus, all of the types of evidence that
13 Dr. Addanki uses are part of the standard approach,"
14 all of the types of evidence. That's not the same
15 thing as the way you asked the question.

16 Yeah, I -- it is true he uses the things that
17 are used in antitrust economics, but it's true he also
18 uses other information that is not part of antitrust
19 economics.

20 So, yes, he does use information that is part
21 of antitrust economics, but he uses other things as
22 well.

23 Q. And you agree with Dr. Addanki that there is
24 not sufficient data to reliably calculate
25 cross-elasticity --

1 (Interruption due to noise.)

2 Sir, you would agree with Dr. Addanki that
3 there is not sufficient data to reliably calculate
4 cross-elasticity of demand between Opana ER and other
5 long-acting opioids; correct?

6 A. I said that in my original report.

7 Q. And so you didn't calculate cross-elasticity --

8 JUDGE CHAPPELL: Wait a second. That's not
9 really an answer.

10 Is he correct?

11 THE WITNESS: Yeah. Oh, yes. I mean, I --
12 that's what I'm saying. I mean, it's not that
13 Dr. Addanki said it. It's that I said it, and he
14 agrees with me. I said it before he did.

15 BY MR. HASSI:

16 Q. And you did not calculate cross-elasticity of
17 demand between Opana ER and other long-acting opioids;
18 correct?

19 A. That's correct.

20 Q. I want to switch to another topic. I want to
21 talk about switching.

22 You would agree that two products are close
23 economic substitutes if a buyer would switch from one
24 to the other in response to a small change in relative
25 prices?

1 A. That's correct.

2 Q. And you agree that patients can switch from one
3 long-acting opioid to another; correct?

4 A. That's correct. It does happen.

5 Q. And in your report, you relied on the
6 Federal Trade Commission/Department of Justice
7 Horizontal Merger Guidelines?

8 A. That's correct.

9 Q. And you agree with the Merger Guidelines that
10 evidence of switching in response to relative price
11 changes is probative of market definition?

12 A. Yes.

13 Q. Yet you dismiss the evidence that we see of
14 switching between long-acting opioids in response to
15 relative changes in price, for example, rebates offered
16 to third-party payers in exchange for formulary
17 placement, as an instance of the cellophane fallacy; is
18 that right?

19 A. There's no evidence of a quantity effect of
20 that of any significance. It is true -- all the stuff
21 about formularies I agree with, that they do attempt
22 to compete for formulary placement, that formulary
23 placement does get affected by the discounts. The
24 issue is how big an effect is that, and there isn't any
25 quantification of that in any expert report, mine or

1 Dr. Addanki's.

2 Q. And I'm sorry. When you say there isn't any
3 evidence of quantification, is that the quantification
4 of switching?

5 A. No.

6 First of all, the -- the quantification at
7 issue here is a quantification of how the -- the
8 offering of more or less discounts to a formulary
9 leads to a change in the degree to which that drug is
10 prescribed and whether that process of competition
11 among drug companies who's selling -- are selling
12 different LAOs is sufficient to cause the price of
13 those LAOs to go -- be driven down to the competitive
14 level. All right. That's the question.

15 And all that you can say about formularies, as
16 is said in my original report, which I -- Dr. Addanki
17 doesn't actually disagree with, is that this is a
18 factor that does cause some degree of price
19 competition.

20 Whether it's significant or substantial in the
21 effect on price we don't know, all right, because we
22 don't actually have observations that would enable us
23 to estimate the cross-elasticities of demand and the
24 degree to which there actually is price competition and
25 the degree to which it actually matters in terms of

1 switching sales. All right.

2 So all we know, both of us, is that this is
3 a -- this is an element that goes into deciding how
4 competitive the market is along with many other
5 elements.

6 There are markets working in favor of
7 competition, like formularies and government
8 procurement programs and generic substitution laws, and
9 there are things working against substitution, such as
10 the promotional activities to emphasize different
11 characteristics and such as switching costs.

