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

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FEDERAL TRADE COMMISSION

I N D E X

IN THE MATTER OF IMPAX LABORATORIES, INC.

TRIAL VOLUME 6

PUBLIC RECORD

NOVEMBER 2, 2017

EXHIBITS	FOR ID	IN EVID	IN CAMERA	STRICKEN/REJECTED
CX				
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RX				
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JX				
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P R O C E E D I N G S

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JUDGE CHAPPELL: We're back on the record.

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

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

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

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

Bingol was filed?

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

JUDGE CHAPPELL: I saw that.

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

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

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

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 If it's been filed, it must be withdrawn.

MR. LOUGHLIN: Understood.

JUDGE CHAPPELL: All right. Next witness.

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

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

- - - - -

Whereupon --

DEMIR BINGOL

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

MR. SPRAGUE: Good morning, Your Honor.

May it please the court.

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

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DIRECT EXAMINATION

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

A. Good. Thank you.

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

A. Thank you.

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

A. A company called Grünenthal.

Q. And what is your title at Grünenthal?

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

Q. What kind of company is Grünenthal?

A. It's a pharmaceutical company.

Q. When did you start at Grünenthal?

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

2013.

Q. 2013?

A. Correct.

Q. Thank you.

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

A. Yes.

Q. Which ones?

A. AstraZeneca.

Adolor.

aaiPharma.

Endo Pharmaceuticals.

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

A. Approximately 18.

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

A. Traditional sales and marketing roles.

Q. When did you work at Endo?

A. From 2006 to 2011.

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

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

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

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

Q. What is Opana ER?

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

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

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

Q. Is Opana ER a long-acting opioid?
A. Correct.
Q. What is Opana ER's active ingredient?
A. Oxymorphone.
Q. What other long-acting opioids contain oxymorphone as the active ingredient?
A. Well, today or --
Q. Well, when you were at Endo.
A. When I was at Endo?
Q. Yes, sir.
A. Oxymorphone was the only one or Opana ER was the only one.
Q. What about today?
A. I'm not quite sure how many variations there may be.
Q. Do you know what variations you're aware of?
A. I just know that there's some generics on the market. I haven't kept up with it since I left.
Q. Understood.
When you were at Endo, was Endo planning to launch a reformulated version of Opana ER?
A. Yes.
Q. Were you yourself involved in those plans?
A. Yes.
Q. What role did you have with respect to Endo's

plans to launch a reformulated version of Opana ER?

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

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

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

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

A. Sure.

Q. What was that?

A. Lidoderm.

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

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

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

A. Sure.

Q. Why was Opana ER an important product for

Endo?

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

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

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

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

A. Yes.

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

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

A. Well, my, again, responsibilities were

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

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

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

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

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

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

a matrix of constituents that you communicate these things to.

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

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

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

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

BY MR. SPRAGUE:

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

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

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

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

communications to them directly.

Q. Thank you.

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

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

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

A. Yes.

Q. And what is a playbook?

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

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

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

THE WITNESS: Sure.

JUDGE CHAPPELL: Thank you.

BY MR. SPRAGUE:

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

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

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

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

it.

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

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

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

A. Yes.

Q. What is Revopan?

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

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

A. Correct.

Q. Ms. Allen, could we please bring up CX 2610.002.

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

A. Yes.

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

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

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

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

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

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

JUDGE CHAPPELL: You were in sales; right?

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

JUDGE CHAPPELL: And you were in sales until when?

THE WITNESS: From '96 to '98.

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

THE WITNESS: Left sales?
JUDGE CHAPPELL: No. When you left the company.
THE WITNESS: Senior director of marketing.
JUDGE CHAPPELL: You just said -- you just referred to your competition.
What drugs do you consider the competition for Opana ER?
THE WITNESS: At that time there were a number of competitors.
JUDGE CHAPPELL: Let's say 2010.
THE WITNESS: It was OxyContin, maybe Avinza and Kadian, generic long-acting morphine. Exalgo perhaps was on the market then. I don't recall if it was there then or not.
So there are a number of other long-acting opioids that a clinician can choose from.
JUDGE CHAPPELL: Was that your job to know what the competition was?
THE WITNESS: Yes, sir.
JUDGE CHAPPELL: Thank you.
MR. SPRAGUE: Thank you, Your Honor.
BY MR. SPRAGUE:
Q. Was true twelve-hour dosing a characteristic that you hoped to differentiate Opana ER from these

other long-acting opioids?

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

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

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

Q. Sure.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Q. What does "low euphoria" mean?

A. In this context with this --

Q. Yes, sir.

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

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

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

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

Q. Understood.

We can take that down, Ms. Allen.

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

A. Yes.

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

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

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

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

Q. Understood.

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

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

A. Yes.

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

A. Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BY MR. SPRAGUE:

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

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

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

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

A. Yes.

Q. Were you involved in that lawsuit?
A. Yes.
Q. In what way?
A. I -- I believe it was technically called an expert witness, but I was -- I testified in that case.
Q. Did you testify in written form?
A. No. I appeared in a court in New Jersey.
Q. Did you also submit a declaration in that lawsuit?
A. Yeah. I think there was a deposition involved.
Q. I'm sorry.
A. I think -- I think a deposition was involved beforehand.
Q. Thank you, sir.
Before the deposition, did you submit a declaration?
A. I don't recall that.
Q. If I were to show you a document, might that refresh your recollection?
A. It could.
Q. Ms. Allen, can we please bring up CX 3273.
Mr. Bingol, could you please take a look at CX 3273.
(Document review.)

Your Honor, does CX 327- -- oh.

Does CX 3273 refresh your recollection as to --

JUDGE CHAPPELL: Is this in evidence?

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

JUDGE CHAPPELL: Go ahead.

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

BY MR. SPRAGUE:

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

Mr. Bingol, is this your signature?

A. It is.

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

A. Clearly I did.

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

Do you recall signing CX 3273?

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

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

A. No.

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

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

You stated in the declaration --

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

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

(Document review.)

THE WITNESS: Okay.

BY MR. SPRAGUE:

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

A. Yes.

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

What is an at-risk launch?

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

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

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

What did you mean with that sentence?

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

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

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

A. Sure.

(Document review.)

Okay.

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

What is the significance of that statement?

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

pressures in terms of budgets and whatnot.

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

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

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

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

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

A number of reasons.

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

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

THE WITNESS: Long-acting opioid.

BY MR. SPRAGUE:

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

regard.

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

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

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

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

JUDGE CHAPPELL: Hold on a second.

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

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

MR. SPRAGUE: I'm asking --

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

MR. SPRAGUE: I apologize, Your Honor.

JUDGE CHAPPELL: So the record is clear.

MR. SPRAGUE: Thank you, Your Honor.

BY MR. SPRAGUE:

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

A. That is perhaps --

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

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

Can we please take the CX 3273 down.

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

MR. SPRAGUE: Thank you, Your Honor.

BY MR. SPRAGUE:

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

Would these clinical differences you mentioned

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

A. They are part of the differentiation.

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

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

JUDGE CHAPPELL: Hold it, hold it.

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

THE WITNESS: Okay.

BY MR. SPRAGUE:

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

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

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

A. Yes.

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

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

(Document review.)

A. Okay.

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

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

A. Because it had been a successful product.

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

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

(Document review.)

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

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

(Document review.)

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

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

fine.

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

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

A. Yes.

Q. How did they assist your marketing efforts?

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

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

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

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

And please take your time to review this paragraph.

(Document review.)

A. Okay.

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

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

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

Q. The next sentence --

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

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

MR. SPRAGUE: Certainly.

BY MR. SPRAGUE:

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

A. Yes.

Q. What does "tier status" mean?

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

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

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

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

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

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

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

A. Often they'll be at tier one.

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

A. Yes.

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

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

MR. SPRAGUE: Understood.

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

JUDGE CHAPPELL: Go ahead.

(Pause in the proceedings.)

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

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

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

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

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

JUDGE CHAPPELL: Take the document down.

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

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

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

BY MR. SPRAGUE:

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

A. I recall forecasts for assuming generic entry.

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

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

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

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

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

Q. Understood.

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

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

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

Q. Why did Endo undertake these efforts to

reformulate Opana ER?

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

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

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

A. Yes.

Q. Why was that the case?

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

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

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

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

generic in 2010?

A. Yes.

Q. Do you recall?

A. Yes.

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

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

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

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

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

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

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

the company.

A. June 2011.

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

A. Yes.

Q. What was the purpose of a commercial update?

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

Q. I understand.

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

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

JUDGE CHAPPELL: Thank you.

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

MR. SPRAGUE: Yes, Your Honor.

BY MR. SPRAGUE:

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

A. Yes.

Q. What is CX 2573?
A. It's an update on the project EN3288, which is the project for the reformulated product.
Q. What is EN3288?
A. That's the project name that -- the internal project name for the reformulated project -- product, rather.
Q. This notes under the -- CX 2573 notes under your name "EN3288 Launch Leader."
What is a launch leader?
A. That just was the designation, that somebody has to be the project leader for each individual project, and in this case to prepare for launch it was me.
Q. CX 2573 at 002 is dated February 24, 2010.
Was that approximately the time you were providing this particular commercial update?
A. That's what it says. Yes.
Q. Can we please move to page 004, Ms. Allen.
JUDGE CHAPPELL: Excuse me. Put that screen back up.
What does it say at the bottom in red?
THE WITNESS: "Draft - Not Approved by Management."
JUDGE CHAPPELL: And you just asked him when he

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

BY MR. SPRAGUE:

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

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

Q. Do you recall creating this document?

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

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

JUDGE CHAPPELL: Go ahead.

(Pause in the proceedings.)

BY MR. SPRAGUE:

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

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

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

A. I don't recall.

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

A. Yes.
Q. Did those forecasts vary depending on the scenario?
A. Yes.
Q. Why would you develop forecasts for various scenarios?
A. It's part of the job. You have to try to plan ahead, see the future if you can, know what's -- what might impact your business and try to articulate that, and it usually comes out through a forecast ultimately.
Q. And what were the different assumptions made in creating these various forecasts relating to reformulated Opana ER?
A. I mean, there's a lot of different assumptions that can go into the forecast, so I wouldn't be able to tell you exactly which ones today.
Q. Ms. Allen, can we please pull up CX 2724.
Mr. Bingol, could you please review CX 2724.
(Document review.)
Your Honor, CX 2724 has been admitted into evidence and is not subject to Your Honor's in camera order.
JUDGE CHAPPELL: Are you going to ask the foundational question before you refresh recollection

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

MR. SPRAGUE: Yes, Your Honor.

BY MR. SPRAGUE:

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

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

MR. SPRAGUE: Okay.

BY MR. SPRAGUE:

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

A. Yes.

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

MR. SPRAGUE: Yes, Your Honor.

JUDGE CHAPPELL: Go ahead.

MR. SPRAGUE: Okay.

BY MR. SPRAGUE:

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

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

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

BY MR. SPRAGUE:

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

A. Not all of them, no.

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

A. Yes.

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

Mr. Bingol, can you please review CX 2724.

(Document review.)

A. Okay.

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

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

Q. Thank you.

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

Do you recall sending CX 2724 to Dave Holveck?

A. No, I don't recall that.

Q. Who is Dave Holveck?

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

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

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

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

A. No.

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

Who is Brian?

A. That would refer to Brian Lortie.

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

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

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

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

What does "advent of generics" mean?

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

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

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

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

What does "commercial strategy scenarios" mean?

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

Q. Did you prepare CX 2724?

A. I don't recall.

Q. Is there anything that would refresh your

recollection as to whether you prepared it?

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

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

A. Yes.

Q. Can we please move to page 005.

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

A. Yes.

Q. What does the column Scenario mean?

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

Q. What does the column --

A. Different events that could occur. Excuse me.

Q. Thank you.

What does the column Launch Date mean?

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

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

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

This is regarding the reformulated product.

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

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

JUDGE CHAPPELL: What does "claims" mean here?

Just the word "claims," what does that mean?

THE WITNESS: Labeling claims.

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

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

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

So we could -- we could demonstrate that the

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

JUDGE CHAPPELL: And there are three scenarios here?

THE WITNESS: Yes.

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

THE WITNESS: Yes.

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

THE WITNESS: Correct.

JUDGE CHAPPELL: Tell me what they are again.

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

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

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

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

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

You're a marketing person; right?

THE WITNESS: Correct.

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

THE WITNESS: Correct.

BY MR. SPRAGUE:

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

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

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

Do you recall seeing this slide before?

A. Yes.

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

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

ahead of generics.

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

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

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

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

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

A. Correct.

Q. What does "AB-rated" mean?

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

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

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

green line?

Q. Green.

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

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

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

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

JUDGE CHAPPELL: Yeah.

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

THE WITNESS: Yes.

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

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

JUDGE CHAPPELL: Thank you.

(Pause in the proceedings.)

MR. SPRAGUE: Thank you, Mr. Bingol.

At this time, Your Honor, I have no further

questions for Mr. Bingol.

JUDGE CHAPPELL: Any cross?

MR. ANTALICS: Yes, Your Honor.

JUDGE CHAPPELL: Go ahead.

- - - - -

CROSS-EXAMINATION

BY MR. ANTALICS:

Q. Good morning, Mr. Bingol.

A. Good morning.

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

A. Yes.

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

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

A. Yes.

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

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

MR. ANTALICS: Right. I think he mentioned a

couple of them.

JUDGE CHAPPELL: He brought up the competitors. I followed up.

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

BY MR. ANTALICS:

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

A. Yes.

Q. Yeah. Okay.

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

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

A. Yes.

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

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

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

Q. Okay. So for example --

JUDGE CHAPPELL: Hold on a second.

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

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

JUDGE CHAPPELL: What you called LAOs earlier today?

THE WITNESS: Yes, sir.

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

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

JUDGE CHAPPELL: Go ahead.

BY MR. ANTALICS:

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

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

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

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

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

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

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

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

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

THE WITNESS: Both actually.

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

BY MR. ANTALICS:

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

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

A. I don't recall specifically.

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

A. Yes.

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

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

that declaration.

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

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

A. Correct.

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

A. Yes.

Q. And how much was that?

A. 3.4 percent.

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

A. Yes.

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

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

A. Correct.

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

A. Yes.

Q. Okay.

JUDGE CHAPPELL: Hold on a second.

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

THE WITNESS: I don't recall exactly.

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

THE WITNESS: No.

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

THE WITNESS: No.

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

THE WITNESS: The case was the patent infringement suit.

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

THE WITNESS: Yes.

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

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

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

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

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

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

JUDGE CHAPPELL: Go ahead.

MR. ANTALICS: Thank you.

BY MR. ANTALICS:

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

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

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

A. Correct.

Q. Okay.

Okay. That's enough on that.

You talked a little bit about formularies on direct examination.

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

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

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

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

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

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

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

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

MR. SPRAGUE: Objection, Your Honor. Foundation.

JUDGE CHAPPELL: Response?

BY MR. ANTALICS:

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

A. Yes.

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

objection.

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

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

Go ahead.

BY MR. ANTALICS:

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

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

MR. SPRAGUE: Objection, Your Honor. Leading.

JUDGE CHAPPELL: He's on cross.

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

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

Overruled.

MR. SPRAGUE: Yes, Your Honor.

THE WITNESS: Generally speaking, they use the

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

BY MR. ANTALICS:

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

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

Q. Okay. And will --

JUDGE CHAPPELL: Hold on a second.

Stand up.

MR. SPRAGUE: Yes, Your Honor.

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

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

MR. ANTALICS: I think these are all --

JUDGE CHAPPELL: Are you doing direct right now?

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

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

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

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

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

Bring it within the scope of the direct with foundation.

MR. ANTALICS: Thank you, Your Honor.

BY MR. ANTALICS:

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

A. Yes.

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

JUDGE CHAPPELL: Go ahead.

BY MR. ANTALICS:

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

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

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

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

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

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

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

A. Yes.

Q. Could you describe how that works.

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

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

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

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

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

A. Yes. It can be.

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

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

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

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

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

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

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

Are you competing with other insurance companies for favorable access?

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

JUDGE CHAPPELL: Hold on a second.

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

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

BY MR. ANTALICS:

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

A. That is correct.

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

A. Yes.

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

A. You do in a clinical sense.

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

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

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

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

JUDGE CHAPPELL: Sustained.

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

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

MR. ANTALICS: Right.

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

BY MR. ANTALICS:

Q. Okay. Let me rephrase it.

Do you --

JUDGE CHAPPELL: The objection is sustained. We're not going to sit here and let you ask

hypotheticals of a fact witness.

BY MR. ANTALICS:

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

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

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

A. Yes.

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

A. Correct.

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

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

Q. And those various scenarios, they contained

different assumptions?

A. Correct.

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

A. Yes.

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

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

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

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

Q. So any potential date when they could enter.

A. Correct.

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

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

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

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

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

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

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

MR. ANTALICS: I apologize, Your Honor.

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

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

(Pause in the proceedings.)

JUDGE CHAPPELL: Yes, you may approach the witness.

I believe you handed a binder to the witness?

MR. ANTALICS: I'm sorry.

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

MR. ANTALICS: Okay.

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

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

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

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

Could you put up on the screen RX 086.

This has been received into evidence, Your Honor. And it's not confidential.

BY MR. ANTALICS:

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

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

A. Yes.

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

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

Q. Okay. Thank you.

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

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

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

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

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

MR. ANTALICS: Right.

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

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

JUDGE CHAPPELL: Sustained.

Lay a foundation or move along.

BY MR. ANTALICS:

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

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

potential competitive threats or marketplace challenges that we were facing.

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

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

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

A. Yes.

JUDGE CHAPPELL: Go ahead.

MR. ANTALICS: Thank you, Your Honor.

BY MR. ANTALICS:

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

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

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

MR. SPRAGUE: Objection, Your Honor. Foundation.

JUDGE CHAPPELL: You mean leading?

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

JUDGE CHAPPELL: Sustained.

MR. SPRAGUE: Thank you, Your Honor.

BY MR. ANTALICS:

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

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

Next question.

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

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

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

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

rest of the document.

BY MR. ANTALICS:

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

MR. SPRAGUE: Objection, Your Honor. Leading.

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

THE WITNESS: Yes.

BY MR. ANTALICS:

Q. Does UBS follow the pharmaceutical industry?

A. Yes.

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

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

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

MR. ANTALICS: Okay, Your Honor.

Could you take the document down.

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

report, et cetera.

MR. ANTALICS: Okay.

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

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

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

We didn't get an answer. Go ahead.

BY MR. ANTALICS:

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

A. No.

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

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

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

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

BY MR. ANTALICS:

Q. In the various forecasts and scenarios created

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

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

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

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

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

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

Q. Okay.

A. -- from Endo.

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

MR. SPRAGUE: Objection, Your Honor. Speculation.

JUDGE CHAPPELL: As phrased, the question is

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

BY MR. ANTALICS:

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

A. Correct.

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

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

Q. Did Endo --

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

THE WITNESS: Yes, sir.

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

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

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

JUDGE CHAPPELL: So did that encompass an authorized generic?

THE WITNESS: Not on that slide, no.

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

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

JUDGE CHAPPELL: All right.

BY MR. ANTALICS:

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

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

MR. ANTALICS: Your Honor, I have nothing

further, Your Honor.

JUDGE CHAPPELL: Any redirect?

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

JUDGE CHAPPELL: Go ahead.

(Pause in the proceedings.)

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

JUDGE CHAPPELL: Thank you. You may stand down.

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

We're in recess.

(Recess)

JUDGE CHAPPELL: We're back on the record.

Next witness.

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

JUDGE CHAPPELL: The motion to compel Reasons?

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

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

MR. LOUGHLIN: Correct.

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

MR. LOUGHLIN: Understood, Your Honor.

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

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

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

- - - - -

Whereupon --

ROGER GORDON NOLL

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

MR. MEIER: Good morning, Your Honor.

And may it please the court.

