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

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

October 24, 2017

10:04 a.m.

TRIAL VOLUME 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Chief Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Josett F. Whalen, Court Reporter

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FEDERAL TRADE COMMISSION

I N D E X

IN THE MATTER OF IMPAX LABORATORIES, INC.

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PUBLIC RECORD

OCTOBER 24, 2017



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P R O C E E D I N G S

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JUDGE CHAPPELL: Okay. Let me call to order Docket 9373.

I'll start with the appearances of the parties, government first.

MR. LOUGHLIN: Good morning, Your Honor.

Charles Loughlin on behalf of complaint counsel.

With me at counsel table is Maren Schmidt and Terri Martin.

MS. SCHMIDT: Good morning, Your Honor.

JUDGE CHAPPELL: For respondent?

MR. HASSI: Good morning, Your Honor.

Ted Hassi for --

JUDGE CHAPPELL: Is it "Hassi" or "Hassi"?

MR. HASSI: It's "Hassi," Your Honor. At least that's the way I grew up pronouncing it.

JUDGE CHAPPELL: It's your choice.

MR. HASSI: Thank you.

With me is Mike Antalics, also from O'Melveny & Myers, Robert Newcombe, our hot seat operator.

And if I might just introduce the rest of my team.

Farschad Farzan, who is with Impax Labs --

JUDGE CHAPPELL: Find a mike. She needs to hear you.

MR. HASSI: Stephen McIntyre from O'Melveny & Myers.

Eric Goldstein, O'Melveny & Myers, Eileen Brogan and Ciara Moran and Dexter Pagdilao.

JUDGE CHAPPELL: Who are the two that didn't stand?

MR. HASSI: I'm sorry, Your Honor?

JUDGE CHAPPELL: Who are the two that didn't stand?

MR. HASSI: These are my paralegals, Your Honor.

JUDGE CHAPPELL: All right. Thank you.

That was the only way I could identify you. I didn't care if you stood while you were being introduced in the first row.

Mr. Loughlin -- is it "Loughlin" or "Loughlin"?

MR. LOUGHLIN: "Loughlin," Your Honor.

JUDGE CHAPPELL: Like an F, F sound. I want to get it right today.

I have a question. I understand that what we have here is a case involving an agreement of two companies, a patent holder and the generic entrant;

correct?

MR. LOUGHLIN: Yes, Your Honor.

JUDGE CHAPPELL: The patent holder is Endo.

MR. LOUGHLIN: Yes.

JUDGE CHAPPELL: I'm looking out here and I don't see any Endo.

MR. LOUGHLIN: Correct, Your Honor. We settled with Endo for --

(Audio difficulty.)

JUDGE CHAPPELL: You were telling me about Endo.

MR. LOUGHLIN: Yes. Endo reached a consent decree settlement with the FTC in I think January of this year, so they're out of the case.

JUDGE CHAPPELL: A consent decree.

MR. LOUGHLIN: Yes, Your Honor.

JUDGE CHAPPELL: So therefore, there was an administrative complaint against Endo?

MR. LOUGHLIN: It was a -- I believe it was a -- it was in federal court, Your Honor.

JUDGE CHAPPELL: Okay. What I need to know -- I don't care about that. What I want to know is, is there any written or unwritten agreement with Endo regarding the government's prosecution of this case or respondent's defense in this case?

MR. LOUGHLIN: There is a written consent decree and I believe preliminary injunction entered by the court.

JUDGE CHAPPELL: I'm getting at whether there's anything in any agreement written or otherwise that provides assistance to the government to prosecute this respondent or has anything to do with the respondent's defending itself in this case.

MR. LOUGHLIN: Oh, I see, Your Honor.

Yes. As part of that agreement, Endo did commit to cooperate with the FTC.

JUDGE CHAPPELL: Is anything in writing?

MR. LOUGHLIN: I believe that agreement is in writing, Your Honor.

JUDGE CHAPPELL: I want a copy of that. It will be in camera.

MR. LOUGHLIN: Okay. We're happy to submit that.

JUDGE CHAPPELL: Does respondent have a copy of that?

MR. HASSI: Your Honor, I believe it's a public document. I believe I've seen it. Yes.

JUDGE CHAPPELL: It might be, but I want a copy in my hand.

MR. LOUGHLIN: Okay.

JUDGE CHAPPELL: Thank you.

I have a few evidentiary rulings and procedural issues to address. Most of those I will leave after opening statement. I am going to deal with one matter before I hear opening.

I note that on August 3, 2017, complaint counsel filed a motion for partial summary decision with the commissioners. These would be the same commissioners that voted out the complaint finding that they had reason to believe respondent -- respondent's conduct had violated the FTC Act.

In this motion, complaint counsel, whose job it is to prosecute the case, asked the two commissioners to determine that certain of respondent's asserted procompetitive justifications for the challenged agreements in this case are invalid as a matter of law, in other words, attempting to strike defenses before the trial even began.

There's been no ruling on that as of today. We are starting trial today on the merits. Respondent has a right to know what defenses they may assert, including affirmative defenses.

This is a rule of reason case. Key questions in such a case include whether there are actual or likely anticompetitive effects and whether such

anticompetitive effects are outweighed by procompetitive effects.

Accordingly, respondent will not be prevented from introducing evidence as to asserting procompetitive benefits. Respondent has a right to defend itself in this proceeding in front of this judge.

With that in mind, you may proceed with opening statements, government first.

MR. LOUGHLIN: Your Honor, before we start with opening statements, can I do a couple of housekeeping matters? We do have a JX 1 --

JUDGE CHAPPELL: Those are the evidentiary matters I'll deal with after.

And by the way, a diligent search was done for any document pertaining to a settlement agreement regarding the prosecution or defense of this case on the FTC's public website that came up with nothing, so if it's out there and it's public, I suggest someone put it on the website for the public to see.

MR. LOUGHLIN: Okay.

JUDGE CHAPPELL: That might be below your pay grade, Mr. Loughlin, but I'm sure you could make that happen.

MR. LOUGHLIN: I will work on that,

Your Honor.

Your Honor, I have copies of our PowerPoint slides that I'll be using in today's opening. I'm happy to hand those up if you'd like.

JUDGE CHAPPELL: Provide them to my staff, please. You're going to have slides. I'll watch the monitor.

MR. LOUGHLIN: Your Honor, may I approach?

JUDGE CHAPPELL: Yes.

Can you put a test slide up so we can check all the monitors.

Go ahead.

MR. LOUGHLIN: Thank you, Your Honor.

As the court noted, this is a case about a reverse payment settlement agreement. It's a case about a branded pharmaceutical company called Endo Pharmaceuticals paying the respondent Impax to end its patent challenge and agree not to enter the market for two and a half years from June of 2010 to January of 2013.

Now, there's no dispute in this case that the parties entered a settlement agreement in June of 2010.

There's no dispute that, pursuant to the terms of that settlement, Endo ultimately paid Impax

$102 million pursuant to a provision called the Endo credit.

There's no dispute that Endo paid Impax $10 million upon signing the agreement pursuant to a related development and co-promotion deal.

And there's no dispute that, pursuant to the settlement, Impax agreed not to launch its generic product until January 1, 2013, two and a half years after the settlement.

Now, what you're going to see from the evidence is that Impax went into the settlement negotiations seeking the earliest entry date it could get. By contrast, Endo went into the negotiations trying to put off generic entry as long as possible.

Now, despite that key area of divergence, you're not going to see much negotiation over the entry date in the settlement. Instead, what you're going to see is negotiation over money. You're going to see negotiations over the payments that Endo would make to Impax to get Impax to agree to an entry date in 2013.

Now, as a result of that settlement agreement, Endo and Impax prevented the risk of generic competition between June of 2010 and January 1, 2013, the date of generic entry under the settlement.

The payment to prevent the risk of competition between June of 2010 and January 1, 2013 is the relevant antitrust harm from this settlement.

That harm occurred, it occurred between June of 2010 and January 1, 2013, and that is the harm that is directly at issue in the Supreme Court's decision in FTC v. Actavis, 133 S. Ct. at 2223.