12 Now, what the net effect of all those things is
13 you can't directly -- you can't directly estimate.
14 They all go into calculating the cross-elasticity of
15 demand. And we can't measure that directly. The best
16 we can do is look at market events that would affect
17 those relative prices and see whether they cause a
18 significant shifting in the quantities. That's the
19 best we can do.

20 Q. And so because you can't tell how significant
21 it is, you dismiss it and look elsewhere; is that
22 right?

23 A. I do not dismiss it. I do not have any
24 disagreement about the effect of formularies. The
25 point is, formularies are not the only thing going on

1 in the market. And the degree of competition among
2 various long-acting opioids is affected in totality by
3 all of the things going on in the market.

4 And the -- the only really test we have is to
5 see if things like introducing substantially lower
6 prices by generic entry in one LAO causes significant
7 effects in sales and prices for another LAO. And we
8 know it's not true. And that means they're not all in
9 the same relevant market.

10 JUDGE CHAPPELL: Hold on a second.

11 I've been listening to this all day. You seem
12 to be trapped in some kind of a -- you're on some
13 track or some system whereby all that matters are
14 theories, models, estimates, projections.

15 What if we have real-world evidence? What if
16 we have actual facts to tell us what's happening in the
17 market? Do you just -- does that not matter if you
18 can't put it in a model?

19 THE WITNESS: No. It's exactly the opposite.
20 The only -- the only -- the only relevant fact we have
21 is what actually happens when changes occur in the
22 sales of one long-acting opioid, what happens to sales
23 of that opioid and to sales of other opioids that might
24 be substitutes for it.

25 JUDGE CHAPPELL: But aren't you talking about a

1 variable that you're trying to plug into a formula or a
2 guideline --

3 THE WITNESS: No. I'm just looking --

4 JUDGE CHAPPELL: -- changes in whatever?

5 THE WITNESS: No. No.

6 JUDGE CHAPPELL: What about common sense? Can
7 we use common sense? In economics and antitrust, is
8 common sense valuable?

9 THE WITNESS: Of course, it is.

10 But the only facts we have are facts about what
11 happens in the conditions in the sale of a particular
12 opioid and what effects does that -- do those
13 conditions have on, A, the sale of that opioid and the
14 sale of other opioids.

15 JUDGE CHAPPELL: Well, you understand this is
16 not like Ford deciding what to charge for an
17 F-150 pickup. There are players here that make this
18 market, unlike other markets, insurance companies that
19 drive the price, how many patients really have any idea
20 what they're going to pay for one opioid versus the
21 other.

22 Are you trying to tell me that you're trying to
23 somehow develop a model or give an opinion that makes
24 this market the same as all other markets that
25 consumers are involved in?

1 THE WITNESS: No. Because you wouldn't be
2 discussing formularies to begin with or insurance
3 companies to begin with or government programs that
4 pay for almost half of all drugs. You wouldn't be
5 discussing those when you're talking about
6 automobiles.

7 So --

8 JUDGE CHAPPELL: Well, what do you think is the
9 most -- who drives the price in this market for
10 opioids?

11 THE WITNESS: I'm sorry?

12 JUDGE CHAPPELL: Who drives the price, who sets
13 the price in this market?

14 THE WITNESS: The price is an interaction
15 among buyers and sellers, and insurance companies are
16 an important component, patients themselves are an
17 important component, and the federal government is an
18 important component.

19 JUDGE CHAPPELL: You don't think that
20 Blue Cross, United, Humana, that they're dictating what
21 the price is more than anyone else?

22 THE WITNESS: No. They do not dictate. They
23 have not been effective in controlling drug prices in
24 the last ten years.

25 JUDGE CHAPPELL: Well, I'm not saying they

1 dictate. That's a poor choice of words. But you don't
2 think that they have a lot to do with what the price is
3 for these drugs.