- - - - -

DIRECT EXAMINATION

BY MR. MEIER:

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

A. Good afternoon. Well.

Q. Professor Noll, would you please introduce

yourself by stating your full name.

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

Q. How are you employed?

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

Q. And where are you a professor emeritus?

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

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

A. That's correct.

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

A. Normally I teach one course a year.

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

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

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

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

it.

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

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

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

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

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

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

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

A. Yes.
Q. Are you having difficulty hearing me?
A. Yes.
Q. I will try to speak up.
Before we get to your opinions in this case, I'd like to ask you about your academic credentials and your research and publications and professional experience that qualify you to reach the opinions you'll be giving.
Before retiring and becoming a professor emeritus at Stanford, what was your position at the university?
A. I was the Morris M. Doyle Professor of Public Policy in the Department of Economics. And I was also the director of the Public Policy Program, which is an undergraduate major at Stanford.
And I was the director of the Program in Regulatory Policy of the Stanford Institute for Economics Policy Research, where I also was a senior fellow.
Q. What courses would you typically teach as an economics --
JUDGE CHAPPELL: Can we put some dates in here?
BY MR. MEIER:
Q. When did you retire?

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

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

A. Yes, I do.

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

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

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

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

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

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

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

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

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

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

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

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

and it also included antitrust.

JUDGE CHAPPELL: Pharmaceuticals?

THE WITNESS: Yes.

JUDGE CHAPPELL: Hatch-Waxman in 1984?

THE WITNESS: Yes.

BY MR. MEIER:

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

A. Yes.

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

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

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

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

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

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

JUDGE CHAPPELL: All right.

BY MR. MEIER:

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

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

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

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

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

A. Yes.

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

A. My primary field in economics is the field of

industrial organization, which includes antitrust regulation and technology policy.

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

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

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

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

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

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

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

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

A. Yes.

Q. How many books have you written?

A. 15.

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

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

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

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

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

A. Most of my publications are in peer-reviewed

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

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

A. I'm not a lawyer.

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

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

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

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

Q. I'm going to keep trying harder.

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

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

Q. Can you explain that a little bit?

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

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

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

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

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

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

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

A. S.

Q. -- S; correct?

A. Yes.

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

A. Oh, yes. Sure.

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

A. Yes, I have.

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

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

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

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

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

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

Q. That was in the 1970s?

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

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

A. Yes, I have.

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

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

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

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

A. Yes, I have.

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

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

Hewlett Packard.

The Minnesota Twins.

The Los Angeles Lakers.

The Oakland Raiders.

United States Football League.

There are others. I mean --

Q. Any companies in the telecommunications field?

A. Oh, yes. AT&T.

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

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

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

Have you consulted with any others?

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

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

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

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

A. Yes.

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

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

A. Yes.

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

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

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

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

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

involving prescription drugs?

A. Yes.

Q. And what cases would that be?

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

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

A. GlaxoSmithKline.

Q. And you testified in trial in that case?

A. Yes, I did.

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

A. The FTC.

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

A. No. It was just depositions.

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

MR. HASSI: No objection, Your Honor.

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

MR. MEIER: Thank you, Your Honor.

BY MR. MEIER:

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

What is your principal opinion in this case?

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

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

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

Q. I'm sorry.

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

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

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

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

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

A. Yes, I do.

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

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

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

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

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

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

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

A. Yes.

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

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

Q. Well, the question --

A. -- certainly they did provide --

JUDGE CHAPPELL: Hold it.

BY MR. MEIER:

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

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

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

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

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

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

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

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

A. Probably close to 10,000.

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

A. Yes.

Q. About how many did you review?

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

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

A. Yes.

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

A. Yes, I did.

Q. And which ones did you read?
A. Dr. Addanki, Mr. Figg and Dr. Michna.
Q. Do you recall what Dr. Addanki's area of expertise --
A. I'm sorry. There was something happened. I didn't hear it.
Q. Do you recall what Dr. Addanki's area of expertise is?
A. He is an industrial organization economist as well, specializing in the drug industry.
Q. And do you recall what Mr. Figg's area of expertise is?
A. A patent lawyer.
Q. And do you recall what Dr. Michna's area of expertise is?
A. He's a physician engaged in pain management, among other things.
Q. In addition to reading Dr. Addanki's report, did you review the discovery materials that he cited in his report?
A. Yes.
Q. Is there anything you saw in the reports of Impax' experts that caused you to revise any of your opinions in this case?
A. No.

Q. Why not?

A. There's two reasons.

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

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

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

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

A. Yes.

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

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

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

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

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

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

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

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

Q. And what is the second way?
A. The second way is called a direct effects analysis where you essentially skip the market definition/market power part because you have enough information that you can simply directly observe what the effect of the conduct was and that it was harmful to the other side of the market.
Q. Going back briefly to the traditional antitrust economic analysis you described a moment ago, did you follow the steps you just outlined in analyzing the competitive effects of the Impax-Endo agreement in your report?
A. Yes.
Q. And now turning to the direct effects analysis, did you apply that analysis in reaching the opinions in this case?
A. Yes.
Q. So you did both a traditional economic analysis and a direct effects analysis?
A. Yes.
Q. Why would a direct effects analysis be appropriate to ascertain the competitive effects in this case?
A. Well, to answer that question I have to go back a little bit.

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

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

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

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

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

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

A. That's correct.

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

A. Yes.

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

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

What is a relevant antitrust market?

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

price increase, small but significant and nontransitory increase in price, the SSNIP test, if they coordinated their activity, they merged to monopoly or they engaged in a price-fixing cartel.

Q. What is, in your opinion, the key issue in defining the relevant antitrust market in this case?

A. The key issue in this case is the degree to which there is price competition that -- among long-acting opioids, that is to say, different APIs in the long-acting opioid category, to cause it to be a competitive market, that is to say, for the prices charged by producers of long-acting opioids to be competitive. That's the crucial issue in market definition in this case.

Q. In giving that answer, you used a phrase or term "different APIs."

What does "APIs" mean?

A. That is the active pharmaceutical ingredient in -- in a drug. There can actually be more than one. Some drugs are compound drugs. In the long-acting opioid case, there are several drugs that are -- that combine an opioid with something else, so it's -- it's either one or more active pharmaceutical ingredients or the elements of the drug that have a therapeutic effect.

Q. Do you happen to know what the API is for Opana ER?

A. Yes. It's oxymorphone.

Q. And what is the -- do you happen to know what the API is for the branded product OxyContin?

A. Oxycodone.

Q. Yeah, I -- thank you.

So how do you start the process of defining a relevant antitrust market?

A. Well, you -- it's sort of like unpeeling the skins of an onion. You start with the things that are the best candidates to be close competitive substitutes, to be -- and by "competitive substitutes" I mean in an economic sense, close substitutes in the sense that a small change in relative prices between the two products would switch consumers from buying one to buying the other. All right.

And the closest candidates for a competitive substitute are other drugs that are basically the same. And the closest you can possibly come to a given reference product in the drug industry would be another drug that was therapeutically equivalent that used exactly the same APIs in exactly the same doses in exactly the same way. And that -- that -- that is a drug that the FDA would say is AB equivalent or

therapeutically equivalent, that they're interchangeable. And that would be the first candidate.

And then the second candidate would be a drug that uses the same API in the same dose but has differences in the formulation and other aspects to the formulation so that it's rated as bioequivalent but not therapeutically equivalent.

And that distinction is important because a therapeutically equivalent drug is subject to state generic substitution laws where pharmacists can take a doctor's prescription and just substitute the generic for the brand name drug. For bioequivalent drugs that's not true.

Q. Okay. So what is the reference product you started your economic analysis with in this case?

A. Well, there's -- there's actually -- through time there's two drugs. There's -- they're both called Opana ER, but one of them is the original formulation and the other -- and the second one is the reformulation that the -- sort of what's called in the case the crush-resistant form.

So we start off with those. And then of course there's the products that the generic manufacturers produce, which is Impax and Actavis, have been the

entities that have produced generic versions of the first version of Opana ER.

Q. So after you identify the reference products, what's the next step in the process?

A. Well, I just described it. It's to find -- it's to find the candidates that are the closest, which are basically the drugs that use the same API in the same way.

The next one beyond that would be other drugs that use the same API but in a different formulation. All right. And the best example there would be immediate-release oxymorphone, which would be Opana IR and its generic substitutes.

Q. Okay. I'm going to be asking you a little bit more about that in a moment. I'm going to kind of go back to just talking about the process a little bit.

A. Okay.

Q. These steps that you were just describing, did you go through these steps in forming your opinions about the relevant antitrust market in this case?

A. I went through these steps plus some more. Yes.

Q. And what opinion have you reached about the relevant product market in this case?

A. That the -- that the -- the relevant market in

this case consists of the extended-release versions of oxymorphone, and it does not include the immediate-release versions of oxymorphone or the other long-acting opioids.

Q. In your opinion, can two drugs be functional substitutes but not necessarily close economic substitutes?

A. Of course they can.

Q. Well, how -- can you explain that?

A. Because the functionality is not the only thing that matters. There are -- there -- in most markets, products are differentiated; that is to say, they have slightly different attributes. And consumers will differ in the values they place upon those attributes.

Secondly, the act of switching from one product to another may be costly. That is to say, it's not just that you buy the product itself, but you'd have to undertake other expenditures or take other costly actions like spend time in switching from one to another.

And either product differentiation or switching costs can take a market that contains products that are used for the same function but that are not close economic substitutes because of consumer

preferences, because of brand reputations, brand loyalties, behavior, sort of being stuck in the mud and, you know, inflexible in behavior, or simply switching costs, for all those reasons, functional substitutes are not necessarily close economic substitutes.

A necessary condition for things to be economic substitutes are that they're functional substitutes, but it's not sufficient. You have to go further than that.

Q. So how can you test whether drugs that are functional substitutes are or are not in the same economic market?

A. The way you do it is you see if -- the -- the first way is you see if changes in the relative prices affect the relative quantities sold. That is, if we think about our SSNIP test, we ask the question, if one product's price goes up relative to the other, does that cause a large enough switch from one category to another that it wasn't profit-enhancing to increase the price.

A related test to that is whether events that affect outcomes in the sale of one product are reflected in changes in prices and quantities for the other product, such as generic entry.

Now, generic entry is actually a price phenomenon as well as a product phenomenon; that is to say, if generic entry occurs in one drug market, say the morphine -- extended-release morphine, what happens to brand name morphine and what happens to other long-acting opioids and are those effects similar or different. And if they're different, then they're not in the same relevant market.

Q. Now that you've described sort of at a high level the process that you went through, which pain relief products did you evaluate as potential candidates to be in the relevant antitrust market with Opana ER?

A. In addition to all the drugs I mentioned before that use oxymorphone, I also looked at all of the long-acting opioids that are used to treat severe pain. There's a longer list of long-acting opioids that are used for modest, less intense pain, but I focused on the seven drugs that are used to treat chronic, severe pain.

Q. All right. I'm going to hopefully try to unpack a little bit of this and kind of go back over some of the things you talked about --

A. Sure.

Q. -- in more detail.

Looking first at generic versions of oxymorphone, what drugs did you find in this category?

A. The -- the -- there are seven different formulations of Opana ER, seven dosage strengths that were at some point on the market, and which ones that are on the market vary through time, but at some point there have been seven dose strengths.

The -- initially, using the Hatch-Waxman procedures, Actavis was the first filer for two of those doses and Impax was the first filer for five of them, so one had generic entry initially. The first generic entry that occurred in the Opana ER market was two doses for Actavis and five doses for Impax, and then later Actavis came in in the other five doses.

So -- and so the -- the -- that's the category -- that's the universe of drugs. And then, as I mentioned before, there's two versions of Opana as well, the original version and the reformulated version.

So if you add up all that together, you have each -- you have each of these companies, these three companies, producing seven different doses of oxymorphone ER.

Q. What information did you use to determine whether these different forms of oxymorphone were in

the same relevant market as Opana ER?

A. I used basically two different kinds of information.

The first kind of information I used was to understand the relationship between the characteristics of the products and what was likely to affect the ability to switch from one to the other in response to a small price change. And that has to do with their therapeutic characteristics and their switching costs.

And the second thing I looked at was the actual effects of generic entry of both Actavis and Impax on sales of Opana ER at the time that that entry occurred.

Q. When you say actual effects of generic entry on sales of Opana, how did you -- how did you get that information? What kind of information were you looking at?

A. We looked at the -- at publicly available information and private information produced from the companies about the -- about the number of prescriptions, about the number of -- sort of the quantity of pills sold and the revenues and average prices of each of the dosage strengths for all of the companies, to the extent we could get the data.

The data are not complete. We didn't have data for every single month in every single year, but we had enough data to be able to perform an analysis about in general what happened to Opana when these entry events occurred.

JUDGE CHAPPELL: I heard you say "we" a lot today. Who is "we"?

THE WITNESS: I was helped out in my analysis by economists on the staff at the FTC.

So the -- I -- the actual data analysis was done at the FTC, but I supervised it.

BY MR. MEIER:

Q. Did this data include data from a company called IMS?

A. Yes.

Q. And what --

A. They are -- yes.

Q. What is IMS data?

A. IMS data is -- there's a whole bunch of IMS data. There's a number of -- there's four different data series they produce.

They do surveys of pharmacies, wholesalers and physicians about prescribing behavior. And the IMS produces data about number of prescriptions and revenues of sales for each of the drugs in the case.

Q. Is it common for industrial organization economists working on pharmaceutical cases to use IMS data?

A. Yes. It's -- well, yeah, it's extremely common because it's really the -- the only game in town and it is the -- it is the -- IMS is the data source that the companies use, and so when you get data from companies about sales and these various measures, frequently it's IMS data that you get. And then, of course, in addition, the FTC acquired some of the data as well directly.

But it is -- it is sort of the main source of data not only in the use -- in use antitrust cases, but there's a lot of published empirical research in economics journals that is based on IMS data.

Q. And when you said a moment ago that's the data source the companies use, you mean pharmaceutical companies.

A. Yes.

Q. Pharmaceutical companies like Impax and Endo.

A. Impax and Endo have data analyses in the discovery record that use IMS data.

Q. Well, what kind of estimates of the effect of generic entry did you see in the Endo data?

A. The first -- the first event of course is the

entry of Actavis. And when Actavis entered in these two doses, these two low-end doses, which are the smallest sales of all the seven dose strengths, they were AB equivalent to the version of Opana ER that was on the market at the time, so when Actavis entered, they very quickly took almost all of the market away from Endo. And indeed, Endo eventually exited that market, the -- you know, the -- and then it came back later.

But that -- that gives you a show of how important generic entry was in those two doses, is that Actavis charged a substantially lower price than Endo and quickly captured almost all of the market.

And then the second event is the entry of Impax in January of 2013, which at that time the formulation of Opana ER had changed to the reformulated version, so there was a similar -- a qualitatively similar reduction in sales of Opana ER, and the price of course charged by Impax was lower. But the process of substituting for Opana ER was much slower and took several years to get up to the point where Impax had half of the quantity sold. But there still was this substitution. There was a -- Impax' prices were lower. The average price of a prescription for Opana ER plus the generic version of

oxymorphone ER, that price declined, and the market gradually switched from Endo to Impax.

Q. So what does the case information you reviewed tell you about the relevant market in this case?

A. It tells me two things, one of which is obvious and one of which isn't.

The obvious point is that generics are close substitutes for brand name drugs that are therapeutically equivalent, Actavis.

It also says that bioequivalent drugs that are not therapeutically equivalent also have a significant competitive effect and are competitive substitutes but that the process doesn't work as well, and that's because you don't have the generic substitution laws going in your favor.

The less obvious point is that, at the time the generics entered, the market for Opana ER could not have been competitive or else the price wouldn't have fallen as dramatically as it did and the quantity shift wouldn't have been as great.

Q. Can you explain that?

A. Yes. Because if the -- if the market already is highly competitive before the generics enter, then you wouldn't expect that there would be any significant effect of generic entry.

If -- to take as an example, if -- if generic morphine is a close economic substitute for brand name Opana ER, and that generic entry occurred several years earlier, if they were close economic substitutes, the generic entry in morphine would have had the same effect as the generic entry in oxymorphone, and it didn't. It didn't cause the price to fall because we know that the price didn't actually fall and the sales decline until generic oxymorphone entered.

Q. So after assessing whether bioequivalent drugs like generic oxymorphone ER are close economic substitutes for Opana ER, what was the next closest candidate product that you identified?

A. I tested whether immediate-release oxymorphone was a close competitive substitute to extended-release oxymorphone.

Q. What's the difference between extended-release oxymorphone and immediate-release oxymorphone?

A. It's -- it's -- if you're going to -- if you're taking essentially the same dose strength over the course of 24 hours, you would take a larger number of pills more frequently if you were using immediate-release than extended-release.

The APIs are the same, but the profile with which the drug is absorbed into the system and then

disappears is much shorter for the immediate-release, because there's -- there's nothing in the formulation that sort of drags out the release of the drug into the system.

So -- but it's the same drug. It's the same API and it has the same effect. It's just that it's quicker. It comes faster and goes away faster.

Q. Well, can a person just take a number of IRs every day?

A. That -- yes, one can, although one would not expect that to be the case because pill burden is a serious problem in almost all drugs in that people are more likely to make mistakes in their dosage if they have to take pills frequently, have to take a large number of pills frequently.

And in some categories this isn't so bad, but in drugs where your life is at stake, in like the HIV/AIDS drugs that I studied in GlaxoSmithKline and like opioids in this case, if you make a mistake, it can be deadly.

And so, you know, doctors, if you're -- if you're going to suffer chronic, long-term pain that requires round-the-clock treatment, they're going to favor an extended-release version, all else equal, over an immediate-release version.

Now, having said that, that doesn't mean that economics couldn't affect it, that relative prices couldn't affect it, but that's the fundamental reason you wouldn't expect that these things would be perfect substitutes.

Q. So what information did you use in this case to determine whether oxymorphone IR is in the same relevant market as Opana ER?

A. We compared the effect of the introduction of generics in the immediate-release version to the -- on the immediate-release sales to the effect of generics in that market on sales of extended-release.

Q. And what did you find?

A. The result that we found was that essentially immediate-release Opana was essentially driven from the market, that the market was taken over completely by the generics at a much lower price.

And while that was going on, there was the -- extended-release version of Opana just continued to go up. There was no visible effect at all on sales of Opana ER from generic -- extremely successful generic entry into immediate-release.

Q. So if I understand correctly, generic IR affected branded IR; is that correct?

A. Generic IR affected Opana IR sales dramatically

and --

Q. But it did not affect Opana ER sales?

A. It had no detectable effect on Opana ER sales.

Q. And again, is that based on using IMS data and other data that you --

A. Yes.

Q. -- were able to look at?

A. And my characterization is true whether you use number of pills, number of prescriptions or revenues.

Q. So what does that tell you about the relevant product market in this case?

A. That tells you that IR is not a close economic substitute for ER, and so my -- the explanation I gave before about why doctors might prefer ER to IR in certain circumstances is sort of confirmed by the data, that that seems to be sufficiently important that it prevents these two drugs from being competitive substitutes.

Q. Even though they have the same API?

A. Same IPA (sic) and same pharmaceutical use. They're both used to treat severe pain.

Q. Same dosages?

A. Well, the dosages are different in the sense that if you're going to -- you know, if you're taking

an ER tablet that's equivalent to an IR tablet, because you have to take the IRs more frequently, the IRs have lower dosage, but they would have the same cumulative dosage over a long period of time.

Q. So after concluding that immediate-release oxymorphone is not in the same product market with Opana ER, what was the next set of candidate products you identified?

A. The -- the other long-acting opioids, the extended-release versions of the other opioids that are used to treat severe pain, which is a subset of all long-acting opioids. Some of them are not used for that purpose. But of the drugs that are used to treat severe pain, the extended-release versions of those opioids.

Q. What are some of the drugs in this category?

A. Well, oxycodone, hydromorphone, morphine. There's -- there's -- tapentadol. There's a bunch of them. They're listed in my report. Exhibit 4 in my report has the list.