JUDGE CHAPPELL: And the date of that Supreme Court decision was what?

MR. LOUGHLIN: It was in 2013, Your Honor.

JUDGE CHAPPELL: And the government's position is anything that occurred prior to that decision is fair game.

MR. LOUGHLIN: Yes, Your Honor.

JUDGE CHAPPELL: Let me ask another question.

If the government is correct here, the result of what you want to do is you want more, not just more but cheaper opioid drugs on the market in the United States. Am I correct?

MR. LOUGHLIN: Your Honor, what we want is --

JUDGE CHAPPELL: That was yes or no.

As a result of what you want, if this deal hadn't happened, the government would have liked to have had more and cheaper opioid drugs on the market in the United States; correct?

MR. LOUGHLIN: Not exactly correct, Your Honor. What I would say is that what is complaint counsel's position is that we would like competition to dictate whether there's going to be generic entry or not, not payments from a branded company to a generic.

JUDGE CHAPPELL: So the fact we're dealing with what is generally recognized as the most abused drug in America is of no import here?

MR. LOUGHLIN: That's a matter for the FDA to determine, and what the FDA does with those drugs is certainly of import. But from the perspective of competition, we are here today to prevent agreements between branded and generic pharmaceutical companies that interrupt the competitive process.

The outcome of that process, whether there's actually going to be a generic on the market or not, is unclear. In any particular case, we don't know what's going to happen.

But what the Supreme Court does in Actavis and what we are trying to do here today is to protect that competitive process, to protect competition, Your Honor.

And as a result, we are asking this court to find that under FTC v. Actavis, the settlement violated

section 5 of the FTC Act and to enter an order prohibiting respondent from entering into such reverse payment settlements in the future.

JUDGE CHAPPELL: So wait a minute. Let me -- I just heard you say that you want the court to find under FTC v. Actavis the settlement violated section 5 of the FTC Act, so your entire case is based on the Actavis ruling.

MR. LOUGHLIN: The Actavis ruling and cases subsequent to Actavis which have interpreted Actavis.

JUDGE CHAPPELL: All right.

MR. LOUGHLIN: But certainly we believe that the Supreme Court's decision in Actavis is the fundamental decision that governs this case.

JUDGE CHAPPELL: Well, let's talk about Actavis. I know that I've seen all the press releases and the FTC figure, you know, goes around doing the touchdown celebration after that case.

But didn't that case -- all it did really, although it provided a lot of guidance, it said to the FTC, you don't get thrown out on a dismissal every time you bring one of these cases.

So the Supreme Court said okay, you don't get thrown out automatically every time, we're not going to allow that, we're going to do some analysis using the

rule of reason. Do I have that right?

You didn't win the case. You just got to bring the case. Am I correct?

MR. LOUGHLIN: Yes, Your Honor.

JUDGE CHAPPELL: That's what actually happened, you were able to bring the case, because it had been dismissed by a district court and a court of appeals; correct?

MR. LOUGHLIN: Correct. And the Supreme Court overturned that motion to --

JUDGE CHAPPELL: I just want to get the procedure correct since you're telling me how big Actavis is for your case, Counselor.

MR. LOUGHLIN: Yes, procedurally you are correct. That was a reversal of a motion to dismiss, and in that decision the Supreme Court laid out the framework for assessing reverse payment settlement agreements.

JUDGE CHAPPELL: We agree there.

MR. LOUGHLIN: And pursuant to that framework, we believe there is a violation of the FTC Act in this case.

And as a result, Your Honor, as I mentioned, we are asking the court to prohibit Impax from entering into reverse payment settlements in the

future.

And that is an important issue because respondent is an active generic pharmaceutical company. It will likely find itself involved in patent challenges on ANDAs with branded companies in the future. And we believe an order to prevent Impax from settling with reverse payment agreements is important to prevent harm to competition in the future.

Now, Your Honor, as I mentioned and as the court indicated in the beginning, the branded pharmaceutical company in this case is a company called Endo Pharmaceuticals.

Endo sold a product called Opana ER. And as the court recognized, Opana ER is an extended-release opioid product used to treat chronic pain. The generic name is oxymorphone ER. And there's a picture of the pills.

Impax filed with the FDA to market generic Opana ER in 2007. It was the first to file with what is known as a Paragraph IV patent challenge on the five most popular dosages, the 5, the 10, the 20, the 30 and the 40.

Now, Endo sued for patent infringement, which triggered a 30-month stay before the FDA could grant

final approval of Impax' generic. The 30-month stay was set to expire on June 14, 2010.

About a month before that, in mid-May 2010, Impax got tentative approval from the FDA. That meant that it was expected to get final approval, final marketing approval, as soon as the 30-month stay expired on June 14, 2010.

Now, if it launched its generic, Impax would be entering as the first AB-rated generic on the five most popular dosages of Opana ER.

An AB rating means that a pharmacist can automatically substitute the generic for the brand without having to go back and check with the prescribing doctor. And pharmacists generally do that because generics cost less and health insurance companies encourage that kind of substitution to save money.

And as a result, it is well-understood that AB-rated generics can take up to 90 percent of brand sales within months.

JUDGE CHAPPELL: Let me ask you something.

You say Impax filed with the FDA to market a generic in 2007.

Did any other generics, any other generic companies, file at the same time? Because I think it's

common knowledge that often you have more than one file.

MR. LOUGHLIN: There was another company called Actavis which was the first generic filer on the 7.5 dosage and the 15 milligram dosage. But Impax was the very first filer on the five most popular dosages. Other generics did file later.

JUDGE CHAPPELL: So were there any other generics other than respondent who had this thing worked through, gotten -- if things had spun the right way, gotten the 180-day exclusivity period?

MR. LOUGHLIN: No. Impax was the only company that was the first filer and got the 180-day exclusivity period on those five most popular dosages.

And as Your Honor pointed out, because of the 180-day exclusivity period, launching would have been very lucrative for Impax.

And in fact, Impax in early 2010 was taking active steps to be ready to launch a generic version of Opana ER.

It had gotten the necessary DEA approval to purchase the active ingredient. And that approval was necessary because oxymorphone is a controlled drug substance by the DEA, but it had gotten approval.

It had actually bought the active ingredient.

It had validated its commercial manufacturing process.

It had produced pills for a commercial launch.

It had prepared the packaging for a launch.

It had created sales forecasts.

It had gotten letters of intent from customers stating that they were willing to buy Impax' generic.

And it had spent millions of dollars on these preparations.

The only thing standing in the way of a launch was getting the FDA approval on June 14, 2010 and getting a decision by Impax' board of directors to actually go ahead and launch.

Now, we don't know if Impax would have launched on June 14, 2010. Impax never actually made that decision because it settled the patent case instead and agreed not to launch until January 1, 2013.

At the time that Impax entered the settlement discussions in May of 2010, it was not thinking about settling for an entry date in 2013.

Just before Impax entered settlement discussions in mid-May of 2010, Impax' CEO, Dr. Larry Hsu, sent an e-mail to Chris Mengler. Mr. Mengler was the president of Impax' generic

division, and he would ultimately become the primary negotiator of the settlement on behalf of Impax.

And Dr. Hsu asked whether Impax should try to settle with Endo for an entry date in January 2011 in exchange for Endo's agreement to a no-AG provision.

Now, a no-AG provision means an agreement by Endo not to launch an authorized generic of Opana ER for the first six months after Impax launched.

Now, as I mentioned, Impax was the first generic company that had 180-day exclusivity on the five most popular dosages of Opana ER. What that meant was that the FDA would not approve any other generic version of Opana ER in those five most popular dosages until 180 days after Impax began marketing.

That's very valuable. It's well-accepted that generics can make a substantial portion of their total sales during that 180-day exclusivity period.

But that marketing exclusivity only prevents the FDA from approving other generics during the 180-day exclusivity period. It doesn't stop a brand from launching its own generic during that period, and that is known as an authorized generic.

Now, the reason that brands launch authorized generics is to try to get back some of the sales that would otherwise be lost to the generic.