4 THE WITNESS: They have an effect on drug
5 prices, but they are not successful in brand name
6 drugs in forcing competitive pricing. They have not
7 been successful in that. They have not been
8 successful in preventing drug prices from going up
9 more rapidly than the rate of inflation by a
10 substantial amount. All right.

11 The best thing they've got going for them
12 that's reflected in the fact that generics always get
13 put in tier one in the formularies is generic entry.
14 That is by far the most important competitive factor
15 affecting drug prices, is whether there's a generic
16 available. And that's more powerful than Blue Cross or
17 Aetna or UnitedHealthcare or even the federal
18 government.

19 JUDGE CHAPPELL: But doesn't Blue Cross
20 determine what's in tier one for Blue Cross?

21 THE WITNESS: They do. And it's all -- if
22 there's a generic, it's always the generic.

23 MR. HASSI: Should I continue, Your Honor?

24 BY MR. HASSI:

25 Q. Sir, you've not analyzed how frequently

1 patients are successfully switched from one opioid --

2 A. I'm sorry. I couldn't hear.

3 Q. You have not analyzed how frequently patients
4 are successfully switched from one long-acting opioid
5 to another; correct?

6 A. No.

7 Q. And you acknowledge that demand for oxymorphone
8 increased -- oxymorphone ER increased after generic
9 entry because new patients who were previously taking
10 other long-acting opioids began taking oxymorphone;
11 correct?

12 A. That's correct.

13 Q. So when generic oxymorphone became available,
14 people switched from other long-acting opioids to
15 generic Opana ER; correct?

16 A. To some degree. It was very small, but it
17 happened.

18 Q. And you acknowledge that Opana ER experienced
19 its highest loss rate in 2012 because physicians
20 switched their patients to other long-acting opioids;
21 correct?

22 A. I didn't hear the beginning of the question.
23 I'm sorry.

24 Q. You acknowledge that Opana experienced its
25 highest loss late in 2012 because physicians switched

1 their patients to other long-acting opioids; correct?

2 A. In part. That -- remember, switch here is not
3 what you're talking about in terms of switching the
4 same patient. This is about new patients as well.

5 And some of what happened was, unfortunately,
6 people who abused drugs switched to heroin, all right,
7 because this was -- the reformulated product was
8 crush-resistant. And the same thing happened to
9 OxyContin.

10 So the degree to which the patient -- the
11 demand for other opioids went up we can actually tell
12 by looking at what happened to sales of other
13 long-acting opioids in the period that the market for
14 Opana ER was shrinking in 2012. And it turns out the
15 market for all opioids was shrinking then, because that
16 was well into the opioid crisis, and in fact people
17 were prescribing fewer opioids of all kinds.

18 Q. Sir, did I understand you correctly that you
19 believe that people who left Opana ER prescribed for
20 them in 2012, some of them left for heroin?

21 A. In general, the decline in the -- in the sales
22 of opioids -- we don't know how to unpack this by LAO
23 versus LAO, but part of what happened with the decline
24 in total sales of long-acting opioids in this period
25 was switching to heroin. And that's documented in

1 these -- in the various government studies of the
2 opioid crisis, some of which I cited in one of my
3 reports. I don't remember which one.

4 Q. So I think you just said you can't unpack where
5 people are going among long-acting opioids; is that
6 right?

7 A. You cannot unpack -- I don't -- I'm not aware
8 at least, my own knowledge, of information about
9 which -- how many of people from each of the
10 long-acting opioids who switched to either -- some
11 form of illegal drugs, heroin or illegally imported
12 fentanyl or whatever. I don't -- I don't know how
13 to -- how to allocate that among each of the
14 long-acting opioids. What I can say is that all of
15 them were declining in sales during this period
16 collectively.

17 Q. Now, you base your assessment of switching
18 costs primarily on the reports of Dr. Savage and
19 Dr. Michna; is that right?