Q. Do you recall in Exhibit 4 roughly how many --

A. Seven.

Q. -- different products you identified?

A. There's seven.

Q. What information did you use to determine

whether these other long-acting opioids are in the same relevant market as Opana ER?

A. The method is exactly the same for testing whether IR and ER are in the same market. You look at whether events in one market affected sales in the other.

So you look at did generic entry in oxymorphone have an effect on morphine and did generic entry in morphine have an effect on oxymorphone.

Q. Did you also look at any therapeutic information?

A. Yes, I did.

I did the same preliminary work, which is to look at all the factors that would both contribute to competition and subtract from it. And the factors that contribute to it are things like formulary rules and placement, things like government procurement rules, the operation and the nature of generic substitution laws, where they affect things and where they don't.

So -- and then the clinical guidelines and the testimony of both of the doctors in the case, the research -- the publications by clinical researchers in the field that talk about what the proper way to treat people with long-acting opioids is.

And all of this information then produces here's reasons to think they might be competitive and here's reasons to think they might not. And the reasons you would think they might not be competitive would be that they have therapeutic differences, the things that the doctors argue about in their two expert reports, and the issue of switching costs again.

And the issue of switching cost is really important here.

Q. Well, let's talk about that a little bit.

What does "switching costs" mean to an --

A. Yes. A switching cost --

Q. -- to an industrial organization economist?

A. Oh. Sorry. I jumped on you. That's bad.

A switching cost is a -- if you are a buyer of a product, then one cost, you know, if you switch is you stop paying X dollars for this product and you start paying Y dollars for that product.

But switching costs go beyond any price difference to other costs you might experience because you undertook the switch. And it's these other costs that actually are important here. The -- you know, the price differences in the drugs are small compared to the costs of switching from one drug to another.

Q. What role did switching costs play in your product analysis in this case?

A. They give me an insight into an economic explanation for why we would not expect pure functional equivalence between two long-acting opioids.

Assuming for the sake of argument that all the therapeutic differences that are emphasized by the firms in their promotional activities, assuming that you found two drugs where they all had the same characteristics, then switching costs constitute a reason independent of that that these might not be close economic substitutes because customers get locked in to one drug because of switching drug costs, and they wouldn't really be induced to change unless there was some therapeutic reason that they had to change.

Q. What are specifically some of these switching costs that you identified?

A. The -- it -- the first part of the switching cost is that you can't just go from the final dose of the first drug to the final dose of the second drug instantaneously. There's -- if you read the testimony of the doctors and the clinical guidelines from the National Institutes of Health about opioids, you're

supposed to taper off the dosage of the first drug to avoid withdrawal symptoms, and then you taper up the dosage of the second drug to find the level where you achieve adequate pain relief, and so you -- it is a long and complicated process. It's not just dropping one and taking the other.

And then the second part is that the whole process of tapering off and tapering in has to be supervised by a physician, and of course, every time you visit the physician, it's another charge. Somebody has to pay, your insurance company or you have to pay.

And so those are the switching costs. It's that you have to invest a significant fraction of your own time and you have to have the supervision of a physician in order to switch from one to the other.

Q. Have you seen any discovery materials in this case showing that Endo was aware of the switching costs between different drugs?

A. Oh, yes. Not only Endo but everybody. I mean, yes, I have seen such evidence.

Q. Okay. Well, can you tell us a little bit about that.

A. The -- when the Novartis shortage occurred, Endo reported that event to the Food and Drug

Administration, and collectively they decided that a warning had to be issued to physicians to terminate prescribing Opana ER to new patients because of fear that the shortage would -- the supply disruption would create a shortage and they would have to switch people and that would be costly.

So that's a -- that's a perfect example of the significance of switching costs. It actually caused a company to say we don't want new customers until this supply disruption is solved.

Q. When you conducted your analysis and you took the step from the oxymorphone ER to IR and found that -- and concluded that they weren't good economic substitutes, could you have stopped your analysis right there?

A. No.

Q. Why not?

A. Because whereas the similarity between ER and IR is they use the same API, there still is this pill burden issue. And that doesn't occur in comparing, say, OxyContin to Opana, all right, that they are both long-acting opioids, so the reason for having a preference between OxyContin versus Opana is going to be different.

So the fact that pill burden was sufficient to

cause a difference between IR and ER doesn't mean that there's going to be a difference between OxyContin and oxymorphone.

Q. Okay. So let's get back to this discussion of the long-acting opioids.

Did you observe anything in Endo's pricing behavior that gave you any insights into whether Opana ER competes with other long-acting opioid?

A. Yes.

Q. And what did you see?

A. The -- the -- the instincts part of the story is, you know, there's a lot of discovery documents that I have read that basically talk about pricing. All right. And there's just -- there's two contexts in which pricing is discussed.

The first is Opana's own -- I mean, Endo's documents and indeed Impax' documents about how they're going to set their prices, all right, and what do they consider.

And then the second is, in their promotional documents, the discovery information about how they're going to market their product. They will sometimes mention the price of some other long-acting opioid.

And so from those documents you get a sense of the degree to which the prices of other products are

perceived by Endo and Impax as important to them. And that -- since we know that these companies engage in extensive modeling, they use the same methods that are used in the economics literature to figure out what their prices ought to be, that this is useful information about who their close economic substitutes are, whose prices they have to take into account when setting their own price.

Q. Did you find similar kinds of information in Impax' documents?

A. Yes. Because Impax has to set a price for its generics as well.

Q. Okay. And what did you see in the Impax documents that helped you --

A. Well, Impax never considers anything other than Opana. All right. It's just purely focused on what the price of Opana is, so it didn't regard the price, say, of either generic morphine or a brand name morphine as significant in setting its prices.

Q. So to wrap this discussion up a little bit on long-acting opioids, can you summarize the conclusions you reached concerning whether other long-acting opioids are close economic substitutes for Opana ER.

A. Well, what I -- what I learned from reading the documents of Endo is that they rarely considered

the prices of other drugs, occasionally they did, they rarely considered the prices of other drugs in setting the price of Opana ER.

Their promotional documents occasionally mentioned the price of something else, but those promotional documents focused primarily on product differentiation, how their product differs from others, so their promotional activity is oriented towards creating a market niche based on product differentiation.

These support the idea that there -- other long-acting opioids are not close economic substitutes. They don't force competitive pricing on Endo.

And then the data about what happens to generic entry in other markets for long-acting opioids versus Opana ER, if a morphine generic enters, its effect on Opana ER, that all confirms this, that there is no spillover effect from state of competition for one long-acting opioid into prices and sales of another long-acting opioid.

Q. Did you review Impax' economic expert Dr. Addanki's method for opining on the relevant antitrust market in this case?

A. Yes.

Q. And what is your opinion of Dr. Addanki's method?

A. Dr. Addanki does not use the method I just described. He does not actually attempt to show that the competitive -- that there's sufficient competition among various forms of generic -- excuse me -- among various forms of long-acting opioids to cause each one to have competitive pricing based upon what's going on with other long-acting opioids. He doesn't use that method.

Instead what he does is he focuses on promotional activity as evidence of competition primarily.

Q. So he --

A. He has some information about formularies and -- but his main focus is on the evidence that they promote against each other.

Q. So you mentioned promotional activities and formularies.

Dr. Addanki has a discussion in his report about the placement of long-acting opioids on health plan formularies. Do you recall reading that?

A. Yes, I do.

Q. So first of all, just real briefly, I think we all probably know this at this point, but what is a

health plan formulary?

A. A formulary is essentially a list of the drugs that will be covered by an insurance plan. And the insurance plan can be traditional insurance or it can be an HMO like Kaiser.

And it basically says -- it ranks -- it puts the drugs in various categories and the -- the -- there are essentially priorities in that the highest category or tier is one in which the patient has the lowest copay and also has the lowest net price to the insurance company as well.

And they try to encourage people to use things in higher tiers, and usually the first tier, the highest tier, the one that they encourage you the most use for is generics. And then the -- the action for brand name drugs, if you have generic competition, is usually whether you're in the second or third tier or you're just not included.

Most formularies will have four different categories, three tiers which are actually covered by insurance and then a fourth category where you need some special reason and approval in order for the physician to even prescribe the drug.

Q. So you agree that health plans use formularies to try to promote competition among drugs.

A. I not only agree that they do that, there's actually a discussion in my original report about how they do it and how to some degree it is effective. They do end up having an effect on price by -- by engaging in this behavior.

The issue is whether it forces these products to be in the same market, which means that they're competitive, that the pricing is competitive.

Q. So where do you take issue with Dr. Addanki's analysis?

A. There's no -- there's no -- there's no actual evidence about prices in Dr. Addanki's report. All he does is observe what formularies do and describe it and -- and observe that there's churn in formulary placement among long-acting opioids. And then he concludes from that that they're competitive substitutes in an economic sense, and that conclusion is not justified by the observations.

You would have to do something like I did, which he didn't really criticize. He never even mentions it. You'd have to show that indeed there was effective price competition, that it was not just getting a little bit of a discount versus forcing them down to the competitive pricing level like a generic does.

When a generic enters, it charges -- when there's generic competition, the price is much lower. And the fact that that's true, the fact that they always put generics in category one and that the prices are a lot lower than the brand name drugs, is simply evidence that the formularies by themselves when there's nothing providing the brand name drugs in the market are not sufficient to drive the price to the competitive level.

Q. In giving that answer, you talked about when there's churn within formularies.

What did you mean by "churn"?

A. By "churn" it means that over time and among formularies are there differences in formulary placements for the same drug.

And Dr. Addanki has a lot of tables in his report that show that there is -- there are differences, all right, and he has -- you know, he has a number of different ways of making these comparisons. And there are differences in formulary placements among the drugs he considers through time and through different kinds of plans and et cetera.

Q. Do you believe that Dr. Addanki's analysis of formulary placement supports his product market conclusions?

A. No. It has nothing to do with whether there's competition or not. It doesn't prove anything and...

Q. So other than competition, what other reasons could there be for observing differences among drugs in formulary placement?

A. Well, let's start off with the very first important fact about it, that some of his tables compare six drugs and some of his tables compare seven.

The cases he looks at are exclusively cases where he had -- observes a year of data for which there's no generic competition, so he's already eliminating from consideration the single most important source of competition in the drug industry, whether it's whether formularies are involved or whether government contracting is involved or whether it's just sort of standard insurance that doesn't have a formulary, Medicare Part B or something like -- or D, rather.

So he -- the very first point is, the single most important source of competition isn't even in the analysis. All right.

The second fact is that in the six-drug category, three of them are versions of morphine, and in the seven-drug category, four of the drugs are

morphine.

Q. What's the significance of that?

A. Well, the -- two different versions of morphine are much more likely to be competitive substitutes than morphine to oxycodone or morphine to oxymorphone, and he doesn't distinguish between how much of his churning is competition among the various versions of morphine.

It strikes me -- I don't -- haven't done the analysis, but a perfectly plausible hypothesis that may turn out to be true is that brand name morphines don't have much market power because there are several of them. All right. And that's different -- that's a different conclusion than looking at a market in which there's only one brand name, which is the case of oxymorphone.

So the failure to take into account the difference between competition among drugs that have the same API versus competition between drugs that have different APIs is a fatal flaw. It means that the analysis is useless.

Q. But in his report, Dr. Addanki points to statements in Endo's documents that suggest that there is competition between Opana ER and other branded drugs, doesn't he?

A. Yes. And -- and he not -- he says it in two ways. But yes, he does.

Q. And in your opinion, does his statements about Endo's documents indicating competition between Opana ER and other drugs support his product market conclusions?

A. No.

Q. Well, why not?

A. Because one of the features of monopoly is you cannot charge an infinite price. You can only raise the price up to a level where the price gets so high that people actually start buying other things.

So the -- a monopolist price is always one in which you're competing with somebody, but you're competing where one firm is charging a monopoly price and maybe the other firms are charging competitive prices. That doesn't mean you're in a competitive market. It just means you've raised the price as high as you can.

This actually is a terminology in economics called the cellophane fallacy, which is that you do not evaluate who the competitors in an economic market are by observing substitution patterns at the current prices if one of those prices -- one or more of those prices could be a monopoly price.

What you have to do is go through this analysis to see if changes in characteristics in the market caused that price to go down, because if there are changes in the characteristics of a market that caused the price to go down, then indeed it wasn't competitive before that change occurred.

Q. You used the term "cellophane fallacy."

Is that from the venerable old Supreme Court case?

A. That is from the venerable and not very popular anymore Supreme Court case.

Q. Did you observe any other problems with Dr. Addanki's arguments about a firm's perceptions of their competitors, of who their competitors are?

A. Yes. I mean, again, it's the story I said before, that -- that he doesn't make the distinction between activities that indicate greater competition, which is competition on the price dimension, versus activities that lead to less competition, which has to do with promotional activities that develop brand name loyalty or emphasize differentiation.

Product differentiation -- in business schools you learn that a great competitive strategy to increase your profits is to figure out ways to differentiate your product from others. And a

promotional strategy that focuses on product differentiation, it's not anticompetitive in the legal sense, it's not a violation of the antitrust laws, but it's an activity that reduces the intensity of competition, it doesn't increase it.

Q. What is the significance of product differentiation to your analysis of the relevant product market in this case?

A. Product differentiation provides one of the explanations for why we wouldn't expect two different APIs in the long-acting opioid space to be close economic substitutes.

Q. Professor Noll, I'd now like to shift gears and --

JUDGE CHAPPELL: If you're shifting gears, we're going to take our lunch break.

MR. MEIER: Yes, Your Honor.

JUDGE CHAPPELL: We'll reconvene at 2:30.

We're in recess.

(Whereupon, at 1:24 p.m., a lunch recess was taken.)

A F T E R N O O N S E S S I O N

(2:30 p.m.)

JUDGE CHAPPELL: We're back on the record.

Next question.

BY MR. MEIER:

Q. Professor Noll, right before we took the lunch break, we were talking about market definition, and now I want to transition from market definition to talk about market power.

First, can you briefly tell us what market power is?

A. Market power is defined as the ability to sustain prices above the competitive level and/or to exclude competitors from the market.

Q. And how do economists measure market power?

A. There's a number of measures. There's -- there's the indirect method and the direct method. And that's -- those are the two categories.

Q. And did you apply both the indirect and the direct methods for measuring market power to the facts in this case?

A. Yes.

Q. And broadly speaking, what opinion did you reach?

A. That -- that both of these measures lead to the

conclusion that Endo enjoys substantial market power, monopoly power, in the market for Opana ER or that for oxymorphone ER.

Q. And was that at the time of the settlement?

A. That was true at the time of the settlement, and it remained true even after Impax entered.

Q. So let's talk about indirect measures of market power first.

How did you go about measuring market power indirectly in this case?

A. The -- the indirect method relies upon theoretical and empirical research in economics that finds that more concentrated markets have to have -- tend to have higher prices or higher price-cost margins.

And the -- this is embodied in the Merger Guidelines by setting thresholds for the -- something called the Hirschman-Herfindahl Index, which is the sum of the squares of the market shares of the firms. And if the HHI exceeds a certain threshold, then presumptively firms are assumed -- in that market are assumed to have market power, at least the large firms in it.

Q. In your opinion, is the market for oxymorphone ER highly concentrated?

A. Yes, it is.
Q. And was that the case at the time of the settlement?
A. It's been -- it's been true throughout the history of oxymorphone ER, right from the beginning to the present.
Q. As part of this indirect method of measuring market power, does barriers to entry matter?
A. Yes.
Q. Can you explain that?
A. Yes. That market power is indicated by a high concentration number only if barriers to entry are present, significant barriers to entry are present.
And the reason for it is that price is in excess of cost, you know, and the ability to earn excess profits attracts entry. And so unless there are substantial costs to entry that dissuade potential competitors from entering the market, then these high prices and high price-cost margins will induce entry.
So barriers to entry is the concept of somebody who wants to enter the market faces some sort of a substantial fixed cost of entry that would dissuade them from entering even if the market was highly profitable.
Q. Can you give us some examples of barriers to

entry?

A. Well, the -- one barrier is patents, that if somebody holds a valid, enforceable patent on a product, then at least you have to figure out a way to invent around the patent in order to enter the market. And perhaps the patent can be blocking. It can be prevent anybody from entering.

So that's the first.

The second is substantial economies of scale, where you -- a firm, in order to take advantage of the high margins, has to capture a very large fraction of sales in the market in order to be -- to be profitable, and so, you know, that's an unlikely prospect. It has to be an unlikely prospect.

A third reason is regulatory entry barriers where you are not allowed to enter the market instantaneously because you need to obtain regulatory approval and the process can be extensive and protracted.

Q. In your opinion, were there barriers to entry to the market for oxymorphone ER --

A. Yes.

Q. -- at the time of the settlement?

A. Yes, there were. There are still barriers to entry.

Q. And can you just describe some of the barriers to entry that you've observed in this case?

A. There's -- first of all, there's the patent barrier to entry, which is the firm's attempt to vigorously enforce their patent rights, and sometimes they win. And when they win, that keeps people out.

And the second is the whole Hatch-Waxman process is a regulatory barrier to entry because you have to wait a certain amount of time, depending on the facts, before you can even submit an Abbreviated New Drug Application to enter as a generic. And then once you've submitted it, as long as the brand name firm says that your product would infringe against them and files an infringement suit against you, that delays your entry for another 30 months at minimum.

So that's a -- those are both examples of why firms cannot respond instantaneously to the incentive to enter a market.

Q. In your opinion, are the barriers to entry that you observed in this case significant?

A. Of course they're significant.

I mean, the fact that you can't enter for at least six and a half years after the brand name drug goes on the market is a huge barrier to entry. It

means that there's a long period of time, which is more -- remember, when I talked about the SSNIP test, I talked about nontransitory increase in price, and we normally think of that as a year, maybe under the max conditions two years, as being the period of a successful price increase. And of course, we're talking much longer periods in the case of generic entry into brand name drug markets.

Q. You talked earlier about product differentiation and loyalty to products.

Can those also be barriers to entry?

A. Yes. And they are related to this issue of regulatory barriers to entry in that if you're entering with a different API, even if you believe that it's going to be such a close therapeutic and -- substitute and that you are intending to engage in price competition with the brand name drug that's already there, then indeed that -- that dimension of product differentiation that is the specific API in a brand name drug that creates this necessity to get another NDA based on another drug is a barrier to entry.

Q. When you say --

A. And the API is related to it of course because it's either a different formulation of the same API or

a new API that would be the basis for an NDA as opposed to a generic ANDA.

Q. You keep saying "NDA." Can you just tell us what that is?

A. A New Drug Application is an application to get -- to the FDA to introduce a drug that is new, that is, either the API or the formulation is different than a drug that's currently on the market.

And the -- the requirements for you to get approval of an NDA are much more rigorous than the requirements for an ANDA, which ANDA you just have to demonstrate it's the same drug. NDA you have to prove the safety and efficacy.

Q. Can an ANDA also be a barrier to entry?

A. Of course. Because you -- it takes time, and in a Paragraph IV case, it takes at least 30 months to get approval.

Q. You're talking about FDA approval?

A. Yes.

Q. What does high market concentration and the presence of entry barriers tell you about whether Endo enjoyed market power in the oxymorphone ER market?

A. It says that that's the -- that the indirect test is at a certain threshold, which is an HHI of roughly 2500, that further increases in concentration

are likely to cause firms that are in the market, the large firms that are in the market, to have greater market power.

And the concentration in the market for oxymorphone ER -- if you believe that's the relevant market, then the concentration ratios in that market have always been substantially in excess of 2500.

Q. Did you actually calculate HHIs in this case?

A. I calculated them a number of ways.

There's a number of possible ways to calculate it. You can calculate it based on quantities or calculate it based on revenues, or you can calculate it based on simply the number of firms in the market. And you get different numbers at different times depending on which one of those you use.