And in fact, the contemporaneous documents show that in 2010 Endo was planning to launch an authorized generic if a generic version of Opana ER appeared on the market. It had prepared some generic pills to be ready to launch. And it was drawing up forecasts of how much revenue it would expect to earn from an authorized generic.

JUDGE CHAPPELL: Let me ask you about this authorized generic process.

A doctor writes a prescription for an opioid, and you're in a state where generic substitution is allowed, actually demanded probably, not just allowed. And let's say there are three generic equivalents for that opioid.

Who decides which brand of opioid the patient gets? Is it the insurance company or the pharmacist?

MR. LOUGHLIN: It is -- who decides which generic version to --

JUDGE CHAPPELL: Yes.

MR. LOUGHLIN: It's the pharmacist.

So, typically, the pharmacy will have a contract with a specific generic manufacturer to buy generics from that manufacturer, and whichever company it has a deal with, it will dispense that generic.

JUDGE CHAPPELL: So if I'm a patient and there

are three generic opioids available that are equivalent, one could cost a nickel a pill, one could be $5 a pill, but if my pharmacy has decided I'm going to get the $5 a pill, that's what I get and that's what I pay for?

MR. LOUGHLIN: Yes, Your Honor. But pharmacies generally try to have the generics compete with each other for the lowest price, so if there are three generic companies all selling generic versions of Opana ER, they would be competing for that pharmacy's business and offering the lowest price.

Now, what the pharmacy charges to the patient is up to the pharmacy. You're right.

Now, getting back to authorized generics, in fact, in this case, Endo forecasted that it would launch an authorized generic if generic versions of Opana ER appeared, and it forecast that it would gain about $25 million in authorized generic sales.

JUDGE CHAPPELL: And just so we're clear, what you're telling me right now, Counselor, is what Endo knew, not what respondent knew?

MR. LOUGHLIN: Yes. I'm telling you from the perspective of Endo, it believed that it would recover about $25 million if it launched an authorized generic.

Now --

JUDGE CHAPPELL: Well, you also said Endo forecasted it would launch; is that correct or a misstatement? It was going to launch.

MR. LOUGHLIN: The documents show that it was forecast -- that it had prepared pills to launch and that it would -- that it had forecasted sales that it would earn if it did launch.

Now, it hadn't decided to launch. It wasn't going to launch unless a generic version appeared in the market.

Now, Impax also was modeling what an authorized generic would do to its sales. Impax projected that if it launched its generic Opana with competition from an authorized generic, it would earn about $25 million -- $28.5 million.

JUDGE CHAPPELL: And so we're clear, now you're talking about what Impax knew, not what Endo knew.

MR. LOUGHLIN: Right. This is an internal Impax document with its own projections for authorized generic effects on its product.

And you'll see in the second line that it's projecting that if an AG launched after -- about two to four weeks after Impax launched, it would earn about

$28.5 million in profit in the first six months on the market, in other words, during the 180-day exclusivity period.

By contrast, if there was no AG, it would earn about $53 million in profit in the six months after launch.

And the reason for those different forecasts are two.

The first is that the first filer without generic competition of course gets all the generic sales rather than having to share with another generic.

The second is that without competition from another generic, the first filing generic's price is higher during the 180-day exclusivity period than it otherwise would be. Now, it's still lower than the branded price, but it's generally higher than if there were additional generic competitors during that period.

And as a result, a no-AG provision is very valuable to the generic company.

And so when Impax' CEO proposed internally that Impax try to settle for a January 2011 entry date in exchange for a no-AG agreement from Endo, the president of Impax' generic division, Chris Mengler,

said, "I'd love that."

Now, from Endo's perspective, Endo knew that Impax had gotten tentative approval in May of 2010.

In fact, a stock analyst sent a news article to Endo about it with the only message being an exclamation point. And that e-mail was forwarded to Endo's CEO at the time, Dave Holveck, and its CFO, Alan Levin, so this was important news.

It was important because Endo understood that getting tentative FDA approval meant that Impax likely would get final approval in June of 2010 when the 30-month stay related to the patent litigation expired.

And Endo understood what generic entry would do to sales of Opana ER.

Endo had projected that generic entry would cost it about 84 percent of Opana ER sales.

Now, this is from 2009 when Endo is projecting generic entry in July of 2011. And what you'll see is that sales go from $205 million in 2010 down to $32 million in 2011. That's a decline of 84 percent.

But Endo also projected in another document that each month after June of 2010 that generics stayed off the market was worth an additional $20 million per month in revenues to Endo.

Now, to be clear, complaint counsel is not asserting that absent this settlement Impax absolutely would have launched its generic Opana in June of 2010. We don't know what Impax would have done.

The point is that Impax was making preparations to be in a position to launch if that's what it chose to do.

JUDGE CHAPPELL: You mean an at-risk launch.

MR. LOUGHLIN: An at-risk launch, Your Honor, that's right.

And in May --

JUDGE CHAPPELL: Because I'm trying to figure out, you know, along a time continuum, had Endo at this point in your -- in your story to me, at this point had Endo already filed an infringement case?

MR. LOUGHLIN: Yes. So --

JUDGE CHAPPELL: So it was clearly -- it would clearly be an at-risk launch.

MR. LOUGHLIN: It would be an at-risk launch.

When Impax filed in 2007, Endo shortly afterwards filed a patent infringement suit. That led to a 30-month stay under which the FDA could not approve Impax' generic. That stay was about to expire in June of 2010, right around the time the patent trial was about to start.

The patent trial was about to start on June 3, 2010, and the final approval was expected on June 14, 2010.

JUDGE CHAPPELL: So it took 30 months to get the case to trial for the trial date?

MR. LOUGHLIN: No, Your Honor. Under the Hatch-Waxman Act -- yes, I think you're right. That is true technically.

Under the Hatch-Waxman Act, the FDA has a -- the Hatch-Waxman Act provides a 30-month stay under which the FDA cannot approve the generic product. And you're right, under this case, it did take about 30 months for the case to get from filing to trial, just about 30 months.

But at that point, as I mentioned, Impax was making preparations to launch. In mid-May of 2010, it was weeks away from having regulatory approval to launch. And at that time Endo understood the risk that a launch by Impax would pose to its sales.

And the risk of an AB-rated version of Opana being launched was a very big deal to Endo. It was a big deal because, at the time, Endo was essentially a two-product company.

It had a product called Lidoderm, which is a patch you put on your skin to reduce pain. And it had

Opana ER, the product at issue in this case.

So losing one of its two biggest products to generics was a very big deal.

It was also a big deal to Endo for a second reason.

At this time Endo was in the process of trying to extend the life of Opana ER by reformulating it. It was trying to create what it claimed was a tamper-resistant formula. And in May of 2010 it was close to filing an NDA with the FDA for a tamper-resistant formulation and expected to launch in 2011.

JUDGE CHAPPELL: Let me ask you a question.

You said that Endo had projected to lose $20 million a month in sales if a generic launched.

MR. LOUGHLIN: No. Endo projected that if -- for every month after June of 2010 that a generic did not launch, it would earn an additional $20 million in revenue.

JUDGE CHAPPELL: Without the competition.

MR. LOUGHLIN: Without competition. In other words, that every month without generic competition was worth an additional $20 million a month in revenues.

JUDGE CHAPPELL: All right. Regarding that,

to put that in some perspective, what kind of a number is that to a company like Endo? Is that an asterisk on their balance sheet? Is this the only product they've got? What about their drug portfolio? Was this a significant amount to Endo, or are they a huge megalith where it doesn't matter, it's just chicken feed?

MR. LOUGHLIN: No. No. Endo was basically a two-product company. Its two biggest products were Opana ER, this product, and a product called Lidoderm, so this was a -- this was a potential generic entry to its second biggest product.

JUDGE CHAPPELL: And its other product was still under patent?

MR. LOUGHLIN: Yes, Your Honor.

And at this time, as I mentioned, Endo was in the process of trying to reformulate, to extend the life of Opana ER with a new so-called tamper-resistant formula.