20 A. That's correct.

21 Q. Your report does not contain any empirical work
22 on switching costs; is that correct?

23 A. It has no empirical estimate of a specific
24 effect of switching costs as opposed to just what the
25 overall degree of competition in price is.

1 Q. And you refer to switching costs as high, but
2 you've not done any empirical work on the cost
3 associated with switching a patient from one
4 long-acting opioid to another; correct?

5 A. I haven't quantified what the magnitude of the
6 switching cost is because it involves elements I can't
7 possibly measure.

8 Q. And so you can't quantify what you mean by
9 "high" when you say switching costs are high; correct,
10 sir?

11 A. No, I can't put a quantification on it, but I
12 can certainly put a lower bound on it.

13 Q. And you're aware that Drs. Savage and Michna
14 agree that patients are switched from one long-acting
15 opioid to another all the time; correct?

16 A. They are. And they're the ones getting the
17 X dollars per visit to monitor the switching, which is
18 the switching costs -- part of the switching costs.

19 Q. Are you suggesting that they're switching
20 people in order to make -- put more money in their
21 pockets?

22 A. No. I'm saying this is a cost. What I'm
23 saying is, if clinically there's some good reason to
24 switch someone from one opioid to another, it's done
25 under the care of a physician, and that's costly.

1 Q. And switches are performed for a variety of
2 reasons; right?

3 A. Yes.

4 Q. For example, when physicians first start
5 patients on a particular long-acting opioid, they test
6 it to see how it's tolerated and opt to switch to
7 another opioid if the first one that they try for that
8 patient doesn't work so well; correct?

9 A. That's true to some degree. Yes.

10 Q. And you're aware that Dr. Savage testified that
11 choosing which opioid to prescribe is often a matter of
12 physician preference; correct?

13 A. Actually, they both testified more or less to
14 that effect, that physicians' habits and experiences
15 influence their choice, which is another -- another
16 impediment to price competition.

17 Q. You're aware that Dr. Savage testified that
18 it's common for patients who are on an IV of one
19 long-acting opioid are given a different long-acting
20 opioid in tablet form when they leave the hospital?

21 A. I'm not sure I understand the process quite the
22 way you described it. I mean, I think I agree with
23 what you're saying, but I wouldn't have used those
24 words.

25 Q. Well, you agree that -- strike that.

1 Long-acting opioids -- or excuse me.

2 Opioids are sometimes used in IV form in the
3 hospital setting; right?

4 A. Those are usually not long-acting.

5 See, that's the -- one of the advantages that
6 oxymorphone has compared to some of the other drugs is
7 that it actually is used in an immediate-release form
8 in -- inside the hospital in IVs, and so if you've
9 already figured out the dose for and you've already
10 found out that the patient can tolerate this
11 particular long-acting -- this particular opioid, then
12 when you switch from intravenous or some other
13 immediate-release form -- it could be a pill inside
14 the hospital -- to the long-acting form, you know that
15 the tolerance test has already been passed. And that's
16 an advantage that drugs have if they're in this
17 category that are used inside the hospital.

18 Q. And yet notwithstanding the fact that the
19 patient may have already passed the tolerance test,
20 physicians very often switch which molecule is used
21 when the patient leaves the hospital; correct?

22 A. That's -- yes, they do.

23 JUDGE CHAPPELL: It's approaching 5:45. It's
24 been long day.

25 MR. HASSI: Yes, Your Honor.

1 JUDGE CHAPPELL: We're going to recess and
2 reconvene tomorrow morning at 9:45.

3 (Whereupon, the foregoing hearing was concluded
4 at 5:42 p.m.)

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CERTIFICATE OF REPORTER

I, JOSETT F. WHALEN, do hereby certify that the foregoing proceedings were taken by me in stenotype and thereafter reduced to typewriting under my supervision; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

s/Josett F. Whalen

JOSETT F. WHALEN

Court Reporter