Q. And did you use all of those measures?

A. Yes.

Q. And what did you find about the concentration?

A. That it was never less than 3333 and it was usually more than that, substantially more than that.

Q. "3333" meaning 3,333?

A. Yes.

Q. Let's turn now from discussing indirect measures of market power to more direct measures.

How do economists directly measure market

power?

A. The -- the first way is actually examples of circumstances where a firm succeeded in excluding a competitor from the market.

And the second are measures of profits to show that the profits are supracompetitive.

Q. Did you try to directly measure market power in this case?

A. Yes.

Q. What information did you examine to do that?

A. Well, the -- they're different depending -- the exclusion part is examples of circumstances where Endo was able to exclude people from the market and that -- their enforcement of patent rights.

Q. Okay. And did you also look at direct measures of market power by looking to whether Endo --

A. Oh, I forgot. I didn't give you a complete answer to the last question.

The other is the 180-day exclusivity window from Impax. It can actually -- once it enters, it can exclude other generics from the market for -- except for authorized generics, for 180 days. That's part of the Hatch-Waxman process.

Q. As part of your work in this case did you also look to see whether Endo could profitably set prices

above a competitive level?

A. Yes, I did.

Q. And what did you find with respect to that?

A. The method that I used, since profitability is extremely difficult to measure, is the Lerner Index, which is the markup of price over some estimate of marginal cost.

Economic theory says that firms will base prices on marginal cost, and the markup of price over marginal cost will depend on the elasticity of demand. The more concentrated the market, the more market power the firm has, the less elastic the demand curve is, so all else equal, you expect firms with greater market power to have higher markups of price over marginal cost.

And the Lerner Index is simply the price minus marginal cost divided by the price, in other words, a fraction of price that is operating profit.

Q. Where did the Lerner Index come from?

A. It comes from an article by Abba Lerner that is very old, that was published decades ago, which was the, you know -- the title of it is An Index of Monopoly Power.

And it's been used extensively in economics right up to the present. There are articles published

in peer-reviewed journals that measure market power on the basis of the Lerner Index.

Q. Is the Lerner Index something that you would teach when you would teach antitrust economics courses?

A. Yes. And it's in all the textbooks. You know, this is not only what I would teach but everybody would teach.

Q. So maybe you could try to explain a little bit more in a little more detail, what can the Lerner Index tell you about market power?

A. It tells you essentially how inelastic or how price elastic the demand curve is if price equaled marginal cost. In a competitive industry, price is driven down to marginal cost. All right.

Now, that doesn't work in a product-differentiated market. Usually there are fixed entry costs that firms must recover to be viable in a product-differentiated market.

So people don't enter the market unless they expect that there's going to be sufficient market power available to them that they can recover their fixed costs.

So it's normal that the Lerner Index is not zero, it's not -- in a perfectly competitive

environment, the Lerner Index would be zero, price would equal marginal cost, so price minus marginal cost divided by price would be zero. Usually, as I cite in the report, when you study competitive products, you get Lerner Indexes between 20 and 50, .2 and .5.

Q. Does -- sorry.

So does a high Lerner Index necessarily mean that a firm has market power?

A. No, it doesn't necessarily mean that.

What it does mean, however, is that a firm has enough market power to sustain price above marginal cost. Whether they have monopoly power depends on other things, but it's always the case, if we -- if we take an industry where fixed costs are extremely high, no one enters that industry unless they expect that it's not going to be very competitive.

And there's nothing particularly wrong with observing a high Lerner Index in something like a software market where all the costs just about are fixed costs. That is to say, you gather around a bunch of people, you write several billion lines worth of code and you produce a program, and then you sell the program. There's almost no marginal cost and very high Lerner Index. No one would enter that market if they thought competition was so intense, it would drive

price down to marginal cost.

So the normal market outcome in an industry with high fixed costs and low marginal costs is for firms to have a lot of market power to be able to sustain a price that is substantially and above marginal cost. But whether there's monopoly profit or not you don't know, but you do know the firms do possess a lot of market power, that is to say, they do have a lot of ability to control price, because they wouldn't have entered unless they did.

Q. Is that a characteristic of pharmaceutical markets like the software market example you gave?

A. Exactly. Because the research and development costs and the NDA costs are high, and so firms normally don't enter unless they expect a period where they will enjoy substantial market power.

And what that means is, it must be -- they must be entering in a business where the existing products are not close competitive substitutes, they're not going to drive the price down to marginal cost, and where they don't expect that other people are going to come in very soon, because they expect -- they -- in order to enter in the first place, they have to anticipate there's going to be a number of years in which they can charge a price substantially in excess

of marginal cost.

Q. Did you calculate a Lerner Index for Endo for Opana ER in this case?

A. Well, I both calculated it and I observed calculations of it by people inside Endo.

Q. And what did those calculations show?

A. Depending on what you assume about what marginal costs are, because it's not absolutely clear, you get some number somewhere between .7 and .9 in every year since the product has been on the market.

Q. Is that a high Lerner Index?

A. Yes. As I said before, the articles in the peer-reviewed economics journals normally find Lerner Indexes that are half or less of that.

Q. You had indicated, in addition to looking at these price issues that you measured Lerner Index, that the fact that a company could exclude competition also tells you something about the presence of market power; correct?

A. Yes.

Q. And what does that tell you?

A. Well, it's the same story. That is, the mechanism that enables people to sustain high Lerner Indexes for a substantial period of time is the presence of the barriers to entry.

If the barriers to entry weren't there, nobody would ever enter the drug industry because the fixed costs of entry are too high. You would never pay hundreds of millions of dollars to do research and development and to get an NDA unless you expected that you would have several years of essentially monopoly, of a circumstance where you could exercise substantial market power.

Q. So to summarize, what do you conclude about Endo's market power in the relevant market based on both the indirect and direct measures of market power?

A. That from the period right after Opana ER was introduced until the end of the data that I have, which is sometime within the last year -- I forget the exact date -- there's always been -- it's always been the case Endo has enjoyed substantial market power, although it's less now than it was at its peak.

Q. Professor Noll, did you review Dr. Addanki's arguments relating to market power?

A. Yes.

Q. What opinions have you reached about Dr. Addanki's arguments about market power?

A. That it was confused.

Q. Can you elaborate a little more?

A. Yes. I mean, the problem is he -- he sort of

mushed together the issue of does a firm have market power with the issue of whether the market power is achieved by anticompetitive conduct.

And he seems to believe that only market power that's achieved by anticompetitive conduct is really market power or monopoly power, and that's just not true, that you can have something called a natural monopoly, where a firm has such great patent rights or there's such strong economies of scale that the market could never have anything more than one firm in it.

And that is a case in which the firm that is in the market has what we call superior efficiency; that is to say, it's so efficient because of economies of scale that no one could ever succeed in competing against it. That's monopoly power, but it's not anticompetitive, because it wasn't achieved by anticompetitive means.

And Dr. Addanki's expert report doesn't actually make the distinction. He just says that unless basically -- he defines market power in a way that it somehow has to be achieved by anticompetitive conduct. And then he actually cites a couple of other articles in the literature that make the same mistake, and so it's just not true that that's the right definition of "market power" in economics.

Q. You've already touched on this, but in general, what are the sources of market power that a firm may enjoy?

A. The first category consists of superior efficiency and foresight, which is another one of these Supreme Court terms, that what it really means is that one firm can produce at lower cost or produce a superior product that nobody else can successfully duplicate.

And that can be a source of market power because it's related to the barriers to entry point; that is, no one can enter against you successfully because you're so good at what you do. That may be backed up by a patent right or it may not, so a patent right may be a source of superior efficiency and foresight.

The other way to obtain market power is anticompetitive conduct. The easiest example and the least controversial example is -- would be merger to monopoly or collusion among firms in an industry that allowed them collectively to raise price.

Q. In your view, is there anything wrong with a firm achieving monopoly or market power as a result of a patent?

A. No.

Q. In your opinion, is there anything wrong with a company achieving market or monopoly power through superior foresight, skill and industry?

A. No.

Q. So what is your concern with Endo's market power in this case?

A. It's -- it's either achieving it or sustaining it through anticompetitive conduct. It has no efficiency component to it. It's engaging in conduct that reduces the intensity of competition that has no offsetting competitive benefit.

Q. And you've used the term "anticompetitive conduct" a number of times.

Can you just give me an industrial organization economist's understanding of what anticompetitive conduct is?

A. It is conduct that increases the market power of a firm in a market that has no efficiency benefit of the form of it was achieved because lower prices and they drove everybody else out of the market, it was achieved because they had intellectual property rights, it was achieved because they had a better quality of product.

In other words, it's -- there's -- there's none of this other component of there was something nice

that they did that is the reason for their market power.

Q. In your opinion, did Impax and Endo engage in anticompetitive conduct when they settled their patent litigation?

A. Yes.

Q. Can you elaborate on that a little bit?

A. The reason that it's anticompetitive is that it extended the period of Endo's monopoly in the market. It gave them insurance or protection against the possibility of generic entry for two and a half years.

Q. So, Professor Noll, let's move away from talking about market definition and market power to talk about your economic analysis of reverse payment agreements.

A. Yes.

Q. First, what is a reverse payment agreement?

A. A reverse payment agreement of a patent, a patent litigation, is an agreement in which on the -- the parties specify a date at which a competitor will be allowed to enter the market, and the incumbent firm whose patent has been allegedly infringed pays the infringer as part of the agreement; that is to say, the money goes in the wrong direction.

Normally we would expect that if somebody were going to enter a market that was protected by a patent, that they would pay royalties to the entity that owned the patent, that held the patent, in order to obtain the right to enter before the patent expires.

A reverse payment is one in which entry occurs before the expiration of the patent, but instead of the infringer paying a royalty to the patent holder, the patent holder pays the infringer.

Q. Where does the term "reverse payment" come from? Do you know?

A. It comes from observations of these results in the drug industry that have been written about first of all by economists and lawyers in antitrust economics and law and economics.

Q. I think you've touched on this already, but maybe go into it in just a little more detail.

What are the general features of a reverse payment agreement?

A. I think -- just a reverse payment agreement, I've already answered it. It's just that the payment goes in the wrong direction, and there's an entry date agreed upon that is before the expiration of the patent.

Q. Okay.

A. It has no other features besides that, just to characterize it.

Q. In your report, have you included a chart that illustrates the parties', that is to say, the brand and the generic companies' incentives to enter into a reverse payment agreement?

A. Yes, I have prepared a chart. But that's a chart about when reverse payments can be anticompetitive.

Q. Okay. Ms. Durand, could you call up Appendix C from Professor Noll's report.

Professor Noll, is that the chart that illustrates --

A. Yes.

Q. -- parties' incentives?

A. It is.

Q. Can you give a brief explanation of what this chart is intended to show?

A. What this chart shows is why both a generic firm and a brand name firm have an incentive to engage in an anticompetitive reverse payment agreement as opposed to just any reverse payment agreement.

And it -- the three circles essentially represent all of the potential welfare to be generated from the market and on -- on the supply side, the drug

firm side, and what happens to that under three circumstances.

Q. So taking the pie chart to the far left, the fully red chart, what does that show?

A. That shows that prior to a generic entering the market, the brand name firm has this big excess of price over marginal cost, which means it has a big positive operating profit; that is to say, a substantial fraction, like 80 or 90 percent, of the revenues from selling the drug are operating profit, which is the result from the Lerner Index analysis.

So prior to any generic entry, there's this big monopoly profit that is arising -- operating profit that is arising from the monopoly power from having only one firm in the market.

Q. So looking then at the pie in the middle, what does that show?

A. This is what the picture looks like after generic entry.

The key -- the key point here is that even if there's only two firms in an industry, the price competition, as weak as it is between only two firms, still produces a total profit, total operating profit for the industry, that's less than monopoly profit. And that is divided between the part that's still

red-orange, which is kept by the brand name firm, the part that's yellow, which is what goes to the generic, and then the green part is captured by consumers in the form of lower prices.

And so what happens when generic firms enter, total profits go down and consumer welfare from the drug go up.

Q. And then there's the last pie chart on the far right.

What does that pie chart show?

A. An anticompetitive reverse payment settlement of a patent infringement case is one which restores the first picture, but the reverse payment is a mechanism for dividing that profit between the brand name firm and the generic firm, so what happens is the generic firm agrees to a -- an entry date that is sometime in the future and in return for that gets paid a fraction of the monopoly profit that accrues between the date of the settlement and the date the generic firm entries -- enters.

And so you'll notice that during that period before generic entry, before we can get to the middle circle, we have to experience some period of the third circle, when the generic firm is simply being paid to stay off the market and they're being paid a fraction

of the monopoly profit.

Q. So what happened to the consumer savings in the --

A. It goes into the -- the profits, the operating profits. Most of it goes to the operating profit of the brand name firm, but a big hunk of it goes to the operating profit of the generic firm.

Q. Ms. Durand, you can take that down now. Thank you.

In your opinion, is a reverse payment agreement akin to a branded pharmaceutical company buying an insurance policy?

A. I'm sorry. I didn't hear you. Can you speak up?

Q. In your opinion, is a reverse payment agreement akin to a branded pharmaceutical company buying an insurance policy?

A. Yes.

Q. How?

A. It's -- what they're doing is they -- they face uncertain prospects that a generic firm may enter as soon as it gets approval from the FDA for its ANDA, which usually comes roughly at the end of the 30-day (sic) stay in the Hatch-Waxman Act. And then there's -- then it may win the patent infringement suit

and enter then.

There's a whole bunch of times it might enter. And what happens is that the generic firm agrees that it will not enter on any of those dates prior to the date in the settlement in return for getting paid.

And that's essentially an insurance policy. The payment to the generic is an insurance payment by the brand name against the risk of competition occurring prior to the date that's agreed in the settlement.

Q. In giving that answer a moment ago -- I just checked this on the realtime -- you said "the 30-day stay."

Did you mean 30- --

A. 30-month. I'm sorry. I'm sorry. Thank you. I mean 30-month.

Q. Okay. Has any economic research been conducted on the settlement of patent infringement litigation?

A. Oh, yes. There's a lot of economics research on it.

Q. In forming your opinions in this case, did you conduct a review of the economic literature on reverse payment cases?

A. Yes. That's in my expert report.

Q. What are some of the main conclusions from the economic literature concerning the brand company's incentives to enter into reverse payment agreements?

A. The conclusions are basically the same as the ones I just gave you, that -- that because of the -- the -- the structure of the Hatch-Waxman Act, which creates this 180-day exclusivity period for the generic first to file, that that firm has the ability to block all generic entry, and so it has a really valuable asset that it can sell to the brand name firm, which is the ability to block further generic entry, and that the -- that that incentive structure that's created by Hatch-Waxman is the principal reason we observe reverse payment settlements of patent infringement cases in the drug industry.

Q. When you were helping the FDA with the precursor to the Hatch-Waxman Act, is that something you had anticipated?

A. No. I -- it completely -- I completely missed it. I plead guilty. One of the worst pieces of policy advice I ever gave.

Q. What else does the economics literature teach about the incentives of parties to enter into reverse payment agreements?

A. Well, the -- the economics literature itself

contains further -- further development of the concept of how do you detect when a reverse payment settlement falls into the anticompetitive category. And that's the -- that is the literature that forms the basis for the theoretical model that I put in my expert report, which actually does develop some more implications from that model than you can find in the literature, but it's still the same basic model that's in the literature.

Q. I'm going to ask you a little bit more about your mathematical model in a moment, but before I do, I want to finish talking about the economic literature.

A. Sure.

Q. Are there any other conclusions from the economic literature that you're aware of on the brand's incentives to settle infringement litigation?

A. Well, the observations that appear in the published literature are that brand name firms have a strong incentive to defend patents even if they're weak. And the reason they do is, first of all, the act of defending them right off the bat gets you the 30-month delay of generic entry, so it's like getting an extra 30 months of value out of a patent.

Even if you know that the patent is not -- is

not enforceable, it's invalid or it's not infringed, even if you know that, you still have an incentive to file an infringement suit.

And then secondly, once you -- that 30-day period has expired, it's -- it's still in your interest to get the brand -- the generic firm not to enter by paying it.

And so those -- those results are in the economic literature on reverse payment settlements.

Q. A moment ago you just said "30-day" again. You meant 30-month?

A. Oh, I'm sorry. 30-month. I thought I said 30-month. I thought really hard about that.

Q. What does the economics literature teach about the generic's incentives to enter into a reverse payment settlement?

A. The generic firm always has substantially less profit than the brand name firm if it enters, and it has less profit for two reasons.

The first reason is it has less than a hundred percent of the market as long as the brand name firm stays in. And indeed, after 180 days, it may have to share even the generic part of the market with other generic firms, so its sales volume is going to be substantially less than a brand name firm.

Secondly, the way the generic firm obtains sales is through price competition. It's through charging substantially lower prices. And indeed, the research on generic entry finds that usually in the range of a few months after generic entry occurs you get price reductions of 30 to 50 percent, and then after multiple generics enter after 180 days, you get reductions in price up to 85-90 percent.

So what that means is that not only does the generic firm, even the first-to-file firm have a relatively small market share after the 180-day period, they also have a much lower price.

Now, what that does is say it doesn't take very much to buy off the generic first-to-file firm because the potential profits in -- for a generic firm to enter a market are far less than the monopoly profits of the brand name firm if it retains the monopoly.

So that means the -- the -- the price -- the minimum price that a generic firm would be willing to accept to delay its entry is much lower than the maximum price that the brand name firm will be willing to pay to preserve its entry, and that -- because that's normally true, it's not always true, because it's normally true, there usually is a potential at

least -- if anticompetitive reverse payment settlements are allowed, then indeed there's almost always a potential for a deal between the brand name firm and the generic firm where the brand name firm pays the generic firm more than it expected to earn by being in the market and in return stays off the market until near the end of the patent for the brand name firm.

Q. In your expert report on pages 101 to 143, you present a mathematical model of reverse payment settlements; correct?

A. That's correct.

Q. And why do economists construct mathematical models?

A. The reason you construct a mathematical model is because the world is complex, and it's -- it's -- there's lots and lots of moving parts, lots of variables and lots of equations. You can -- you can get insights from the mathematical model that you can't get from just trying to think through it on your own, and that's the purpose of mathematical models, is to generate insights you wouldn't otherwise have.

And a lot of the results are counterintuitive. They're things that normal people, even normal economists, if they're not doing the math, they're not

building a model, would not think of.

Q. Is mathematical modeling something you taught as a professor at Stanford?

A. Oh, yes. I mean, you can't teach economics without using mathematics. That's been true ever since I was a graduate student.

Q. That's back to the '60s?

A. Yes.

Remember, my undergraduate degree is in mathematics. And I spent part of my time as a graduate student teaching the other graduate students mathematics that hadn't had it in a sufficient quantity to do economics.

Q. So why did you construct a mathematical model in this case?

A. To see if it -- what I could learn about the nature of the market and in particular the bargaining relationship between the brand name and the generic firm, you know, what insights could I get that I wouldn't otherwise get that would be counterintuitive.

Q. Did you just make up this mathematical model for your work in this case?

A. No. As I said before, it's basically the model that economists have used to -- it starts with a paper by Joe Farrell and Carl Shapiro, who used to be

the chief economists at the FTC and the Department of Justice, called Probabilistic Patents, which is, the way you think about patents is that whether they're really a property right or not is probabilistic. They may be good and they may be bad, and you don't know that until you litigate them.

And then I -- then the people who have studied reverse payment take that basic idea and apply it to the context of the drug industry. And I took that model and then just did more things with it in the report.

Q. So your model is derived from published peer-reviewed economic articles?

A. Yes. The basic structure of the model is exactly the same as appears in several other articles.

Q. Does your mathematical model provide any useful insights on the likely competitive effects of the reverse payment agreements?

A. Yes.

Q. And does it provide any useful insights on the likely competitive effects of the reverse payment agreement in this case?

A. Yes.

Q. Let's talk a little bit about some of those insights.

What insight does your mathematical model reveal about the incentives of brand firms to settle?