But what Endo knew was that if the market -- if it launched after generics came on the market, the market would go for -- Opana ER would go generic and then Endo would never get that market back.

JUDGE CHAPPELL: You mean for the branded drug.

MR. LOUGHLIN: That's right, Your Honor, for the branded -- for the new reformulated product that it wanted to launch, it would never get -- it would never recover that market.

Here's a -- this is a presentation --

JUDGE CHAPPELL: Wait a second.

That wasn't what I asked you.

MR. LOUGHLIN: Okay.

JUDGE CHAPPELL: When you're saying they wouldn't get the market back, I wasn't talking about this new crushproof, reformulated drug that was out there in the Netherland at the time, at least as far as respondent was concerned.

Endo's position was they would never get the market back for Opana ER or for the crushproof or any -- for any opioid in this category?

MR. LOUGHLIN: For both original Opana ER and the reformulated Opana ER.

In other words, what happens is that and what Endo believed was that if -- what it wanted to do was launch its reformulated Opana ER, switch patients away from the original Opana ER to the reformulated version. That takes time.

JUDGE CHAPPELL: And cooperation of physicians.

MR. LOUGHLIN: And cooperation of physicians. It would have to go and detail physicians, market to physicians and get them to write prescriptions for the new reformulated product.

JUDGE CHAPPELL: If I'm not going to crush it and sniff it, why do I care if its crushproof? If I'm the patient and the doctor says, Well, there's a generic that's five cents a pill, but we've got this crushproof here, it's still $10 a pill. I'm going to set you up with the $10 a pill.

MR. LOUGHLIN: You're exactly right. And that's why --

JUDGE CHAPPELL: What I'm getting at, was Endo in fantasyland, thinking that people would want to buy this expensive version just because it was crushproof? I'm talking about legitimate people that were actually taking the medication for pain relief rather than drug abuse.

MR. LOUGHLIN: No, Endo was not in fantasyland. Endo -- what Endo's position was is that it was trying to get its reformulated product on the market before there were generic versions of Opana ER, original Opana ER.

In other words, what Endo knew was that if original Opana ER went generic before it launched its

reformulated, the market was gone. It was not going to be able to do exactly what you're suggesting. It was not going to be able to convince doctors to prescribe a more expensive, reformulated product in place of a generic to the original.

And so what it needed to do was get its product on the market before generic entry, shift customers from branded original Opana ER to branded reformulated Opana ER, and then when the generic version of the original came on, there was no market left. That was the idea.

JUDGE CHAPPELL: Which is why a branded company generally will launch their own generic.

MR. LOUGHLIN: The reason the generic -- yeah. The reason a branded company will launch its own generic is that, regardless of the reformulation issue, it will try to recover some of those sales that would otherwise be lost to the original -- to the generic to the original formulation. Yes.

So the launching of your own product is a strategy not to reformulate, it's a strategy when a generic comes on to your product and the brand wants to recover some of those sales, it will launch its own generic to compete.

JUDGE CHAPPELL: Or another strategy, which

doesn't apply in this case with opioids, where they get the FDA to approve over-the-counter, then they reap untold millions that way.

MR. LOUGHLIN: That's another strategy as well, Your Honor.

Your Honor, this document explains that I think quite well.

This is a document from Endo from January 2010. And you see the title of the document is EN3288 Forecast Scenarios.

Now, EN3288 was Endo's internal code for the reformulated version of Opana ER.

And what you'll see is that the chart is assuming generic entry in early 2011. That's the first pink line that you see.

Now, the yellow line going up to the right --

JUDGE CHAPPELL: I don't see a pink line. I see a pink column.

MR. LOUGHLIN: A pink column, yes, Your Honor. Sorry. The first pink column is generic Opana ER in early 2011.

So what you see from the yellow line, that is reformulated Opana ER. And what this shows, you're seeing, is that if they launch the reformulated product before 2011, what they'll do, what their plan

is is to shift sales away from the original Opana ER -- that's the green line -- and sales of original Opana ER will decline dramatically.

Meanwhile, sales of reformulated Opana ER under the yellow line continue to go up. And they continue to go up even after generic entry. That's because the generic entry presumably is an AB-rated version of the original Opana ER, not the reformulated Opana ER.

JUDGE CHAPPELL: What does it mean where it says "No Claims" or "With Claims"? What claims?

MR. LOUGHLIN: Your Honor, I believe they mean insurance -- prescriptions, insurance claims.

I'm sorry, Your Honor. I'm being told that it's claims that it is actually tamper-resistant.

But the point is, the product, the yellow line, will continue to grow even after generic entry to the original product, because at this point the market has been switched from the original to the reformulated.

Now, the chart also shows what Endo projected if it launched its reformulated product around the same time the generic versions of original launched. That's the black line at the bottom.

And what that shows is that Endo understood

that if it couldn't launch its reformulated version until right around generic entry of the original, it would only make a fraction of the sales that it had made under the original Opana ER.

JUDGE CHAPPELL: Doesn't the chart also show that generic entry by respondent foiled their plans of Endo, because they didn't just keep gaining market share for the branded drug, and consumers were given a lower-priced alternative, so this chart never came into play, these projections were wrong, because Impax introduced the generic drug?

MR. LOUGHLIN: No, Your Honor. This -- this chart is being done in January of 2010.

JUDGE CHAPPELL: This is a projection.

MR. LOUGHLIN: It's a projection, exactly.

JUDGE CHAPPELL: And this is not what happened, right.

MR. LOUGHLIN: It is not what happened, you're right. That's correct. But it has nothing to do with Impax.

JUDGE CHAPPELL: This projection was completely wrong; correct? Or we'll never know?

MR. LOUGHLIN: We'll never know because generic entry happened in 2013, not 2011, under the settlement.

But understanding this phenomenon, Your Honor, and knowing that Impax had just gotten tentative approval in May of 2010, Endo needed time. It needed time to get FDA approval of its reformulated Opana ER and to switch patients to the reformulated product before generic Opana ER entered the market. That's because they wanted to get the yellow line and not the black line.

And so to get more time, time to launch the reformulated product and switch patients to that product before generic entry, Endo approached Impax about settling.

Impax -- Endo proposed a no-AG provision, just as we saw that Impax wanted. But it suggested an entry date in March of 2013, over two years after the January 2011 date that Impax had been looking for internally.

JUDGE CHAPPELL: Who proposed the no-AG provision originally?

MR. LOUGHLIN: Your Honor, in terms of the discussions, we don't know. But the first document with that provision is in a document from Endo. It's a term sheet that Endo sent to Impax with a March 2013 entry date and a no-AG provision in it.

JUDGE CHAPPELL: But if you were entering into

a deal like this, of course you would want a no-AG provision if you're the generic, wouldn't you?

MR. LOUGHLIN: Absolutely.

Now, when Impax got this proposed March 2013 entry date with a no-AG provision, it was concerned about that entry date, both because the date was two years later than what it had wanted and because it suspected what Endo was up to.

Impax believed that Endo was planning to launch a reformulated version of Opana ER and to try to shift the market before Impax could launch its generic.

And Impax feared that if Endo reformulated, its generic would not be AB-rated to Endo's reformulated product; and therefore, it would be much harder for Impax to make generic sales even with the 180-day exclusivity and even with a no-AG agreement.

JUDGE CHAPPELL: Now, wait a second. You're telling me now what Impax believed. And I have read the trial briefs. And we don't have any evidence yet. But you're going to prove at this point Impax believed that Endo was going to launch the reformulated Opana?

MR. LOUGHLIN: Mr. Mengler, who was the president of Impax' generic division and was the primary negotiator, has testified in this case and we

presume will testify again at trial that he was concerned, that he believed that they were going to launch a reformulated product, that he said that to Endo during the negotiations.

JUDGE CHAPPELL: And was he told by Endo that they were not going to launch a reformulated drug?

MR. LOUGHLIN: Yes, he was told that. And he didn't believe it.

JUDGE CHAPPELL: But he was told that.

MR. LOUGHLIN: He was told it.

JUDGE CHAPPELL: No dispute there?

MR. LOUGHLIN: I don't believe there's a dispute that --

JUDGE CHAPPELL: All right.

MR. LOUGHLIN: -- that Endo said no, we're not going to launch a reformulated product.

But he didn't believe it. And that's why he insisted on getting the Endo credit.

JUDGE CHAPPELL: Are you talking about the negotiator for Impax?

MR. LOUGHLIN: Yes.

JUDGE CHAPPELL: Well, if he's worth his salt, he's going to suspect things like that. That's his job.

MR. LOUGHLIN: I agree.

Now, in response -- because of Endo's -- excuse me. Let me start that over.

Because Impax was concerned about the potential launch of a reformulated product by Endo before it could get on the market with its generic, Impax responded to Endo's proposal of a March 2013 entry date.

And this is Mr. Mengler responding to Endo. And he proposed an entry date of January 1, 2013 with no authorized generic and acceleration triggers. This was an acceleration provision that would allow Impax to enter earlier in January 2013 if Endo launched a reformulated product that lowered the value of the original Opana ER market.

Now, rather than allowing for the possibility of earlier entry under an acceleration provision, Endo put more money on the table. And as a result, the negotiations shifted away from discussing possible earlier entry by Impax to -- and it moved to ways to compensate Impax if Endo launched a reformulated product.

And the parties worked out what is sometimes referred to in the parties' documents as a make-good payment or a make-whole provision.

And here's an e-mail from Mr. Mengler, dated

June 3, 2010, reporting on the current status of the negotiations with Endo. And the current proposal was that they enter on January 1, 2013, and they had a provision that if the units, meaning the units of Opana ER, Endo's Opana ER, declined by more than 50 percent at launch that a make-whole provision would kick in to protect Impax.

The basic idea here was that the no-AG and the make-whole provision would work hand in hand to ensure that Impax got the value that it expected out of the settlement.

And so if Endo didn't launch a reformulated product and didn't shift the market away from original Opana ER, then Impax would launch its AB-rated generic of Opana ER on January 1, 2013. It would get the value that it expected from its 180-day exclusivity period by selling AB-rated generic Opana ER without competition from Endo's authorized generic.

But if Endo did launch reformulated Opana ER and reduce the market for original Opana ER, then Impax would get value from the make-good cash payment from Endo.

This make-good payment or this make-whole provision became a term in the settlement called the Endo credit. The Endo credit sets forth a mathematical

calculation to determine the make-whole payment from Endo to Impax.

JUDGE CHAPPELL: And just so we're clear, there was no payment guaranteed unless certain conditions were met; correct?

MR. LOUGHLIN: That's correct, Your Honor.

But as I mentioned, those conditions, those two provisions, work hand in hand so that if one provided value and the other didn't, Impax would get value; if the other provided value and the other didn't, Impax would still get value.

JUDGE CHAPPELL: So is your point that Endo knowingly entered into a deal that was a bad deal for Endo?

MR. LOUGHLIN: It wasn't a bad deal for Endo. It was a great deal for Endo. What Endo got was no --

JUDGE CHAPPELL: Even today, even today, and we don't have evidence yet, but knowing that certain things had to be recalled and the way things actually worked out in the market for this drug?

MR. LOUGHLIN: Absolutely, Your Honor. This was a fantastic deal for Endo, and here's why.

What Endo got out of the deal was a guarantee of no generic competition from January -- from June of 2010 to January of 2013. It was going to get no

competition from Impax, and because Impax was the first filer on the most popular dosages, it was going to get no competition from any other generic on those most popular dosages.

JUDGE CHAPPELL: Okay. Well, let's talk about at the date this was signed and agreed to. Let's put a pin in that.

And then I think as you stand here today I think at least we've heard representations that Endo at some point was not allowed to sell Opana; correct?

MR. LOUGHLIN: No.

At some point -- in September of 2017, the FDA asked Endo to voluntarily withdraw the reformulated product from the market, which it did.

JUDGE CHAPPELL: All right.

MR. LOUGHLIN: The FDA did not prevent Endo from launch -- from relaunching the original Opana ER. It could have done that.

JUDGE CHAPPELL: Did Endo ever launch a generic equivalent, an authorized generic?

MR. LOUGHLIN: No. Endo -- to my knowledge, Endo has never launched an authorized generic version of original Opana ER.

But to get back to Your Honor's point, recall that I told you earlier that there's a document where

Endo projected that every month that a generic stayed off the market after June of 2010 was worth $20 million to it.

Just using that calculation, the 30 months that there was no generic competition between June of 2010 and January of 2013 was worth $600 million, under Endo's own estimate, to Endo. That's additional revenue to Endo. The payment was $102 million, so this was a great deal --

JUDGE CHAPPELL: Wait a minute.

You mean the payment that was eventually paid based on the terms of the agreement because certain conditions were met.

MR. LOUGHLIN: Yes. Absolutely.

JUDGE CHAPPELL: But that was zero the day it was signed.

MR. LOUGHLIN: No, it was not zero, Your Honor.

JUDGE CHAPPELL: I'm not talking about the ten million.

MR. LOUGHLIN: I understand the ten million. But the -- the value of the settlement was not zero at the time it was signed. The parties understood --

JUDGE CHAPPELL: No. I'm saying nobody cut a check the day it was signed under those two provisions

of the agreement.

MR. LOUGHLIN: Correct.

JUDGE CHAPPELL: Until conditions were met at some point in the future.

MR. LOUGHLIN: That's correct. Under those two provisions, the Endo credit was not paid until 90 days after January 1, 2013, after Endo -- after Impax entered the settlement. That's correct.

Now, as I mentioned, in discussing the Endo credit, it sets forth a mathematical calculation, a mathematical formula, that compares Opana ER sales from just before Impax' launch in January 2013 to whatever the peak sales were between June of 2010 and the fourth quarter of 2012. And it works so that the more that sales of original Opana ER declined, the greater the payment from Endo to Impax.

JUDGE CHAPPELL: I'm trying to figure out the government's position here after reading the pretrial briefs.

Are you saying that these two conditions, this was some brilliant disguise and not -- rather than in lieu of some naked payment of a hundred and some million dollars, that there's some nefarious conduct in these two provisions, and it was just a way to hide a naked payment on day one?

MR. LOUGHLIN: It is a naked payment, Your Honor. It is not a way to hide it.

JUDGE CHAPPELL: How is it a naked payment if conditions had to be met before the money was paid?

Let's just use my definition. A naked payment is X number of dollars, a check written day one when the agreement is signed, no conditions whatsoever.

MR. LOUGHLIN: Okay. Under that definition, you're right, it is not a naked payment. That's true. It is not that. It is -- there's no provision that said we will pay you X on the day of signing other than in the co-promotion deal.

JUDGE CHAPPELL: Don't have anything in writing saying we're going to pay you to stay out of the market or to come into the market, you don't have that, in those words.

MR. LOUGHLIN: In those precise words, no, Your Honor. What we have is a provision that says you will stay off the market until January 1, 2013 in exchange for a no-AG agreement.

That no-AG agreement was expected to be very valuable to Impax. That's what Impax wanted. But because Impax was concerned that Endo was going to do something to the market that would harm the value of that no-AG provision, it got some additional protection

in the form of Endo credit.

And the parties -- and you'll hear from our expert economist, Professor Noll of Stanford University, who will testify --

JUDGE CHAPPELL: I'm more interested in what fact witnesses have to say about what really happened than expert opinions, but go ahead.

MR. LOUGHLIN: Okay. Well, then let me get to the fact witnesses.

This is testimony from Mr. Mengler. Again, Mr. Mengler is the president of -- was the former president of the generic division of Impax and he was the primary negotiator. And he explains the Endo credit.

"It was basically a calculation that would have given whatever money or an approximation of the profits, if you will, that Impax would have earned in that six-month period based on pricing and share and just assumptions like that, just basically a calculation that would have said, you know, we're going to take your peak sales and do some math to it and come up with a number that we would have made had -- if we had a generic in that six-month period."

JUDGE CHAPPELL: Doesn't that look like a valid business decision that a company would make? Isn't

that his job, to make sure he makes a well-reasoned business decision?