A. Well, that part of the model is the same results as I just described. It says that there is this big incentive, but it has one additional result, which is that given that any reverse payment settlement is feasible, that is to say, there is at least one circumstance in which the brand name firm and the generic firm could agree to an anticompetitive reverse payment settlement, if any such agreement is feasible, then the incentives of both parties are to extend the duration of the agreement, to delay the entry date as far as possible, that is to say that the profit-maximizing bargain for the brand name and the generic firm is to delay entry as long as possible and -- now, the thing that gets in the way, of course, is the 180-day exclusivity period because that's really valuable to the brand name firm, so -- and then in addition to that, if a brand name firm sold its exclusivity period entirely, so it never entered before the expiration of the patent, that would be a red flag for antitrust enforcement.

So, you know, you would never observe a reverse payment settlement that actually allowed entry the date of patent expiry, so you -- but you observe

them that are close to that, and that's the result in this case.

Q. A moment ago, in giving that answer, you said the 180-day period is very valuable to the brand company.

A. Yes.

Q. Did you mean to the generic company?

A. The generic. The 180-day exclusivity period for the generic company, yes.

Q. Thank you.

Does a brand's willingness to litigate the patent reveal anything about the strength of its patent case under the mathematical model?

A. No. And that's -- that's the point I made earlier before. But I'll make a stronger statement now because the model says something stronger than that.

The earlier statement I made was that a brand name firm is willing to defend even a really weak patent because of these two opportunities, the 30-month delay and then the possibility of a reverse payment settlement that blocks entry for the first filer.

But then there's an additional result, which is the actual incentive to engage in reverse payment settlements does not depend on the probability that

the brand name firm is going to win the patent infringement suit. As long as that probability is substantially less than one, in other words, as long as there's any chance at all they could lose it, they have an incentive to engage in a reverse payment settlement of the patent dispute. And it doesn't depend on how big that probability is.

Q. What does your mathematical model reveal about the incentives of the generic firm to settle if it expects to win the patent litigation?

A. If they expect to win the patent infringement case, there's no reason for them to allow entry before the expiration of the patent. They can always get a date at the expiration date.

The only incentive they have is that they can save some litigation costs if they let the generic in earlier, but those litigation costs are tiny compared to the profitability of most brand name drugs, so that would not be a sufficient incentive to settle an antitrust case if you were certain or virtually certain to win the antitrust case. You would simply wait it out and let entry occur when the patent system allowed it.

Q. If a generic firm would expect to win the patent infringement case, would it settle without a

large reverse payment?

A. No. It would never -- the generic -- the generic firm, if it's certain to lose the antitrust suit, again wouldn't pay the cost of litigating it. It would probably fold. But if it got a settlement, it would have to be something where the entry date was really close to the patent expiration date, because it has no bargaining power over the brand name firm in that case.

Q. Okay. So my question was actually whether, if the generic firm expects to win --

A. Oh, I'm sorry.

Q. -- the patent --

A. I misheard you.

(Counsel and witness speaking at the same time and cautioned by court reporter.)

BY MR. MEIER:

Q. Let me start the question over.

A. Yeah.

Q. What does your mathematical model reveal about the incentives of a generic firm to settle if it expects to win the patent litigation?

A. If it expects to win the patent litigation, then it's going to want to enter at or soon after the date of the -- at or very soon after the date that its

ANDA is approved by the FDA. It's not going to enter later than that unless it's paid a great deal of money, because it has to sacrifice the certainty of earning generic profits after entry.

Now, that is a beautiful example, incidentally, of a circumstance where a reverse payment can be extremely harmful to consumers, because the brand name firm still has the incentive to pay a lot of money to the generic firm to delay entry, but with certainty or near certainty, without that settlement, entry would occur much sooner and consumers would derive that big green benefit that was in my picture.

Q. So now I'm going to reverse it and ask, what does your mathematical model reveal about the incentives of a generic firm to settle if it expects to lose the patent litigation?

A. If it expects to lose the patent litigation, then that's the point I've already -- that's the question I answered that you didn't ask. It has no bargaining strength, and it knows it has no bargaining strength, so it -- if it gets anything other than the date of patent expiry out of the settlement, that's a benefit. And it doesn't need to be paid to stay off the market until at or near the date of expiration of

the patent.

Q. What does your mathematical model reveal about the relationship between the payments and the patent?

A. The relationship is that the weaker the patent, the bigger the payment will be. But it doesn't affect -- in the absence of antitrust, it doesn't expect (sic) the profit-maximizing solution to the bargaining game, which is always delay entry as long as you can get away with, because you can -- the brand name firm always has more profits than the generic firm, so there's always an incentive, regardless of that probability of the patent's validity, to settle as late -- an entry date as late as possible.

Q. Does your mathematical model depend on knowing the merits of the underlying patent litigation?

A. No. That's the -- that's the -- the great insight from the economic theory of reverse payment settlements is that the -- the -- you don't need to know anything about the viability of the patent to know that a reverse payment settlement is anticompetitive. Instead, you have to know other things that we haven't talked about yet.

Q. Well, why is that true?

A. Because what the probability does is tell you how they're going to share the profits. And it

doesn't tell you anything about whether they have an incentive to settle.

And the main incentive to settle here is not avoided litigation costs, which in most civil disputes the main reason you settle is because you can avoid litigation costs that are significant. In this case, in the case of patent infringement cases, that incentive is really small in most circumstances compared to the profitability of brand name drugs that have a monopoly position, so that the dominant factor in driving settlements in patent infringement cases in the drug industry is just completely different than it is in other patent infringement areas or in other kinds of civil litigation.

In most kinds of civil litigation, settlement is a good thing because it saves litigation costs. In this case, the saved litigation costs are tiny compared to the profitability of the drug companies and the amount of consumer welfare at stake in the settlement.

Q. Are there any published papers in the economics literature that argue that reverse payment agreements can be procompetitive?

A. Yes.

Q. And what is your opinion of these arguments?

A. Well, there's a -- again, the -- there's a -- the papers themselves are correct in what they state, but they're not statements about whether a reverse payment settlement will be or is procompetitive. They're statements about -- there's an existence there -- they're -- they're a statement that is -- there are circumstances in which the only way you can get a procompetitive reverse payment settlement -- a procompetitive settlement -- excuse me -- that is a settlement that avoids litigation costs and occurs on the date that entry would otherwise be expected to occur anyway, all right, that there are circumstances where you could only get that with a reverse payment.

What they do not say is that will actually be the outcome. All right. They just say it's -- that such a settlement in principle could happen or it could -- you know, that it could be the case you can't achieve a settlement at -- at approximately the expected date of generic entry without a reverse payment.

Q. As part of your work in this case, have you read the Supreme Court's Actavis decision?

A. Yes.

Q. Why?

A. First of all, as I said earlier, in teaching

antitrust and regulation, I need to teach cases. And the whole history of Hatch-Waxman litigation is really interesting. It's one of the more important areas of antitrust in the last 30 or 40 years. It's right up there in the hall of fame of antitrust issues, so it would be impossible to teach an antitrust course of -- a good, high-quality antitrust course and ignore it.

So that's the first reason.

The second reason is that we economists, just like you lawyers, like reading Supreme Court decisions, but in our case, the reason we read them is to see if they got the economics right or to interpret what the economics implications of the decisions are.

And indeed, a lot of people have written articles -- a very large number of people have written articles in the last couple of years about what is the proper economic interpretation of the Actavis decision.

Q. Does the economic analysis you did in this case address the economic issues the Supreme Court identified as relevant to determining the circumstances under which a reverse payment agreement can harm competition?

JUDGE CHAPPELL: His opinion on what the Supreme Court has to say legally in Actavis is not

relevant in this case. Rephrase your question.

MR. MEIER: Your Honor, if I may --

JUDGE CHAPPELL: Not relevant, not acceptable and won't be heard.

MR. MEIER: I did not ask --

JUDGE CHAPPELL: Then rephrase.

MR. MEIER: My question was about the economic issues the Supreme Court identified. I'll try the question again.

BY MR. MEIER:

Q. Does your economic analysis address the economic issues the Supreme Court identified as relevant to determining the circumstances under which a reverse payment agreement can harm competition?

A. Yes. It does -- it addresses exactly the same issues. My -- the conditions I conclude are the conditions to identify an anticompetitive reverse payment settlement. The economic conditions are exactly the same issues.

Q. So let's now turn to your application of these economic analyses to the facts of the Impax-Endo agreement.

In your opinion, what are the key issues to consider in applying economic analysis to the facts in this case?

A. The key issues are: one, were there plausible possible entry dates before the date that's in the settlement agreement; number two, was there a reverse payment; number three, was that reverse payment large and unjustified, where "large" means bigger than the saved costs of litigation and "unjustified" means it was not a transaction involving the exchange of some other services or assets or products that were obtained by the brand name firm from payments to the generic firm.

Q. All right. We're going to break that down a little more by looking at the market for Opana ER before the settlement agreement.

What did the market for Opana ER look like before the settlement agreement with Impax?

A. At that time there was nobody in it except Endo, that neither Impax nor Actavis had entered, so they had complete monopoly.

Q. Was Endo, in your opinion, concerned about the possibility of Impax' generic entry?

A. Yes. The discovery information, the discovery documents show that they not only expressed concern, but they actually did financial modeling of what the effect on them would be from various entry dates of the generics of Impax in particular, starting with an

entry date soon after the FDA approved the NDA through entry dates that would be a little bit more than a year later when the court of appeals decision would have been decided. You know, the intermediate there is the district court patent infringement decision and then there's the court of appeals.

So they looked at scenarios where Impax might enter in June of 2010 all the way to Impax might enter at the end of the summer of 2011.

Q. In giving that answer a moment ago, you said "starting with an entry date soon after the" --

A. I'm sorry. I'm not hearing you. I'm sorry.

Q. In giving that answer a moment ago, you said that "starting with an entry date soon after the FDA approved the NDA." Did you mean --

A. ANDA.

Q. -- ANDA?

A. I thought I said ANDA. I may have slurred it together. I'm sorry. I apologize.

Q. That's all right. I just wanted to make sure the record is clear.

A. Okay.

Q. Based on your review of the discovery materials in this case, what were Endo's plans for dealing with its concern about Impax' generic entry?

A. The -- the -- the discovery documents show two different strategies. All right. The first strategy --

JUDGE CHAPPELL: Are you asking him for an opinion, because he's not a fact witness? Let's make that very clear. He's talking about this like he's a fact witness, like he was there, so let's be real clear for the record these are opinions.

MR. MEIER: Absolutely, Your Honor.

BY MR. MEIER:

Q. Based on your review of the discovery materials, in your opinion, what were Endo's plans for dealing with its concerns about Impax' generic entry?

A. They had two contingency plans.

The first was to develop and introduce a reformulated version of Opana ER that would mitigate to some significant effect the impact of generic entry.

And the second was, if they failed to introduce the reformulated product, to introduce an authorized generic, which would save them roughly one-third of the profit loss that they would experience from the entry of Impax.

Q. In your opinion, was the timing important to Endo's plans for launching its reformulated Opana ER product?

A. Exactly -- it was extremely important, because it would determine which of those two strategies would have to be implemented, because the reformulated product had not yet been fully developed and approved by the FDA, and that -- so the date at which they could enter was uncertain.

The longer they delayed entry, the more likely it was that they were going to have a reformulated product on the market and thereby reduce the impact of generic entry.

Q. Professor Noll, the FTC and Impax' counsel have entered certain factual stipulations in this case, and Judge Chappell has admitted those stipulations as Joint Exhibit Number 1.

And stipulation number 19 states as follows:

"On June 8, 2010, Impax and Endo entered into the Settlement and License Agreement."

So you can take that fact as a given.

A. Okay.

Q. Do you understand that?

A. Yes.

Q. In your opinion, what did Impax get from its June 8, 2010 settlement agreement with Endo?

A. It got three things -- well, it got four things actually.

It got, first of all, the guarantee of an entry date of -- in January of 2013 instead of facing the same uncertainty that Endo faced about when generics would actually enter and who would win various patent infringement cases, et cetera, et cetera. All the stuff involving patent litigation, that uncertainty, is resolved.

Secondly, it got a $10 million payment for co-development and co-promotion of a drug that was under development.

Third, it got the guarantee that Endo would not enter with an authorized generic during the 180-day exclusivity period for Impax, which is relevant if Impax enters before the reformulated product is on the market.

And last, it got this formulaic-determined payment. If the reformulated product did enter and/or for some other reason the market for the original formulation of Opana ER substantially deteriorated, fell by more than half, they would get a payment to compensate them for the loss of sales below what would have occurred had the original version of Opana ER retained 50 percent of its peak sales between the signing of the agreement and the date of entry of the generic version that Impax was going to produce.

Q. So I want to talk a little bit more about --
JUDGE CHAPPELL: Hold on a second.
Are you reading from something there?
THE WITNESS: No.
JUDGE CHAPPELL: All right. I just saw you looking down.
THE WITNESS: You just saw me looking to try to remember things. That's all. I'm not reading anything.
JUDGE CHAPPELL: For the record, I'm just trying to figure out, did you just have the witness give us his opinion on what the contract gave to respondent? Is that what I just heard?
MR. MEIER: I asked -- yes, I did essentially ask that.
JUDGE CHAPPELL: Do we need expert opinion on what the contract gives to one side or the other? We can read the contract.
MR. MEIER: That's right. But I wanted his understanding. It's a setup. It's basically a foundation for me to go and now explore each of those elements, Your Honor. I just wanted to recite what the elements were, and now we're going to go march through them and get his opinions on the value of those.

BY MR. MEIER:

Q. Taking the no-authorized-generic provision first, in your opinion, was the no-authorized-generic provision valuable to Impax?

A. Yes. It was -- it was extremely valuable if -- under the condition that you thought you were going to enter competing against the original formulation of Opana ER, so it's a conditional value, but it's a value.

Q. Are you opining that Endo would have launched an authorized generic in competition with Impax if it had not introduced reformulated Opana ER before generic oxymorphone entered?

A. No. I'm not making a prediction about what Endo would do, no.

Q. Did you see anything in Endo's discovery materials that shed any light on that issue?

A. Yes.

Q. And is that relevant to your opinions in this case?

A. Yes.

Q. And what is that that you saw?

A. That in the case where the reformulated product was not introduced, then Endo had made plans to enter with an authorized generic. And its own

financial statement is consistent with the results in the economics research literature, which is that a substantial fraction of the profit impact of generic entry can be avoided by entering with an authorized generic at the same time the generic enters.

So what I conclude from that is that, A, Endo had the same incentives most all brand name drug companies do, which is to enter with an authorized generic; and number two, they knew that, and they had made plans to do it. It doesn't mean they would actually do it, but it means it was credible and plausible that they would do it.

Q. In your opinion, did the no-authorized-generic provision have value to Impax even if there was uncertainty about whether Endo would have launched an authorized generic?

A. Right. Of course. Because you're trading the possibility for the certainty of no entry, and this was -- based on the record of other circumstances, similar circumstances, authorized generics are extremely common, so this was a valuable property to Impax to be guaranteed that if it did enter in competition against the original formulation of Opana ER that it in fact would not face generic competition from the brand name firm.

But you -- typically the authorized generic gets more than half of the generic market during that 180-day exclusive period, so this is a very big deal for a generic company to keep the authorized generic off the market.

Q. In your opinion, was the Endo credit valuable to Impax?

A. Yes.

Q. Based on your review of the discovery materials, what, in your opinion, did those materials reveal about the purpose of the Endo credit?

A. The purpose of the Endo credit was to protect Impax against a consequence of agreeing to a late -- this late entry date relative to all the possible entry dates that were available to them, that -- that if it should be the case that they waited so long that the market for the original formulation of Opana ER had disappeared, they would be compensated for it.

Q. Did you see any discovery materials showing whether Endo calculated the potential payment to Impax under the final version of the settlement agreement?

A. Yes. They did make some calculations about what that value was.

Q. What, in your opinion, do these calculations show about what Endo thought at the time of the

June 2010 settlement?

A. That -- that the -- the -- if -- if the reformulated product were introduced substantially before January of 2013 that they would owe a substantial amount of money.

But of course, how much they would owe is uncertain because you don't know what the peak sales of the original formulation are going to be. And the reason you don't know that is partly because you don't know for certain what the market is going to -- how it's going to grow. But more importantly, you don't know when you're going to be able to enter with your reformulated product.

And the longer the reformulated product is delayed, the bigger the peak sales date is going to be for the original formulation of Opana ER, and so their liability kept growing as the date of entry of the reformulated product get pushed -- kept getting pushed into the future.

Q. You used the term "peak sales" a couple times in that answer.

Is peak -- is your understanding that peak sales is part of the formula for calculating the Endo credit?

A. Yeah. The Endo credit is based on 50 percent

of peak sales in the -- in the period from June of 2010 until January of 2013.

The calculation is, if sales fall below 50 percent of peak sales, then there's going to be a compensation paid to Impax based upon how far below 50 percent they went.

Q. What conclusions have you reached about the drift terms in the settlement agreement?

A. That the value of the -- these provisions we've been discussing was -- to -- to Endo were large and unjustified, that is, unexplained by exchange of other goods, services and assets, and so as a consequence were anticompetitive.

Q. Do you have an opinion on the value of the development and co-promotion agreement to Impax?

A. No.

I just know what the magnitude was. It was $10 million. But how much that was actually worth in terms of an asset transaction, that wasn't part of my responsibility.

Q. Let's turn now to the January 1, 20- -- let's turn now to the January 1, 2013 entry term in the settlement agreement.

In your opinion, what was the effect of the January 2013 entry term?

A. It eliminated from possibility any of the entry dates that could have occurred between January 8 and -- 2010 and -- excuse me -- June 8, 2010 and January 1, 2013. Those are now off the table as possibilities.

And secondly, that means that not only would Impax not enter but also that whatever the consumer benefits were from having earlier generic entry occur would never happen. Instead of being a possibility, they became a nullity. They couldn't happen.

Q. In your opinion, was the January 2013 entry term valuable to Endo?

A. It was extremely valuable to Endo because it guaranteed that they would not lose their -- that big red-orange ball for that two and a half years between the date of the settlement until January 1, 2013, that that big ball would continue to flow, minus the liability they had to Impax from the settlement.

Q. "That big red-orange ball" is referring back to the pie charts we looked at earlier?

A. Exactly.

Q. Based on your review of the discovery materials in this case, can you tell the court whether you actually identified other possible earlier entry dates for Impax' generic entry?

A. Yes.

Q. And what were some of those other possible entry dates?

A. These were the same ones that are analyzed in the -- in the various discovery documents, that the big -- the big-ticket dates are the date of the approval of the ANDA, which is June 10, and then the next big date is when the district court would have decided the patent infringement case because -- and then the -- which is probably sometime in the late summer of 2010.

And then the next big date is when the court of appeals decision would have come down reviewing the district court decision, which was sometime in the second half of 2011. We can't be real precise about when it would be, and there's some quibbling among the experts about when it would be, but it's sometime in that period.

And then, you know, there could be a later date if what the district -- if the appeals court decision was not definitive, if it said, oh, you got to redo the following elements, some sort of remand.

So there's various possible dates. Each date has a different profile in terms of how risky it is for Impax to enter on that date, and so the -- they

represent important changes in the information that Impax would have that would -- might affect its decision whether to enter.

Q. When you said "June 10" in that last answer, did you mean June 10 of 2010?

A. I thought that's what I said. What did I say?

Q. It just says "June 10." And I think you meant June 2010.

A. I said June -- I thought I said June -- I started to say January, and then I thought I corrected it to June 10.

Q. Are you opining in this case that Impax would have launched generic Opana ER at risk?

A. No. I'm -- what I'm opining on is that these were possibilities that were considered by both firms as sufficiently plausible that they actually did financial planning on the basis of those events actually occurring.

Q. Do you have an opinion in this case as to whether the payments from Endo to Impax in the form of the no-AG agreement, the Endo credit and the co-promotion and development deal were large?

A. Yes.

Q. What is that opinion?

A. That the combined value of all of these things

is substantially in excess of the costs of completing the patent infringement litigation.

Remember that this -- when the settlement was made, they were already into the trial, so most of the costs of the litigation had already been spent, so the amount they had to save was relatively small. And so it doesn't take much of a value for these things to exceed saved litigation costs.

Q. Is saved litigation cost a benchmark you used to determine whether the payment was large?

A. The economic model in my first expert report holds out the sum of the saved litigation costs as a benchmark for whether a reverse payment settlement is large.

And if the -- because those saved litigation costs represent the resources that society would have to devote to resolving the patent case. And if you could save those, those are resources that otherwise wouldn't have to be used.

And the amount of the reverse payment is a lower bound on the loss of consumer welfare arising from the reverse payment settlement, so if the reverse payment settlement is less than the saved litigation costs, then you have a prima facie case that the cost to consumers of the settlement are less than the saved

litigation costs or at least comparable to the saved litigation costs, so my conclusion is those wouldn't be regarded as anticompetitive. As an economist, I wouldn't regard them as anticompetitive.

But if the reverse payment was in excess of the summation of the saved litigation costs, then the costs imposed on consumers would in fact be greater than the resources saved in completing litigation, and that would make the settlement anticompetitive.

Q. Why?

JUDGE CHAPPELL: Hang on a second.

I just heard you refer to your first expert report and I've heard you refer earlier at least once to something you call your original expert report.

Just so the record is clear, how many expert reports do you have in this case?

THE WITNESS: There are two in this -- I have -- I have an original -- oh, oh, wait a minute. You're right. Corrected -- there's the original liability report which is full of typos, then there's the corrected report, and then there's the rebuttal report. By "the first original report" I mean the corrected one and by "the second report" I mean the rebuttal report.

JUDGE CHAPPELL: I don't think I've heard you

refer to a second one, but I've heard you say "the first" and "original."

THE WITNESS: Yeah. The first one will actually be the second because it would be the corrected report.

JUDGE CHAPPELL: Which report is a part of JX that's submitted in this case?

MR. MEIER: We submitted both his original or what he called the first report and the rebuttal report, and they're both in. The first report --

JUDGE CHAPPELL: The one he calls corrected.

MR. MEIER: -- is the corrected version. It's a -- as Professor Noll explained, there was a lot of typos, and we cleaned that up and resubmitted it as a corrected report. That's the report that Professor Noll was deposed on at his deposition, the corrected report, and the rebuttal report.

BY MR. MEIER:

Q. Why as a matter of economics is saved litigation costs an appropriate benchmark to use in determining whether a payment is large?

A. Because litigation costs are a real cost not only to the companies but to society. Where lawyers see income economists see costs, and if you can save those costs, that's a good thing.

Q. Based on your review of the discovery materials and in your opinion, what were Endo's and Impax' saved litigation costs?

A. The -- on the order of $5 million, something like that.

Q. That's for both companies together?

A. Both companies together.

Q. And that would have been the cost of continuing the litigation rather than settling it?

A. That would have been continuing the trial to conclusion and then doing the appeal.

Q. In your opinion, how do the saved litigation costs in this case compare to the payments in this case?

A. Well, obviously the payments that were actually made are huge compared to the saved litigation costs, but that's not the right comparison. The right comparison is what is the full range of the costs that might have come about.

And I've also calculated what those payments could have been under various scenarios, and no matter how I do it, it -- the saved litigation costs are always smaller than the benefits to Endo and the payments to Impax of the settlement.

Q. Let's talk a little bit about some of the

other benchmarks you used beyond the saved litigation costs.

JUDGE CHAPPELL: I have a quick question.

You predict -- you projected or predicted what litigation would cost; is that correct?

THE WITNESS: Yes.

JUDGE CHAPPELL: What did you refer to for hourly rates?

THE WITNESS: The -- there's two sources of information.

The first is the annual study that's done on what patent infringement litigation costs cost, and I took the number for the maximum value of litigation, patent infringement litigation.

And the second was the discovery information from the parties about how much they had already spent and expected to spend on litigation.

JUDGE CHAPPELL: Did you look at any recent numbers, for example, what attorneys who specialize in patent litigation charge per hour in trial?

THE WITNESS: I haven't looked at the per-hour charges, but I've looked at them all -- outside --

JUDGE CHAPPELL: Those hours matter.

THE WITNESS: Huh?

JUDGE CHAPPELL: Those hours matter.

THE WITNESS: Oh, of course they matter. They go into the survey results about the total costs and they go into data of how much they actually paid.

The financial records of the companies show how much they had spent on litigation up to the point at which the trial ended, and then they have projections of how much -- Endo has projections of how much they expected to spend afterwards, so -- and then the surveys that are done are basically of this. They're not about, you know, what's the hourly rate or billable hours. They're about how much do you spend, and they get, you know -- I don't -- a lot of -- these are used, commonly used, in research papers about the costs of patent infringement litigation.

JUDGE CHAPPELL: What are these surveys? Who does these surveys?

THE WITNESS: I -- I -- what is the name -- I forgot the name. It's in my -- it's referenced in my expert report. I've gust forgotten the name.

BY MR. MEIER:

Q. Professor Bazerman, what are --

A. Pardon?

Q. Sorry. Bazerman. I'm sorry. I'm getting tired myself.

Professor Noll, when you talk about the survey

results, you're talking about results that are surveyed by the American Intellectual Property Lawyers Association?

A. Yes.

Q. And this is an annual survey that they do?

A. I'm not sure it's done every year. I wouldn't want to swear to that. But I know it's done periodically.

Q. And so these are surveys done specifically of patent litigation?

A. Not only surveys of patent litigation, but they break them down to how much was at stake in the litigation, because, obviously, the more valuable the case, the more parties tend to spend on it.

Q. So I was starting to ask you a question about whether you used other benchmarks other than saved litigation costs in coming to your conclusion that the payments in this case were large.

Did you use other benchmarks?

A. I'm sorry. I didn't fully -- I must have missed something in the question. I didn't hear.

Q. All right. I'll try again.

Did you use any other benchmarks --

A. Oh.

Q. -- in reaching your conclusion that the

payments from Endo to Impax were large?

A. Yes.

Q. And can you tell us what some of those other benchmarks were.

A. How they compared to Impax' actual profits from both, you know, overall and the anticipated profits they expected from generic entry.

Q. Do you recall using any other benchmarks to determine whether the payment was large?

A. Other than saved litigation costs and the profitability of the firms, I don't recall any others.

Q. Do you recall looking at the -- whether it was large in relation to the total annual revenues for Impax?

A. Oh. But that -- I meant -- when I said "the profits," I meant -- since revenues and profits are almost the same thing in the drug industry, it's not much of a difference.

Q. So in your opinion, under the settlement agreement, was it possible that Impax could make more money by settling the litigation than by actually entering with its generic product?

A. It is the case that the information we have on the -- both the projections and the actual experience of Impax, that the magnitude that they received in the

payment was larger than the stakes they had in actually entering the market.

JUDGE CHAPPELL: How much more time do you think you need for direct?

MR. MEIER: I have what looks based on so far about 20 minutes, 25 minutes.

JUDGE CHAPPELL: Go ahead.

MR. MEIER: I'd be happy to take a break now, Your Honor, if it --

JUDGE CHAPPELL: Would it elongate or shorten your questions?

MR. MEIER: Excuse me, Your Honor?

JUDGE CHAPPELL: Would your questions become longer or shorter?

MR. MEIER: After the break, I think they'd probably be a little shorter.

JUDGE CHAPPELL: I'll buy that. Be it true or not, I'll buy it. Sometimes during a break these things expand like monsters.

MR. MEIER: Actually, I'd try to shrink it.

JUDGE CHAPPELL: We'll reconvene at 4:15.

We're in recess.

(Recess)

JUDGE CHAPPELL: We're back on the record.

Next question.

BY MR. MEIER:

Q. Professor Noll, before we took the break, we were talking about whether the payments in this case were large, and I'd like to pick that up again.

In forming your opinion that the payment was large, did you review Endo's and Impax' contemporaneous plans and forecasts about the payment?

A. Yes, I did.

Q. Did you find any plans or forecasts by either Endo or Impax projecting that Impax would not receive any payment from Endo?

A. Only in the case where the reformulated product never entered. Then the AG -- no-AG provision would be the factor that would be providing benefit to Impax.

There's no -- there's no example in the financial projections in which the reformulated product is introduced and the Endo credit is not paid, nothing is paid from the Endo credit.

Q. Have you prepared a table in your report that illustrates the approximate value of the no-AG and Endo credit at the time of the settlement?

A. Yes.

Q. Ms. Durand, could you please call up Appendix F from Professor Noll's original report. Thank you.

Before we get into -- can you see that very well?

A. Yeah. I can sort of see it. That's fine.

Q. Maybe we can blow that up just a little bit.

A. Oh, much better.

Q. Before we get into the details of this chart, can you explain generally what it's intended to show?

A. Yes.

This shows the calculation of the payment or the no-AG provision under various assumptions about what happens at the more -- you know, what happens in the intervening period and what the state of the world is at the date of entry by Impax.

Q. So looking at the top row, when it says "Scenario," what does "Scenario" mean?

A. "Scenario" means a condition of the market at the time of Impax entry.

And the major condition of concern here is what the status of the reformulated product is, is it on yet or not.

Q. Okay. And then moving at the top row across to the right where it says "Form of Payment," what does that mean?

A. That means the provision of the settlement agreement that would be in force if that scenario

occurred.

In three of the four examples here in this illustrative example, it's the no-AG provision that is the component of the settlement agreement that is actually operative as opposed to the Endo credit provision.

Q. And then continuing to the far right at the top row, it says "Approximate Value," and what was that?

A. Well, that's two things.

First of all, it's a calculation of what the payment would actually be under the assumptions by -- next to the Scenario and the -- then the discounted present value of that to the date of the settlement agreement.

Q. Yeah, what does -- what does the discounted present value mean?

A. The discounted present value is a procedure that actually both companies used to represent a future stream of income in present dollars, that is to say, how much would you -- if you're going to get a hundred million dollars five years from now, how much is that worth today, what's the amount you'd be happy to be paid today to be indifferent between a hundred million dollars five years from now and X

dollars today, what's the value of X that makes that equality.

Q. So does the present value reflect the fact that the settlement was entered in 2010, but the payment might not come till sometime later?

A. The payments actually came I think in April of 2014 -- 2013, so you would take -- it's almost three years of discounting you -- and I used a rate that's higher than either company uses. I used 15 percent.

Q. Is that a rate that's essentially more conservative in the favor of the companies?

A. Yes. It assumes that you are more impatient, that you value the future less than either company actually values it.

Q. And did you actually do the mathematical calculations that are reflected in the Approximate Value column of this exhibit?

A. Yes. And then they were checked by one of my economist colleagues at the FTC.

Q. But you did the original calculations?

A. I did the calculations.

Q. And is the work that you did, the calculation work, detailed in your report?

A. Yes. It's how -- how I did it is in the report, and the actual mechanical part of the how is I

just did it on my computer with a calculator that's built into my computer and just wrote down into the report what the numbers were after I did them. I don't have any intermediate product.

Q. So let's take a look at the first scenario at the very top.

What's that, basically the facts of that scenario?

A. This is basically under various scenarios about when the original formulation of Opana ER would be withdrawn and when the new formulation would come on the market.

We know what the actual payment was, which was a date of entry, you know, in 2012, but there are some other dates in the documents, in the Endo documents, that are earlier in that. And of course, the earlier that the reformulated product enters the market, then the lower the peak sales are for original Opana ER, and so the magnitude of the Endo credit goes down.

And of all the entry dates I considered, the lowest one was a $62 million payment in April of -- or whenever the right date is -- I think it's April -- of 2013, which has a -- the -- you know, the discounted present value of 33 million.

And then there's a bunch of other values that

are higher and higher. As the date of entry of the reformulated product gets later and later and later, that number -- both the amount paid and the discounted present value keep growing.

Q. So as we know, the actual payment that ended up in this case was greater than this.

A. Yes. Because I -- this is to cover all the possible eventualities.

Remember I said earlier that the -- that one of the sources of uncertainty is when the reformulated product would be brought on the market. And Endo's original plans were to bring it on the market much sooner than it actually came on the market, so -- and those plans were never realized because of the delay in getting approval from the FDA.

Q. The bullet point in the first scenario, the second bullet point that says "Lowest possible payment under the Endo credit," how did you arrive at that?

A. That's the earliest entry date that was in the documents, and so you use the loss of half of the sales from what would have been the peak sales of original Opana ER had that earlier date transpired.

Q. Is this lowest possible payment under the Endo credit something the companies would have known at the time of the settlement?

A. Well, it knows what the -- it knows the formula because it negotiated it, and it knows what its own sales were, and it knows what half of those sales were, so it has all of -- it knows for certain every single element that goes into the formula.

Whether they actually calculated this number or not I don't know. They calculated some of them, but they didn't calculate all of them.

Q. Looking at the approximate value for the first scenario where it says 62 million and 33 million present value, in your opinion, is that a large payment?

A. Well, of course. It's substantially larger than the saved litigation costs of the settlement.

Q. Looking at the second scenario just generally, what's -- what does that scenario reflect?

A. Okay. This one is the circumstance in which Endo does not withdraw Opana ER from the market, and there's no growth at all after the settlement agreement in the revenues from Opana ER, so all you're getting here is the benefit of no AG if the sales at the time of entry are the same as they were in the quarter the settlement agreement was signed.

Q. And then for the approximate value for the second scenario, you said 33 million and 22 million

present value?

A. Yes.

Q. Just in your opinion, was that a large opinion?

A. Well, again, it's -- it would be a large payment because it's substantially larger than the saved litigation costs.

Q. Taking a quick look at the third scenario, what does that scenario -- what's the significance of that scenario?

A. This one is -- is based on Endo's -- you know, the original Opana ER continuing to grow and the -- the value of the no-AG provision is based upon the sales of original Opana ER at the very end of the period when -- you know, what those sales would have been in the first quarter of 2013, which is the quarter when you would get the benefit of the no-AG provision, assuming continued growth of the sales of Opana ER.

Q. And you estimated the approximate value of that scenario to be 53 million or 35 million in present value; correct?

A. That's correct.

Q. And in your opinion, is that a large payment?

A. Again, the same story. It's bigger than

$5 million, which is the saved litigation costs.

Q. And then there's the fourth scenario.

Can you give us the gist of what that scenario reflects.

A. Again, it assumes that the original formulation is not withdrawn. It assumes that there is a 50 percent decline in sales so that the maximum possible reduction in sales of original Opana ER occurs, but not because of the reformulation but because simply something bad happens in the market for oxymorphone ER.

And so this -- this is the worst possible result in terms of the value of the no-AG provision without triggering the Endo credit.

Q. And your approximate value there is 16.5 million or 11 million in present value?

A. Yes.

Q. And again, in your opinion, is that a large payment?

A. Yes. Because again it exceeds five million.

Q. And in going back to the scenario, the fourth bullet point says "Lower bound on benefit to Impax."

What does that mean?

A. This is -- this is as bad as it could get for Impax from the agreement, well, under the circumstance

where the reformulated product is never introduced.

Q. Why didn't you include a scenario in which Impax didn't receive any payment from Endo?

A. Again, remember that these are all based upon circumstances they actually considered, and so I didn't consider one like the scenario imagined by Dr. Addanki in his report because the first time I'd ever heard about that scenario in any kind of detailed way was when I read his report.

Q. Okay. We're going to get back to that in a moment.

A. Uh-huh.

Q. Did you calculate an expected value of the payments to Impax incorporating all possible scenarios?

A. I didn't create an expected value because I don't know how to assign probabilities to all of these events.

An expected value is the probability-weighted sum of every conceivable event. That means you multiply the probability that event will occur times the present value of that number. And you can't do that without making an assumption about what the probabilities are.

I did do a calculation about what the

probability of the event that Dr. Addanki describes, the one you just asked me about, what that would have to be in order for the value of the settlement agreement to Impax to be small, not to be large.

Q. What would the probability of the scenario in which the value of the settlement to Impax was zero have to be for the total expected value of the payments in this case to no longer be considered large?

A. The event in question, just to clarify, is that reformulated Opana ER has to be introduced in such a way that in the fourth quarter of 2012 sales exceed 50 percent of the peak, and then they go to zero, so that by the time January 1, 2013 comes, there is zero sales, so that you get the maximum possible effect of the fact that the generic is not an AB-rated therapeutic substitute and the generic substitution laws come in.

So you have to -- it has to be an extremely precise timing of when the reformulated product is introduced. And that creates the circumstance in which there's a zero -- where the value of the no-AG is zero and the value of the Endo credit is zero.

The probability of that event happening has to be over 90 percent to get the expected value of the

agreement to Impax to be less than the saved litigation costs.

Q. What does that mean, that the probability would have to be over 90 percent?

A. That means an event that does not appear in any of the financial planning of either party has to be by far the most likely event and that the event that actually did occur has to have almost zero probability assigned to it. It has to be like one one-hundredth of 1 percent likely to happen.

Q. What assumptions did Dr. Addanki have to make in order to find that the payment wasn't large?

A. He had to -- he had to assume that the timing of the entry was so precise that you -- there was not enough of a decline in sales in the fourth quarter of 2012 to trigger the Endo credit and that the sales of the original formulation of Opana ER in the first quarter of 2013 were essentially zero so that you got no benefit to Impax from generic substitution laws. That has to be the assumption.

So that means you get no Endo credit and you get no value from the generic substitution laws and you get no value from the no-AG provision. All right. That -- and in order to do that, you'd have to have a very precise date at which you introduced the -- the

Opana ER.

And I don't know what that date would be. It would probably be sometime around the 1st of November or the middle of November or something, because you'd have to -- in 2012, because you'd have to have enough sales in the first part of the period that you kept total sales for the quarter above the 50 percent threshold, and then when the crash came, it would have to be sufficiently late that -- you know, that you would then have -- you'd stay above the 50 percent threshold for the quarter, but you'd be into the zero territory in the first quarter of 2013.

Q. To summarize then, what do you think of Dr. Addanki's argument that Endo's $102 million to Impax was not large?

A. I think it's -- it's extremely implausible because I don't think it's possible to time the entry of -- of a generic -- of a -- of the reformulated product that precisely, that we know from the experience that Endo actually had that its ability to plan for its launch date was highly uncertain because of all kinds of things.

They had -- they -- a -- they differed -- that the assumed launch date of reformulated Opana ER in the various financial forecasts varies by more than a

year, and so the differences that occur are because of differences in events that were -- that occurred that they couldn't really predict with complete certainty.

So it seems to me highly unlikely that Endo would have been able to time everything so precisely to meet that target, but you have to be able to assume that their ability to do that was so precise that it was the -- by far the most likely outcome and -- in order to get the value of the entire settlement agreement to Impax to get down to the saved litigation costs.

And I might add that even if you do this, you still haven't dealt with the $10 million. All right. That is to say --

Q. What $10 million?

A. -- even if you could assume this thing went to zero, you still have the $10 million payment for the co-development and co-promotion agreement.

So even if that's all there, you have to make the additional argument that you have to knock off at least half of that as payment for something of value in order to get the entire value of the agreement to go below saved litigation costs.

Q. Shifting gears now, have you reached an opinion on whether Impax' agreement with Endo was

justified?

A. Yes. There's -- I have reached an opinion on that.

Q. And what is your opinion?

A. My opinion is it was not justified.

Q. And what is the basis for that opinion that Endo's payment to Impax lacks a justification?

A. That there was -- there was no goods, service or assets acquired by Endo that were compensation for the money that was or the value that they delivered to Impax in the agreement.