MR. LOUGHLIN: Your Honor, it's -- from a business perspective, it's fantastic. It made them a lot of money. But lawfully, it is unlawful.

There's no doubt that paying a generic not to enter the market is a fantastic business decision. It makes -- it can make a ton of money for a branded company. But it is unlawful because it harms -- it reduces competition.

Now, this is the testimony of Roberto Cuca. Mr. Cuca is an Endo witness. He is the person that during the negotiations supported the Endo negotiator and actually did calculations of the Endo credit. He came up with the Endo credit formula. He did calculations of it during the time of the negotiations to help Endo negotiate that term.

And he explained that if sales of Opana ER had decreased, the Endo credit would kind of fix that by making a true-up payment to Impax. The Endo credit would correct for the lost value of the market that had occurred before the generic entry date.

In other words, what they are explaining is that the Endo credit and the no-AG provisions worked together to ensure that Impax would get value out of

this settlement either by -- either by selling its product without competition from an AG or, if Endo had done something to the market, from a cash payment under the Endo credit.

Now, as it turned out, Endo did launch a reformulated version of Opana ER and ended up paying Impax over $102 million in cash under the Endo credit.

And as I mentioned, that was well worth it to Endo. As I mentioned the calculation that Endo had forecasted that every month that it stayed off the market, that a generic stayed off the market, was worth $20 million, that's equivalent to about $600 million in additional revenue to Endo.

It also ensured that Endo would not face generic competition on the five most popular dosages of Opana ER while it tried to switch the market to the reformulated version of Opana ER. It ensured that it wouldn't face generic entry from Impax and it ensured that it wouldn't face generics from any other generic company on those five dosages because of the 180-day exclusivity.

And this was a great deal for Impax as well.

Now, this is a slide that we created using information from what's been marked as CX 514. This is a five-year forecast from Impax.

And what Impax was projecting in May of 2010 was that if it launched generic Opana ER in June of 2010, it would earn a total of about $53 million in net sales between 2010 and 2012. It earned twice that by agreeing not to sell during that time period.

In fact, Impax' public financial documents show that the payment was larger than Impax' entire net income for 2013.

And Impax' current CFO testified that the Endo credit increased Impax' profitability by about 50 percent in 2013.

Now, in addition to the no-AG/Endo credit payment, the parties also agreed to a development and co-promotion agreement.

And Endo, under that agreement, agreed to pay Impax $10 million with a potential for additional payments for the right to co-promote a Parkinson's disease drug that Impax had in early stage development.

Now, I say early stage development. In fact, it wasn't actually a product at all yet. It was a concept that hadn't even been formulated. But nonetheless --

JUDGE CHAPPELL: Isn't that why it was only

$10 million?

MR. LOUGHLIN: No, Your Honor. In fact --

JUDGE CHAPPELL: Because based on the numbers you're throwing around, ten million is nothing.

MR. LOUGHLIN: No, Your Honor. In fact, the parties -- during that negotiation, the parties had started negotiating over a product that was in Phase III development. It was a similar drug, called IPX-066. It was in Phase III development. That's the final stage before submission to the FDA for approval.

The parties had negotiated $10 million -- a $10 million upfront payment on that Phase III product with $5 million in milestones.

But then, during the negotiations, Impax pulled that product, IPX-066, off the table and said we're only going to do a deal on what we're going to call the next-generation product of IPX-066 and we'll tell you what that is upon signing.

Nonetheless, despite that change in product from a very late-stage product to a conceptual product that didn't even have a formulation, the parties didn't restart the negotiations. They didn't start over and do new due diligence. They continued to negotiate.

And in fact, on June 3, 2010, they had reached

basically an agreement where Impax was going to -- Endo was going to pay the same $10 million upfront payment plus additional milestones, and yet at this point Impax hadn't provided any information, any additional new information on this new reform- -- next-generation product to Endo.

In fact, Impax didn't provide any new information about this specific next-generation product, this conceptual product, until the next day, Friday, June 4, in that evening. And yet, by the end of the weekend, by Monday or Tuesday, they had agreed to a deal.

And the only information that they actually provided on June 4 was just some revisions to information that Endo already had about 066, the original product.

JUDGE CHAPPELL: So the -- according to your chart here, since this was, in your opinion, a payment for nothing, the four million was paid, the two million and the two million and the two, those were all paid since this was for nothing?

MR. LOUGHLIN: No.

JUDGE CHAPPELL: No, they weren't, were they? Because those conditions weren't met, were they?

That's why the agreement said what it did;

correct? If you meet these conditions, you get to Phase II, we pay the $4 million; right?

They didn't get to Phase II with the drug, so that wasn't paid, or was it?

MR. LOUGHLIN: No.

JUDGE CHAPPELL: Ten million on signing means when you sign it you pay ten million. You know about contracts, don't you?

MR. LOUGHLIN: I do, Your Honor. And they paid $10 million upon signing.

JUDGE CHAPPELL: You understand a drug that -- anything to do with Parkinson's, what a gold mine that would be for a pharmaceutical company to have a taste of that? $10 million is a joke in this industry.

MR. LOUGHLIN: Your Honor, I don't think that's true. In fact, in this industry --

JUDGE CHAPPELL: You can think what you want, as can I.

MR. LOUGHLIN: You're right.

JUDGE CHAPPELL: But you're talking about billion-dollar drugs. Have you ever invested in a medical start-up, someone researching drugs? Have you ever done it? Because when you do, whatever money you put in, you better be willing to just tear it up that day, because it's a lottery ticket.

Now, are you saying that Endo is so unsophisticated that they had no idea what they were paying, they weren't buying an opportunity, a lottery ticket, that this payment, your position as the government is this $10 million was absolutely for nothing? Is that what you're telling me?

MR. LOUGHLIN: No, it wasn't for nothing. It was to induce -- it was part of a payment to induce --

JUDGE CHAPPELL: So it wasn't just for nothing, it's for nothing because it's -- and it's also nefarious and fraudulent; right? That's what I'm getting.

MR. LOUGHLIN: Your Honor, I haven't said it was fraudulent.

JUDGE CHAPPELL: You didn't use the word, but you've used the words. That's the point you're making.

MR. LOUGHLIN: No. Let me -- I'll be clear about the point I'm making.

JUDGE CHAPPELL: Are you saying that respondent defrauded Endo Pharmaceuticals?

MR. LOUGHLIN: No.

JUDGE CHAPPELL: They made this whole thing up about a possible Parkinson's drug for $10 million and it was all a lie and a fraud?

MR. LOUGHLIN: No, that is not my position, Your Honor.

JUDGE CHAPPELL: All right. I'm just trying to get your position clear.

MR. LOUGHLIN: My position is the parties knew exactly what they were doing and they knew exactly what they were getting.

What Endo knew it was getting was the right to co-promote a product that it was in conceptual phase development, and Impax knew that it was providing that product and it was getting $10 million.

The point is that this is not a deal that Endo would ever do absent this settlement. This is not the way that pharmaceutical companies do business. They don't say, Okay, we'll pay you $10 million up front plus $5 million in milestones for a product that's just about to come on the market, and then when the -- when the company says, No, no, no, we're not going to do that deal anymore, we're going to switch it to a product that isn't even in development yet, the company -- the other company doesn't say, Well, that's fine, we'll still pay you $10 million for that.

JUDGE CHAPPELL: Well, let's talk about that since we're just speculating here because we haven't heard any evidence.

But let's say that this drug that was identified with a number, as I recall, let's say that it came to fruition, that it became marketable. Don't you think Endo would have been glad they bought that lottery ticket for $10 million?

MR. LOUGHLIN: They may have.

JUDGE CHAPPELL: They had a chance, didn't they? They paid for an opportunity to get in, to get a taste of a drug that might be marketed. Am I wrong?