Q. In giving that answer, did you say there were no goods, services or assets?

A. Yes.

Q. Have you been able to identify any plausible procompetitive justification for Endo's payments to Impax?

A. I don't believe there are any, but I can recite what I believe they're asserted to be.

Q. Has the parties made -- has Impax made or asserted some procompetitive justifications?

A. Dr. Addanki has. That's the only person I can talk about. I can talk about him.

Q. What is your opinion of Dr. Addanki's asserted procompetitive justifications for Endo's payments to

Impax?

A. That it's -- it's -- it has no basis in reality basically.

Q. Are you opining that Impax would have entered earlier than January 2013 if it had not received a large, unjustified payment from Endo?

A. I'm not opining anything about the likelihood of Impax entering at any date.

That -- the -- the -- the economic model and analysis of reverse payment settlements that's in the literature and that's in my report says you don't need to know that. All right.

That's the crucial fact. You don't need to know what the probability of entry was on any given day. You don't have to re- -- you don't have to litigate every conceivable patent infringement case. You don't have to evaluate at the value of at-risk launch.

All these contingencies that are mentioned in Dr. Addanki's report and Mr. Figg's report, you don't have to deal with them, because the reverse payment itself embodies the value of all those things. It's a number. It tells you what the -- what the -- what in fact was being purchased, the value of what was being purchased. And it's the sum of the values that Endo

perceived from being guaranteed that none of these potential entry scenarios would actually happen before January 1, 2013.

Q. Are you opining that the only way a brand and a generic pharmaceutical company can settle their patent litigation without running afoul of antitrust law is through a pure time-split settlement?

A. No, I'm not opining that.

But I am opining that the -- the rule of reason test here says that if there's no exchange of goods and services and assets and nothing being acquired of value, then a reverse payment that is larger than saved litigation costs combined with the plausibility of entry prior to that date is sufficient for the settlement to be anticompetitive.

MR. HASSI: Your Honor, I have an objection to the witness testifying about the rule of reason test.

JUDGE CHAPPELL: He did so like he was trying to sneak a legal opinion in there on us.

To the extent that's a legal conclusion or opinion, you're sustained.

MR. HASSI: Thank you, Your Honor.

Move to strike?

MR. MEIER: Your Honor, may I be heard?

JUDGE CHAPPELL: I will strike that answer if

the witness doesn't clarify that he's not intending to give a legal opinion. Then you may be heard.

BY MR. MEIER:

Q. Professor Noll, were you intending to give a legal opinion?

A. No. I'm talking about the antitrust economics of rule of reason. I'm not talking about law. I'm talking about what the test is for anticompetitive harm to have occurred as economists do a rule of reason test. Whether the legal system wants to pay attention to that is up to the legal system to decide.

Q. Thank you.

What are some examples of patent settlements pharmaceutical companies could enter into that in your opinion wouldn't be anticompetitive?

A. If in the course of negotiating a settlement they did identify a product they would like to develop together and they in fact did in good faith try to develop that product and it had an expected value that exceeded the development costs, then in fact that would be a perfectly reasonable justification for a payment that was associated with a settlement.

Likewise, if the reverse payment were less than the saved litigation costs, that would be fine.

Q. What if the payment ran from the generic firm

to the brand firm?

A. Oh, of course. That's like a royalty. That's -- that's not a reverse payment. That's -- that's what we would expect in a -- what one -- one common outcome of patent infringement cases is that the infringer says, Okay, you know, what if I pay you a license fee and you let me compete. And that's a perfectly legitimate outcome of a patent settlement negotiation.

Q. Professor Noll, does your analysis in this case ignore what happened in the real world?

A. No. It considers what happened in the real world and all the possible real-world events that the parties considered not only at the time of the settlement agreement but in the year or so afterwards.

Q. I'd like to now turn to something that you identified in your rebuttal expert report as the elephant in the room.

A. Yes.

Q. Professor Noll, in your opinion, what is the elephant in the room?

A. The elephant in the room is in reference to the conclusions expressed by Mr. Figg and Dr. Addanki, which is that the -- remember I said there was an

alleged procompetitive benefit.

The alleged procompetitive benefit is that Impax actually got to enter earlier than it otherwise would have been allowed to enter because it would have lost not only the patent infringement suit at issue at the time of the settlement, but it would have lost a whole bunch of other patent infringement settlements, and it would never have been able to enter.

So the elephant in the room is, Endo signed an agreement in which it ended up paying 120 -- $112 million to Impax and gave them the right to enter earlier than they would have entered had nothing happened, and so the question is why did Endo make a $112 charitable contribution to Impax to achieve a worse result from it than it could have achieved by just doing nothing.

MR. MEIER: Your Honor, if I may consult with counsel briefly?

JUDGE CHAPPELL: Go ahead.

(Pause in the proceedings.)

MR. MEIER: I have no further questions, Your Honor, at this time

JUDGE CHAPPELL: Cross?

MR. HASSI: Yes, Your Honor.

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CROSS-EXAMINATION

BY MR. HASSI:

Q. Good afternoon, Professor Noll.

A. Good afternoon.

Q. Sir, you -- I want to go back to your experience which you talked about late this morning, early this afternoon.

You retired 11 years ago; is that right?

A. 2006. Yes.

Q. When was the last time you taught a course in antitrust and regulation?

A. Three or four years ago. I co-taught a course. It was the person who replaced me teaching the course.

Q. And you currently teach one course in economics each year, a course on fun for profit and sports and entertainment; is that correct?

A. I don't teach it every year, but I taught it this year. And I don't know whether I'll teach it again next year. It depends on the demand, how many students want to take it.

Q. And you mentioned doing some work for GlaxoSmithKline; is that right?

A. Yes.

Q. And what kind of case was that?

You were an expert economist in that case?

A. Yes.

Q. What kind of case was that?

A. It was an antitrust case involving conduct by Abbott that inhibited the ability of GlaxoSmithKline and another company to introduce a protease inhibitor for HIV/AIDS treatment that competed with a protease inhibitor that was being sold by Abbott.

Q. It was not a reverse settlement case I take it?

A. No, it was not -- it was not about patents at all. It was about -- it actually was -- had to do with the contract between GlaxoSmithKline and Abbott regarding a license to promote their drug in combination with another drug that was produced by Abbott and how that contract -- whether -- the issue was whether that contract was legitimately adhered to or not.

JUDGE CHAPPELL: Was it private litigation or was the government a party?

THE WITNESS: There's no -- the government was not involved at all.

BY MR. HASSI:

Q. Sir, other than that one case for GlaxoSmithKline and the work you've done for the

Federal Trade Commission, have you done any other work in the pharmaceutical industry?

A. I've never done any consulting, litigation consulting. No.

Q. And you've never worked for a pharmaceutical company.

A. I've never been employed by a pharmaceutical company in any capacity ever.

Q. You've done a lot of reading of Impax documents, for example, in this case.

You've never worked for Impax, have you, sir?

A. No.

Q. And you've read a lot of Endo documents.

You never worked for Endo, did you, sir?

A. I've never worked for Endo.

And I've never worked for Actavis either.

Q. You were involved in -- well, strike that.

What was your involvement in the original effort of what later became Hatch-Waxman?

A. Became what?

Q. Became Hatch-Waxman.

You're familiar with Hatch-Waxman?

A. Oh. Of course, I'm familiar with Hatch-Waxman. It just -- the words didn't compute. Okay?

I was not involved with Hatch-Waxman per se. I was involved in the original proposal for ANDAs for -- as a way to facilitate speedy generic entry, that proposal that came out of -- that came from Don Kennedy in the late 1970s. And then I -- A, I helped them with the design of what that proposal was, and then I testified before Congress to support it. And I don't remember the precise date, but it was probably '79 or something like that.

Q. Did that proposal get incorporated into the Hatch-Waxman bill?

A. No. It kept getting amended and amended and amended until the final version that was passed years later was much more complicated than what we were proposing.

JUDGE CHAPPELL: Did that proposal allow a generic in the market without safety or efficacy studies?

THE WITNESS: It -- that was the crucial fact. The crucial fact was the demonstration of bioequivalency and that the ANDA would not have the safety and efficacy requirement, that demonstration of bioequivalence would be sufficient. That was the -- and then there were some timing proposals as well, but they were not the ones that ended up in Hatch-Waxman.

JUDGE CHAPPELL: To avoid all the clinical trials and skip that --

THE WITNESS: Yeah.

JUDGE CHAPPELL: -- monetary burden.

THE WITNESS: The skipping of the clinical trials was the crucial part.

BY MR. HASSI:

Q. In your opinion, did Congress make some errors in drafting the Hatch-Waxman Act?

A. I -- well, we know that they've amended it since, so they thought they did.

Again, I think I answered this question. I didn't see it coming. I didn't see the problems with Hatch-Waxman coming.

Moreover, it took more than ten years for these problems to appear, so I think it's fair to say that no one, the drug companies, the advocates for the bill, the members of Congress, the FDA, my -- you know, anybody else providing economic advice to the government, I don't think anybody foresaw what started to emerge 15 years later as the problems arising from Hatch-Waxman.

Q. And can you be specific as to what you're referring to when you say the problems with Hatch-Waxman?

A. Reverse payment settlements and excessive litigation with respect to patent infringement.

JUDGE CHAPPELL: Hold on a second.

(Pause in the proceedings.)

Go ahead.

BY MR. HASSI:

Q. Sir, you don't have a degree in medicine, do you?

A. No.

Q. You don't have a degree in pharmacology?

A. No.

Q. You don't have a degree in pharmacy?

A. No.

Q. You're not an expert in the therapeutic differences between long-acting opioids, are you?

A. I wouldn't be in a position to try to match therapeutic differences to patient conditions, but I do know what they are and -- and from -- I'm able to interpret them in an economic context, but not in a medical context.

Q. And with respect to those therapeutic differences, would you defer to the physicians that are testifying in this trial?

A. I'm sorry. I can't hear you.

Q. With respect to the therapeutic differences

between long-acting opioids, if any, would you defer to the physicians who are testifying in this trial?

A. Yes.

Q. You worked with the Federal Trade Commission in the Cephalon case; is that right?

A. That's correct.

Q. And the opinions that you offered in the Cephalon case are similar to the opinions you're offering in this case; is that right?

A. That's correct.

Q. And the work you did in the Cephalon case, that was before the Supreme Court's Actavis decision; is that right?

A. Yes, it was.

Q. And in the Cephalon case, you offered the same three-part test that you've explained this afternoon?

A. Yes. It's basically the same, although I used the words a little differently because I -- as you may notice, there was some further elaborations of the model between the two, so there are some small differences, but yes, it's basically the same conclusion.

Q. You talked this afternoon about a mathematical model in your report. Do you recall that?

A. I do.

Q. And you derived that mathematical model from the work of other economists?

A. The model is built upon the published research and literature. Yes.

Q. Have you published your model?

A. No. I've -- something very close to mine has been published by Einer Elhague, who was another expert in the Cephalon case, but the full-blown stuff in my own, I haven't gotten around to writing it yet, and I intend to, but I haven't done it yet.

Q. So your model hasn't been peer-reviewed; is that right?

A. That's correct.

Q. You talked a little bit this afternoon about patent cases.

You've never litigated a patent case; right?

A. I'm sorry. I can't hear you again.

Q. You have never litigated a patent case; is that right, sir?

A. I have never been an expert witness in a patent infringement case, yes.

Q. And you're not an expert in patent law, are you?

A. I don't hold myself to be an expert in any kind of law notwithstanding my articles in law

reviews.

Q. You're not an expert in evaluating the strength of a patent case; correct?

A. Well, actually I have testified in evaluating intellectual property, just not patents. I've testified in evaluating copyrights.

Q. But not patents; right?

A. Not patents.

Q. You've been thinking about the three-part test that you talked about this afternoon since the Schering-Plough case was decided; is that right?

A. Yeah. I've been -- I've been thinking about what's the right way to think about these things since Schering-Plough. The details of the three-part test didn't come about instantaneously, but they were -- the thought process that led to it was the Schering-Plough decision.

JUDGE CHAPPELL: What do you mean, since Schering-Plough? Do you mean the initial decision, the commission's reversal, the appeals court's reversal of the commission, the Supreme Court not taking the case and leaving the appeals court decision in place?

THE WITNESS: The appeals court. The crucial case to me and the one that got on my radar screen was

the appeals court decision.

BY MR. HASSI:

Q. You believe the appeals court decision was incorrect as a matter of economics?

A. Yes, I do.

Q. And your colleague at Stanford, Tim Bresnahan, Professor Tim Bresnahan, testified for the FTC in the original Schering-Plough case?

A. Yes, sir.

Q. And you and he discussed this three-part model that has evolved since then?

A. We discussed the decision in the case. The -- I don't know that the term "three-part model" or "three-part test" was ever used, but yes, the basic contours of how you think about it, we did discuss it after the Schering-Plough decision and before I had any involvement with the FTC.

Q. And that was at least ten years ago?

A. I don't know -- I think so, and I don't know precise -- I don't have the exact dates in my head, but it's something on that order. Yes.

Q. This afternoon, you gave an explanation of a demonstrative from your report in Exhibit F with three circles --

A. Yes.

Q. -- one red and one red and orange.

Is that something you created?

A. The picture itself, no. The picture itself was done by one of the staff people at the FTC. The concept behind it was mine.

Q. The concept behind that picture was yours; is that right?

A. That's right.

Q. Do you know whether that demonstrative was used in the Schering-Plough case 15 years ago?

A. I have no idea. All I did was talk to them about what it -- what -- what my views were about what the three circumstances were. And if they've used it before, that's news to me.

Q. So you conceived of that Exhibit F in the context of your work on this case; is that right?

A. A verbal description of what that picture says was in my original report, and they asked me if it was okay to draw a picture of it. I said yes. And if they'd already drawn the picture in the past, that's -- that's news to me. I didn't know about it.

JUDGE CHAPPELL: Was that exhibit your opinion or an opinion you adopted that was handed to you?

THE WITNESS: No. It's mine because the -- notice the picture has notation from my mathematical

model, so I think the proposition that this was used in Schering-Plough is probably technically incorrect because my notation for what the profitability of the generic company and the brand name company are are actually on the picture.

But I accept I think, you know, that the -- the assertion that maybe that was used before with somewhat different words and somewhat different notation, that's possible.

I mean, one of the nice things about economics is that everybody who studies it and does it in an objective fashion is going to reach the same conclusion, which is that the representation of what happens to the profits of the brand name firm under two different scenarios is going to look like that.

So, you know, it's not surprising to me that other people would have made a similar diagram to the one that is in my report.

BY MR. HASSI:

Q. I think you said this morning, or maybe it was this afternoon, you've written over 400 articles and papers; is that right?

A. I said nearly 400. I'm -- my CV does keep growing, even though I'm as old as I am.

Q. And am I correct that none of those nearly

400 articles and papers addresses reverse patent settlements?

A. That's correct. I haven't written that paper yet.

Q. And so, for example, the three-part test that you described this afternoon, you've not written about that.

A. I personally haven't, but others have. It's in the paper by Einer Elhague.

Q. You've read the Supreme Court's Actavis decision?

A. I have read the Supreme Court decision, yes.

Q. And the Supreme Court's Actavis decision didn't change your formulation of the three-part test, just changed some of the nomenclature; is that right?

A. Yeah. I -- well, it's not the right way to describe it. I actually -- the reason for the change in wording is because of extensions of the model, but yes, I did -- I did relate what the conclusions of the model were to the words that were used in the Actavis decision, because they didn't use exactly the same words that I did.

Q. And you believe your three-part test is consistent with the FTC's litigation strategy for these cases; is that right?

A. I don't know. I -- I actually never even have thought about that question. You know, what their litigation strategy is I don't know about or care.

Q. Well, did you testify a couple of weeks ago that you thought it was consistent with your three-part test?

A. I thought that the complaint, you know, if you want to say what's the complaint in the case, I think that what I've done is consistent with the complaint, yes.

But that's different than litigation strategy. I think -- when I think of litigation strategy, I don't -- I wasn't -- I thought you meant what goes on in the trial and what goes on in terms of legal arguments that are presented to a judge, and I don't know that, anything about that.

Q. Maybe you could look at your deposition, which is in the binder the FTC gave you --

A. Sure.

Q. -- at page 20 and specifically the lines 16 to 25, which is the end of the page.

(Document review.)

A. Okay. I see I used the term "litigation strategy."

But I'm not using it in the same term here --

way here I just had in the answer to you.

Q. Sir, does that refresh your recollection that you view your test from your perspective as consistent with the FTC's litigation strategy?

A. Yeah. Only I shouldn't have used the word "litigation strategy." The test -- you're absolutely right about the test.

I didn't interpret the word "litigation strategy" as you used it as being the test. I agree that the test is consistent with the test they're using, and I agree that I've talked to them about this for years, and there is a commonality of how they think about what the appropriate test is and what I think the appropriate test is. I just didn't interpret "litigation strategy" as being about the test.

Q. Thank you. You can set that aside. Thank you.

I want to talk about some of the bases for your opinions.

Is it fair to say that in your expert report you relied upon the opinions of Dr. Seddon Savage for clinical information?

A. Yes. In the original report, the corrected liability report, my -- I relied upon her.

Q. And I'm sorry. The corrected report, that's the first report as corrected for typos that you issued

in this case?

A. That's correct.

Q. And you would agree that prescribers can choose among long-acting opioids when deciding what to prescribe a patient who has chronic pain?

A. I'm sorry. I didn't hear all --

Q. You would agree, sir, that a physician can choose among the various long-acting opioids when deciding what to prescribe a patient with chronic pain; correct?

A. Of course.

Q. And you would agree that no one long-acting opioid is superior for a particular new patient.

A. I don't -- I don't have knowledge to know whether any particular patient has a superior long-acting opioid -- I wouldn't be anyone -- I couldn't decide that. If somebody says that's true, okay. But I'm not someone to say what's the superior long-acting opioid for this particular patient.

Q. And if Dr. Savage says she can't tell you which long-acting opioid is superior for a patient with no history of opioid use, you have no reason to doubt that; right?

A. Well, I think that's absolutely right. In the abstract, without more information, I don't think even

a doctor knows what the superior prescription is.

Q. In other words, there are a variety of long-acting opioids that a doctor could choose from for a new patient and test for that patient; right?

A. Yes. But that's -- the question of whether in principle with perfect knowledge there is a superior one is different from without any further information could you know, could you identify what the superior one was. I don't see any way to identify it just on basic principles, first principles.

My understanding of how doctors behave is they try to match the drug to the conditions of the patient, but again, I'm not a doctor and I'm not going to perform that match.

Q. Do you understand that no particular opioid is a priori any better for any particular condition?

A. I don't have an expert opinion about that. That's not -- I would rely upon Dr. Michna or Dr. Savage to be the one who said for any given set of conditions of a patient is there a single best prescription or not. And I don't know the answer to that in any kind of an expert capacity, and I don't need to know it for anything I do.

Q. And you understand that physicians, in choosing a long-acting opioid for any particular

patient, may make decisions based on formulary tiering and prices.

A. Among other things, yes. They make it on the basis of a long list of things of which those are one.

Now, a lot of them don't make it on the basis of formularies because their patients are not in formularies, so that would only be true for someone who has insurance that covers drugs that has a formulary.

Q. Do you know what percentage of patients in this country have insurance that covers drugs on formularies?

A. If you -- the fraction of patients on private insurance is 55-60 percent. The rest are paid for by the federal government in one form or another.

Q. So the majority of patients have private insurance; right, 55 to 60 percent?

A. Something on that order. I don't remember the precise numbers because you're asking me fact questions, but that's roughly -- roughly right. It's somewhat less than half are paid by one or another federal program.

JUDGE CHAPPELL: But -- hang on a second.

But just because the federal government pays it doesn't mean it's not insurance; correct?

THE WITNESS: Oh, it doesn't mean it's not insurance. But the mechanism by which drug choice and drug prices are controlled is different in federal programs than it is in private insurance programs.

BY MR. HASSI:

Q. Does sometimes the federal government pay for private programs such as Medicare Part D?

A. That's right.

There's -- there's an array of federal programs, and Medicare Part D is one which may involve, but is not mandatory, you know, the use of private insurance. And then there -- and there are people who don't have Medicare Part D, like me. And then there's people under Medicaid. And then there's veterans. Then there's people who are in other smaller federal programs than those two.

Veterans and Medicaid are very big, so -- and each one of those is treated differently. The whole mechanism for doing drugs is different in almost every one.

Q. Do they have formularies for veterans programs?

A. Not of the form we think about for private insurance companies. They have approved drugs, but it works differently. It's a different system than the

formulary system in private insurance.

Q. Do you know whether drug companies compete to be on the formulary, for example, that the VA provides?

A. To some degree, yes. But the prices they can charge in VA and Medicaid are governed by formulas for price discounts, and so -- but they don't apply in the private cases.

Q. Sir, you didn't assess the duration of therapy for the average Opana patient; is that correct?

A. I'm sorry. I can't hear you again.

Q. You did not assess the duration of therapy for the average Opana patient; correct?

A. I made no attempt to assess it. I knew it at some point and I know -- remember you examined me about it at my deposition, but it's -- I don't remember what I learned from that process, no.

Q. You don't know it as you sit here today.

A. I don't recall -- again, it's asking me a fact question, and I don't remember what the right fact is, that -- there's a reasonably high turnover rate in the use of long-acting opioids, but I don't remember precisely what it is.

Q. Sir, you're not aware of any identifiable group of patients for whom oxymorphone is the only safe and

effective long-acting opioid; correct?

A. I'm not aware of any patient in particular who can only use any particular LAO, oxymorphone or anything else.

Q. And you acknowledge that a given drug, such as oxymorphone, may be listed differently on different formularies or even not listed at all on a formulary; correct?

A. Well, there's explicit examples of that in my expert report. Yes.

Q. And you did not attempt to determine whether oxymorphone is listed differently on different formularies due to economic or therapeutic differences; correct?

A. I -- what I did is say that all these things go into it, and then I gave examples of how the same facts about different drugs lead to different formulary placement, and I made a comparison between the two largest private insurance companies, so I -- you know, that -- it's in there, and I did it, and it speaks for itself.

Q. Sir, you've not considered the extent to which the demand for oxymorphone is in fact price-elastic; correct?

A. I did not attempt to estimate the elasticity of

the demand curve for any drug. I just inferred it from facts about market events.

Q. And you would agree that physicians pay attention to price and insurance coverage when prescribing particular drugs; correct?

A. Sometimes. Some do and some don't. Yes.

In general, the reason that formularies work is because they can impose some consideration of price on physicians who otherwise don't have much of an incentive to consider it.

Q. And your opinion that there's no significant competition between brand name drugs with different active ingredients is not based on your review of either Endo or Impax documents; correct?

A. I'm -- I've -- most -- no. I mean, it -- I did consider the documents in the sense, but I didn't find much in them with respect to price sensitivity, that the degree to which formularies affect price.

They contain documents about not only what price changes they're considering in list price but what the implications of those price changes are for their actual net revenues. And the -- the actual net revenues would take into account the discounts that they give to formularies, and so when they -- when you read a pricing document from Endo that says we're

going to increase the list price by X percent, then they will follow that with, well, this will lead to an increase in revenues of Y percent.

And Y is usually quite a bit less than X. And it's less than it for two reasons. One is there's some elasticity of the demand curve. And two, they're actually giving discounts.

So you can -- you don't know precisely what the discount is to any particular formulary, but you know what the -- what their estimate of the net revenue impact is that takes into account the discounts to the formularies. And they actually talk about that in their documents, but they don't quantify it. They don't -- they just talk about it in a qualitative sense.

Q. And is that a way of saying you couldn't tell actual prices from looking at the Endo documents, only --

A. When --

(Counsel and witness speaking at the same time and cautioned by court reporter.)

THE WITNESS: When they tell you --

BY MR. HASSI:

Q. She didn't get my question, sir.

A. I'm sorry. I thought she was -- I stepped on

you. I'm sorry.

Q. Sir, is that a way of saying you couldn't tell the actual prices Endo was charging its customers from Endo's documents?

A. You could not tell the specific price to a specific customer from the estimates of overall revenue effects. All you can tell is what happened to average price and sales. You can't tell what the specific price to any specific customer was.

Q. You would agree, based on your review of Endo's documents, that it regards Opana ER as competing with other long-acting opioids, not just generic oxymorphone; correct?

A. I said that in my direct testimony. Of course, it regards itself as competing with other LAOs.

Q. And you're aware that Endo measures itself as having a less than 10 percent share of the long-acting opioid market; is that right, sir?

A. I wouldn't put it that way because I don't think it's a market, but I agree that their total sales are less than 10 percent of the total sales of all LAOs.

Q. And you've seen internal Endo documents where they did calculate a share, their share, of the long-acting opioid market; correct, sir?

A. They -- they col- -- yes. They calculated their own share, but their use of the term "market" is not the same as it is in antitrust economics. They're just --

Q. And when they calculate --

JUDGE CHAPPELL: Hold it, hold it. He wasn't finished.

THE WITNESS: They're using the term "market" to refer to sales of all long-acting opioids without actually doing any test as to whether that is a relevant market from the point of view of antitrust economics.

BY MR. HASSI:

Q. So you disagree with Endo about what the definition of the relevant market is; is that right?

A. They don't define the relevant market. They're using the term "market" in a common parlance way, and I'm using it in a -- in the detailed way that it's used in economics. And neither one of us is wrong. We just are using the term in a different way.

Q. And you would agree when they use -- when they calculate their share of the long-acting opioid market, whether it's the market as you define it or the market as they define it, they compute that their share is less than 10 percent; right?

A. Yeah. But that's not the way I would define it, so you -- if you wouldn't have qualified it by saying as I would define it, then I would agree with you, but I didn't define the market that way, and that's not a relevant antitrust market.

Q. Sir, in defining the market, you did not conduct a SSNIP test; is that right?

A. No. I had to infer it from observed sales behavior from changes that -- in market conditions that I knew were related to price.

Q. And you made some criticism of Dr. Addanki's report, but you would agree that all the types of evidence that Dr. Addanki uses are part of the standard approach to market definition in antitrust economics; correct?

A. No, I would not agree that all the things he uses are relevant, that are application -- are uses of standard measures that are used in antitrust economics.

Q. Sir, that wasn't my question.

My question was, would you agree that all of the types of evidence that Dr. Addanki uses are part of the standard approach to market definition in antitrust economics?

A. No.

Q. Yes or no?
A. I would not agree that all the things he uses -- some of them are but not all of them.
Q. Okay. Could you look at your report, your rebuttal report -- that's the second report you filed in this case -- at paragraph 24.
A. Sure.
(Document review.)
Okay. I'm there.
Q. So, sir, would you agree with me that you wrote in your report -- and I'm referring to the first full sentence on page 12, paragraph --
A. I thought you said page 24.
Q. Paragraph 24. It carries over --
A. Oh, paragraph. I turned the page. I'm sorry.
(Document review.)
Yeah, it identifies other sources of information that are useful to ascertain, yes.
Q. And sir, did you or did you not write in your rebuttal report -- and again, this is paragraph 24, page 12, the first full sentence -- "Thus, all of the types of evidence that Dr. Addanki uses are part of the standard approach to market definition in antitrust economics"?
Did you write that, sir?

A. I -- you said paragraph 24?
Q. Yes, paragraph 24.
A. The first sentence as I'm reading it is: "The Addanki Report identifies other sources of information that are useful to ascertain the extent of competition amongst pharmaceuticals."
Q. That's the paragraph, sir. And if you go over to page 12 --
A. Oh, you --
Q. It's a lengthy paragraph.
A. Oh, it's the end of it.
"Thus, all of the types of evidence that Dr. Addanki uses are part of the standard approach," all of the types of evidence. That's not the same thing as the way you asked the question.
Yeah, I -- it is true he uses the things that are used in antitrust economics, but it's true he also uses other information that is not part of antitrust economics.
So, yes, he does use information that is part of antitrust economics, but he uses other things as well.
Q. And you agree with Dr. Addanki that there is not sufficient data to reliably calculate cross-elasticity --

(Interruption due to noise.)

Sir, you would agree with Dr. Addanki that there is not sufficient data to reliably calculate cross-elasticity of demand between Opana ER and other long-acting opioids; correct?

A. I said that in my original report.

Q. And so you didn't calculate cross-elasticity --

JUDGE CHAPPELL: Wait a second. That's not really an answer.

Is he correct?

THE WITNESS: Yeah. Oh, yes. I mean, I -- that's what I'm saying. I mean, it's not that Dr. Addanki said it. It's that I said it, and he agrees with me. I said it before he did.

BY MR. HASSI:

Q. And you did not calculate cross-elasticity of demand between Opana ER and other long-acting opioids; correct?

A. That's correct.

Q. I want to switch to another topic. I want to talk about switching.

You would agree that two products are close economic substitutes if a buyer would switch from one to the other in response to a small change in relative prices?

A. That's correct.
Q. And you agree that patients can switch from one long-acting opioid to another; correct?
A. That's correct. It does happen.
Q. And in your report, you relied on the Federal Trade Commission/Department of Justice Horizontal Merger Guidelines?
A. That's correct.
Q. And you agree with the Merger Guidelines that evidence of switching in response to relative price changes is probative of market definition?
A. Yes.
Q. Yet you dismiss the evidence that we see of switching between long-acting opioids in response to relative changes in price, for example, rebates offered to third-party payers in exchange for formulary placement, as an instance of the cellophane fallacy; is that right?
A. There's no evidence of a quantity effect of that of any significance. It is true -- all the stuff about formularies I agree with, that they do attempt to compete for formulary placement, that formulary placement does get affected by the discounts. The issue is how big an effect is that, and there isn't any quantification of that in any expert report, mine or

Dr. Addanki's.

Q. And I'm sorry. When you say there isn't any evidence of quantification, is that the quantification of switching?

A. No.

First of all, the -- the quantification at issue here is a quantification of how the -- the offering of more or less discounts to a formulary leads to a change in the degree to which that drug is prescribed and whether that process of competition among drug companies who's selling -- are selling different LAOs is sufficient to cause the price of those LAOs to go -- be driven down to the competitive level. All right. That's the question.

And all that you can say about formularies, as is said in my original report, which I -- Dr. Addanki doesn't actually disagree with, is that this is a factor that does cause some degree of price competition.

Whether it's significant or substantial in the effect on price we don't know, all right, because we don't actually have observations that would enable us to estimate the cross-elasticities of demand and the degree to which there actually is price competition and the degree to which it actually matters in terms of

switching sales. All right.

So all we know, both of us, is that this is a -- this is an element that goes into deciding how competitive the market is along with many other elements.

There are markets working in favor of competition, like formularies and government procurement programs and generic substitution laws, and there are things working against substitution, such as the promotional activities to emphasize different characteristics and such as switching costs.

Now, what the net effect of all those things is you can't directly -- you can't directly estimate. They all go into calculating the cross-elasticity of demand. And we can't measure that directly. The best we can do is look at market events that would affect those relative prices and see whether they cause a significant shifting in the quantities. That's the best we can do.

Q. And so because you can't tell how significant it is, you dismiss it and look elsewhere; is that right?

A. I do not dismiss it. I do not have any disagreement about the effect of formularies. The point is, formularies are not the only thing going on

in the market. And the degree of competition among various long-acting opioids is affected in totality by all of the things going on in the market.

And the -- the only really test we have is to see if things like introducing substantially lower prices by generic entry in one LAO causes significant effects in sales and prices for another LAO. And we know it's not true. And that means they're not all in the same relevant market.

JUDGE CHAPPELL: Hold on a second.

I've been listening to this all day. You seem to be trapped in some kind of a -- you're on some track or some system whereby all that matters are theories, models, estimates, projections.

What if we have real-world evidence? What if we have actual facts to tell us what's happening in the market? Do you just -- does that not matter if you can't put it in a model?

THE WITNESS: No. It's exactly the opposite. The only -- the only -- the only relevant fact we have is what actually happens when changes occur in the sales of one long-acting opioid, what happens to sales of that opioid and to sales of other opioids that might be substitutes for it.

JUDGE CHAPPELL: But aren't you talking about a

variable that you're trying to plug into a formula or a guideline --

THE WITNESS: No. I'm just looking --

JUDGE CHAPPELL: -- changes in whatever?

THE WITNESS: No. No.

JUDGE CHAPPELL: What about common sense? Can we use common sense? In economics and antitrust, is common sense valuable?

THE WITNESS: Of course, it is.

But the only facts we have are facts about what happens in the conditions in the sale of a particular opioid and what effects does that -- do those conditions have on, A, the sale of that opioid and the sale of other opioids.

JUDGE CHAPPELL: Well, you understand this is not like Ford deciding what to charge for an F-150 pickup. There are players here that make this market, unlike other markets, insurance companies that drive the price, how many patients really have any idea what they're going to pay for one opioid versus the other.

Are you trying to tell me that you're trying to somehow develop a model or give an opinion that makes this market the same as all other markets that consumers are involved in?

THE WITNESS: No. Because you wouldn't be discussing formularies to begin with or insurance companies to begin with or government programs that pay for almost half of all drugs. You wouldn't be discussing those when you're talking about automobiles.

So --

JUDGE CHAPPELL: Well, what do you think is the most -- who drives the price in this market for opioids?

THE WITNESS: I'm sorry?

JUDGE CHAPPELL: Who drives the price, who sets the price in this market?

THE WITNESS: The price is an interaction among buyers and sellers, and insurance companies are an important component, patients themselves are an important component, and the federal government is an important component.

JUDGE CHAPPELL: You don't think that Blue Cross, United, Humana, that they're dictating what the price is more than anyone else?

THE WITNESS: No. They do not dictate. They have not been effective in controlling drug prices in the last ten years.

JUDGE CHAPPELL: Well, I'm not saying they

dictate. That's a poor choice of words. But you don't think that they have a lot to do with what the price is for these drugs.

THE WITNESS: They have an effect on drug prices, but they are not successful in brand name drugs in forcing competitive pricing. They have not been successful in that. They have not been successful in preventing drug prices from going up more rapidly than the rate of inflation by a substantial amount. All right.

The best thing they've got going for them that's reflected in the fact that generics always get put in tier one in the formularies is generic entry. That is by far the most important competitive factor affecting drug prices, is whether there's a generic available. And that's more powerful than Blue Cross or Aetna or UnitedHealthcare or even the federal government.

JUDGE CHAPPELL: But doesn't Blue Cross determine what's in tier one for Blue Cross?

THE WITNESS: They do. And it's all -- if there's a generic, it's always the generic.

MR. HASSI: Should I continue, Your Honor?

BY MR. HASSI:

Q. Sir, you've not analyzed how frequently

patients are successfully switched from one opioid --

A. I'm sorry. I couldn't hear.

Q. You have not analyzed how frequently patients are successfully switched from one long-acting opioid to another; correct?

A. No.

Q. And you acknowledge that demand for oxymorphone increased -- oxymorphone ER increased after generic entry because new patients who were previously taking other long-acting opioids began taking oxymorphone; correct?

A. That's correct.

Q. So when generic oxymorphone became available, people switched from other long-acting opioids to generic Opana ER; correct?

A. To some degree. It was very small, but it happened.

Q. And you acknowledge that Opana ER experienced its highest loss rate in 2012 because physicians switched their patients to other long-acting opioids; correct?

A. I didn't hear the beginning of the question. I'm sorry.

Q. You acknowledge that Opana experienced its highest loss late in 2012 because physicians switched

their patients to other long-acting opioids; correct?

A. In part. That -- remember, switch here is not what you're talking about in terms of switching the same patient. This is about new patients as well.

And some of what happened was, unfortunately, people who abused drugs switched to heroin, all right, because this was -- the reformulated product was crush-resistant. And the same thing happened to OxyContin.

So the degree to which the patient -- the demand for other opioids went up we can actually tell by looking at what happened to sales of other long-acting opioids in the period that the market for Opana ER was shrinking in 2012. And it turns out the market for all opioids was shrinking then, because that was well into the opioid crisis, and in fact people were prescribing fewer opioids of all kinds.

Q. Sir, did I understand you correctly that you believe that people who left Opana ER prescribed for them in 2012, some of them left for heroin?

A. In general, the decline in the -- in the sales of opioids -- we don't know how to unpack this by LAO versus LAO, but part of what happened with the decline in total sales of long-acting opioids in this period was switching to heroin. And that's documented in

these -- in the various government studies of the opioid crisis, some of which I cited in one of my reports. I don't remember which one.

Q. So I think you just said you can't unpack where people are going among long-acting opioids; is that right?

A. You cannot unpack -- I don't -- I'm not aware at least, my own knowledge, of information about which -- how many of people from each of the long-acting opioids who switched to either -- some form of illegal drugs, heroin or illegally imported fentanyl or whatever. I don't -- I don't know how to -- how to allocate that among each of the long-acting opioids. What I can say is that all of them were declining in sales during this period collectively.

Q. Now, you base your assessment of switching costs primarily on the reports of Dr. Savage and Dr. Michna; is that right?

A. That's correct.

Q. Your report does not contain any empirical work on switching costs; is that correct?

A. It has no empirical estimate of a specific effect of switching costs as opposed to just what the overall degree of competition in price is.

Q. And you refer to switching costs as high, but you've not done any empirical work on the cost associated with switching a patient from one long-acting opioid to another; correct?

A. I haven't quantified what the magnitude of the switching cost is because it involves elements I can't possibly measure.

Q. And so you can't quantify what you mean by "high" when you say switching costs are high; correct, sir?

A. No, I can't put a quantification on it, but I can certainly put a lower bound on it.

Q. And you're aware that Drs. Savage and Michna agree that patients are switched from one long-acting opioid to another all the time; correct?

A. They are. And they're the ones getting the X dollars per visit to monitor the switching, which is the switching costs -- part of the switching costs.

Q. Are you suggesting that they're switching people in order to make -- put more money in their pockets?

A. No. I'm saying this is a cost. What I'm saying is, if clinically there's some good reason to switch someone from one opioid to another, it's done under the care of a physician, and that's costly.

Q. And switches are performed for a variety of reasons; right?

A. Yes.

Q. For example, when physicians first start patients on a particular long-acting opioid, they test it to see how it's tolerated and opt to switch to another opioid if the first one that they try for that patient doesn't work so well; correct?

A. That's true to some degree. Yes.

Q. And you're aware that Dr. Savage testified that choosing which opioid to prescribe is often a matter of physician preference; correct?

A. Actually, they both testified more or less to that effect, that physicians' habits and experiences influence their choice, which is another -- another impediment to price competition.

Q. You're aware that Dr. Savage testified that it's common for patients who are on an IV of one long-acting opioid are given a different long-acting opioid in tablet form when they leave the hospital?

A. I'm not sure I understand the process quite the way you described it. I mean, I think I agree with what you're saying, but I wouldn't have used those words.

Q. Well, you agree that -- strike that.

Long-acting opioids -- or excuse me.

Opioids are sometimes used in IV form in the hospital setting; right?

A. Those are usually not long-acting.

See, that's the -- one of the advantages that oxymorphone has compared to some of the other drugs is that it actually is used in an immediate-release form in -- inside the hospital in IVs, and so if you've already figured out the dose for and you've already found out that the patient can tolerate this particular long-acting -- this particular opioid, then when you switch from intravenous or some other immediate-release form -- it could be a pill inside the hospital -- to the long-acting form, you know that the tolerance test has already been passed. And that's an advantage that drugs have if they're in this category that are used inside the hospital.

Q. And yet notwithstanding the fact that the patient may have already passed the tolerance test, physicians very often switch which molecule is used when the patient leaves the hospital; correct?

A. That's -- yes, they do.

JUDGE CHAPPELL: It's approaching 5:45. It's been long day.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: We're going to recess and reconvene tomorrow morning at 9:45.

(Whereupon, the foregoing hearing was concluded at 5:42 p.m.)

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