MR. LOUGHLIN: No. You're right that they paid for a chance, but they paid the same -- they were going to pay the same amount of money for a product that was a lot more of a sure thing than a product that they paid the same amount later --

JUDGE CHAPPELL: So are you saying this wasn't arm's length, that respondent had no right to say -- I don't know -- just for example, This drug we talked about, we're going to keep that in house, we're a smaller company, we've got something else in mind, and they put that on the table, and the parties can't agree to that? Apparently, they did agree to it. The deal was signed, wasn't it?

MR. LOUGHLIN: It was signed. Of course, they can do that. There's nothing stopping Impax and Endo from reaching a deal.

The point is, it was not in Endo's interest to do this deal absent the settlement. And the reason they did it was because it was a way to get money to Impax to induce them to stay off the market.

Endo, as a rational company, if it was willing to pay $10 million up front for a product in near -- that was just about to be filed with the FDA, would not pay the same amount of money without having almost any information about this new product.

No company would do that. They would start over the negotiations. They would say okay, let's start fresh, let's go through due diligence and then enter a negotiation to figure out how much this product was worth. They didn't do that.

JUDGE CHAPPELL: Well, let's get down to brass tacks.

Is it the government's position that $10 million is both large and unjustified?

MR. LOUGHLIN: Yes.

JUDGE CHAPPELL: All right. Go ahead.

And just so we're clear, I don't care who wins this case. I'm coming in here with an open mind, but I'm going to find out what happened. That's why we're here. I don't care right now who wins. I have no skin in the game. I didn't issue a complaint in this

case. I'm totally neutral, objective and independent, so I do not care who wins, but I'm going to find out the truth. That's what I'm here for.

Go ahead.

MR. LOUGHLIN: Understood, Your Honor. I completely understand that you're an independent decision maker in this case, no question about that.

But the point is that with the Endo credit/no-AG provision and this $10 million payment, the parties now had a deal.

And what you're going to hear, Your Honor, from the witnesses, from the evidence, is we're going to support all the things I just told you. You're going to see all of this in the parties' contemporaneous documents, you're going to see it in their deposition testimony, and you're going to hear it live in this courtroom.

Your Honor, we plan to call live the three individuals that negotiated the settlement on behalf of Impax. You're going to hear from Mr. Art Koch, the former CFO of Impax, you're going to hear from Ms. Margaret Snowden, the in-house counsel for Impax, and you're going to hear from Mr. Mengler, the former president of Impax' generics division, the three people who negotiated the settlement on behalf of

Impax.

And you're going to hear from these witnesses that Impax went into the settlement wanting an entry date and a no-AG provision.

You're also going to hear that Impax was concerned about Endo reformulating its product before Impax could enter under the settlement and that, as a result, Impax believed it was very important to get protection in the settlement from that possibility.

And you're going to hear that Impax gave up its efforts to get an entry date before 2013 in exchange for that protection. That ended up being the Endo credit.

JUDGE CHAPPELL: I thought you told me earlier that Endo was talking about June 2013 and then I thought you told me -- or maybe May. I don't know -- but then I thought you told me that the agreement allowed entry in January. Isn't that an earlier period? Didn't they talk about -- didn't the time period change, the entry date?

MR. LOUGHLIN: The original provision proposal from Endo was March of 2013.

JUDGE CHAPPELL: March.

MR. LOUGHLIN: It ended up being January of 2013. You're right, that is two months earlier than

March of 2013. However, it is 30 months -- it is 30 months after the settlement and it is some 24 months after what Endo -- excuse me -- what Impax wanted when it started the negotiations, which was January of 2011.

Now, you're also going to hear, Your Honor, from Roberto Cuca. Mr. Cuca is a former Endo employee who supported Endo's primary negotiator during the settlement. And he's going to testify that he developed the Endo credit formula, that he ran numbers through the formula during the time period of the settlement negotiations to assess how much Endo might have to pay under the Endo credit, and he did that so that Endo could negotiate the terms of the credit better.

You'll hear from Bryan Reasons, Impax' current CFO. Mr. Reasons will testify that Impax got $102 million under the Endo credit provision of the settlement, and he will explain how that payment compares to Impax' sales revenue in 2013 and how it compares to Impax' expected patent litigation costs.

You will hear from Joseph Camargo, who will testify about Impax' preparations to be ready to launch generic Opana ER before January 1, 2013.

You will hear from Todd Engle, who will explain

how Impax forecasts generic entry and the impact on the branded product.

And you will hear from Demir Bingol, Mr. Bingol a former Endo employee, who will testify about the expected effects of generic entry from Endo's perspective.

JUDGE CHAPPELL: A lot of former employees. What is this, a musical chairs industry?

MR. LOUGHLIN: Your Honor, the settlement was seven years ago and people have moved on.

JUDGE CHAPPELL: Before I forget, the document I talked about when we began today, any agreement regarding Endo's cooperation in this case, I want that in my hand by the time respondents finish their opening statement today.

MR. LOUGHLIN: Okay.

JUDGE CHAPPELL: I don't know why I don't have it yet. You've got an army of people here who could get that for me.

MR. LOUGHLIN: Okay.

JUDGE CHAPPELL: I want three copies, one for me and two for these ladies (indicating).

MR. LOUGHLIN: Okay.

Now, in addition to the fact witnesses, Your Honor, we're going to have expert witnesses that

I'll mention in a moment.

But together we'll present all this evidence in the context of the current legal standard for assessing reverse payment settlements. That is the legal framework set forth by the Supreme Court in FTC v. Actavis and the decisions since Actavis.

And under Actavis and cases since Actavis, the settlement is unlawful under the rule of reason if the brand had market power at the time of the settlement, if the generic abandons its patent challenge and agrees to stay off the market in exchange for a large payment, and if the respondent cannot justify the large payment.

Now, if respondent proves its justification, then we address a fourth factor, which is whether the anticompetitive effects outweigh --

JUDGE CHAPPELL: Did you leave something off your slide there? Did you leave the word "and" off between 2 and 3?

MR. LOUGHLIN: Yes, Your Honor. I should have put "and" on there.

JUDGE CHAPPELL: 1, 2 and 3; correct?

MR. LOUGHLIN: 1, 2 and 3, that's right.

And the fourth factor is whether the anticompetitive effects outweigh any procompetitive

justifications for the payment.

Now, this standard comes straight out of Actavis and cases interpreting Actavis.

And what you don't see in this standard is any requirement that complaint counsel prove what actually would have happened absent the settlement.

You don't see any requirement that complaint counsel prove what would have happened in the patent case had it continued.

You don't see any requirement that complaint counsel prove that there actually would have been generics on the market earlier as to the settlement. In other words, there's no requirement that complaint counsel prove injury.

And that's because the reason that such a settlement, a reverse payment settlement, is unlawful is that the brand is paying the generic to prevent the risk of competition.

That's the anticompetitive harm identified by the Supreme Court in Actavis.

Here's what it said: "[T]he [large] payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm."

In other words, Your Honor, as I mentioned, the harm is to the competitive process. We don't know the outcome of that process in any particular case.

JUDGE CHAPPELL: Let me ask you this.

Is the government's position that no branded drug company can ever enter into a license agreement with a generic company? Is there any licensing agreement between a patented -- a drug company with a patent and another company -- are all licensing agreements suspect according to the FTC?

MR. LOUGHLIN: No, Your Honor. A brand --

JUDGE CHAPPELL: Because a patent does mean something; correct?

MR. LOUGHLIN: Of course. And a brand --

JUDGE CHAPPELL: Because I don't think I've heard you use the word "patent" in an hour and a half here. Maybe you did and I missed it. But I have never heard you say the word "patent" at all.

MR. LOUGHLIN: Your Honor, that's because the patent case here is not directly at issue in the antitrust case.

But to answer Your Honor's question, absolutely, a branded company with a patent can settle with a generic company and enter into a license that gives the -- that has an entry date under which the

generic can come into the market without risk of infringement. It just can't do that with a reverse payment -- or it can't do that without a large reverse payment. That is what Actavis says.

JUDGE CHAPPELL: You mean large and unjustified.

MR. LOUGHLIN: Large and unjustified, that's correct. That's what Actavis says. And Actavis draws a distinction.

JUDGE CHAPPELL: Well, you know, you can keep throwing up lines from the case, but we're all lawyers, we're all going to read the case, and we're going to form our own interpretation of the case.

You're free to cite it, put it up on the screen, but we're all attorneys, and we're not necessarily going to agree on what the case means, I mean, with you or respondent. I might not necessarily agree with either one of you.

MR. LOUGHLIN: Understood, Your Honor.

JUDGE CHAPPELL: And thankfully, it's not even a long decision. It's a very short one as far as Supreme Court decisions go.

MR. LOUGHLIN: Yes, that is true. It is relatively short.

But what the Supreme Court is saying in this

case, in terms of preventing the risk to competition, is that consumers are better off when the competition -- when the competitive process dictates the outcome rather than reverse payments. That is the point of FTC v. Actavis.

And other courts have held the same.

Here's the Third Circuit in the Lamictal case saying that "Actavis embraces the concept that a patent 'may or may not be valid, and may or may not be infringed,' and holds that the anticompetitive harm is not certain consumer loss through higher prices, but rather the patentee's 'avoidance of the risk of patent invalidation or a finding of noninfringement' -- that is, 'prevention of the risk of competition'...."

The District of Connecticut made the same point in the Aggrenox case: "The anticompetitive harm is not that the patent surely would have been invalidated if not for the settlement, and that a generic surely would have entered the market sooner.... The anticompetitive harm, under Actavis, is that the reverse-payment settlement 'seeks to prevent the risk of competition.'"

Now, under the elements, the first element is market power.

Now, in terms of market power, we will show that the relevant market is oxymorphone ER tablets,

which include branded and generic versions of Opana ER, and at the time of the settlement Endo had 100 percent of that market.

Now, it is certainly true that Opana ER is in a class of long-acting opioid products used for treating pain. But market definition is about determining which products are economic substitutes, not just functional substitutes, and that requires looking at which products constrain each other's prices.

Now, in support of our showing of market power, we will present the testimony of an economic expert, Professor Roger Noll of Stanford University.

Professor Noll will show that other long-acting opioid products did not constrain the price of Opana ER. Other branded and generic long-acting opioid products entered the market, but Endo was able to maintain the price of Opana ER without losing substantial sales to those other products.

Some of those products had their own generics, but those generics did not take substantial sales from Opana ER in the same way that they took sales from their own branded reference products.

The only product that constrained the market

price of Opana ER -- of oxymorphone ER is generic oxymorphone ER. And that's because generics have a unique and profound effect on the sales of the branded product.

Generics enter at a lower price, and because they can be substituted for the brand by the pharmacist, the brand can lose up to 80 to 90 percent of sales within six months on the market. No other competitor has that kind of effect on the brand's sales.

And Endo and Impax both recognized this. They both forecasted effects of generic entry on the sales of branded Opana ER, and the projected effects are very similar.

Moreover, when Impax forecasted sales of generic Opana ER, it looked only at branded Opana ER for reference. It set its price as a discount off of Opana ER's list price. It projected generic substitution as a percentage of Opana ER sales that go generic. And it projected its market share in a market that includes only branded and generic oxymorphone ER, the same market that complaint counsel proposes here.

We will also present the testimony of Dr. Seddon Savage. Dr. Savage is a professor at the

Dartmouth University Medical School. She is an expert on the use of opioid drugs.

And she will testify that there are important clinical differences between various long-acting opioid products and there are important differences in patients, and so when prescribing long-acting opioids doctors have to take those differences into account to find the right drug for each patient.

And importantly, once a patient is on a drug, switching to a different long-acting opioid product is a complex process, it creates risk for the patient, and it increases costs, and so doctors don't switch patients among different long-acting opioids in response to a small price difference.

And it's also worth pointing out what the Supreme Court said in Actavis about market power. It said that "[T]he 'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power' -- namely, the power to charge prices higher than the competitive level.... Neither is a firm without that power likely to pay 'large sums' to induce 'others to stay out of its market.'"

Now, complaint counsel will also present the testimony of Professor Max Bazerman.

Professor Bazerman is a professor at Harvard Business School and an expert in negotiations.

And he will testify that given the way the negotiations were conducted and the settlement terms themselves, the only plausible explanation is that the settlement was a mechanism to induce Impax to agree to stay out of Endo's market until January 1, 2013 in exchange for a large payment.

And that leads to the second element under Actavis, Your Honor, which is that Impax agreed not to market its generic version of Opana ER until January 2013 in exchange for a large payment.

Now, there's no dispute in this case that Impax agreed not to enter until January 1, 2013. That's written expressly into the settlement. But there was also a large payment.

Under Actavis, the payment must be large in terms of its size and its scale in relation to the brand's anticipated future litigation costs.

Now, here in terms of its size, the total payment was $112 million. As we saw, that's twice what Impax projected to earn from generic Opana sales in 2010, and it's far greater than any saved litigation costs to Endo, which were about $3 million.

As I mentioned, the payment had two

components.

The first is what we call the guaranteed no-AG payment. This is the combination of the no-AG provision and the Endo credit.

The second is the side deal payment, the $10 million upfront payment as part of the side deal.

Now, as the court has mentioned, the settlement of course does not specify a precise amount that Impax would receive under the settlement, and so complaint counsel's economic expert, Professor Noll, ran numbers to assess the amount of money that Impax would have expected to earn under the settlement either under the Endo credit or the no-AG provision.

JUDGE CHAPPELL: Well, among those projections would have been zero if conditions were not met?

MR. LOUGHLIN: One of those --

JUDGE CHAPPELL: Or is that not one of the projections we're going to hear from your expert? Because if no conditions were met, it would have been zero; correct?

MR. LOUGHLIN: Your Honor, there was a theoretical possibility of zero, but --

JUDGE CHAPPELL: So that would be included in the expert's projections if they're accurate; correct, the possibility of zero?

MR. LOUGHLIN: The possibility of zero. But what he's going to show is that the probability of that has to be so likely, has to be over 90 percent likely, that that was going to happen compared to everything else for there to be a payment of zero. And as I've already explained, the likelihood of there being zero is tiny. And it's inconsistent with the evidence.

The evidence will show that Endo planned to launch its generic -- excuse me. Let me start that over.

What the evidence will show is that Endo planned to launch its reformulated product as soon as they could. The only way that the -- that the Endo credit could end up being zero is if Endo launched its reformulated product -- and this is a possibility thrown out by respondent's expert, Dr. Addanki, and he said there was a possibility of this.

He says there's a possibility that if Endo launched its reformulated product just before January 2013, then there's a possibility that Opana ER sales would go down to just above 50 percent, which is the trigger mechanism in the settlement for the Endo credit.

JUDGE CHAPPELL: I'm just -- you know, it just

occurs to me that there's a lot of assumptions being made, for example, that everything goes swimmingly with the generic launch.

What if the generic is being made at a plant in Puerto Rico recently? It's not going to happen, isn't it? Not even going to have anything to sell. Things go wrong.

So when you're talking about assumptions, you've got to allow for the fact that things don't always go swimmingly or as planned.

MR. LOUGHLIN: Yes, Your Honor. But what we have to look at is what were the expectations of the parties at the time of the deal. And what Dr. Noll will show is that --

JUDGE CHAPPELL: So all we care about are expectations. We don't care about the facts about what actually happened and how it actually shook out in the real world. The real world doesn't matter at all; is that what you're telling me?

MR. LOUGHLIN: No, Your Honor. The real world does matter. And what happened in the real world is that Endo paid Impax $102 million. That does matter.

And the reason it matters is that because it helps indicate the likelihood that Endo -- at least what -- that this was going to be a product of

substantial -- or a settlement of substantial value to Impax.

And what Dr. Noll does, to be conservative, he compares the highest Opana ER sales to the Opana ER sales -- he compares the highest Opana ER sales to the sales that occurred just before Impax would enter in January 2013. And he assumes that those highest peak sales are the sales in June of 2010.

In other words, he assumes that the highest sales that Opana was going to have occurred in June of 2010, and he compares those to what they would have had on January 1, 2013.

And he determined, based on that, based on what Impax and Endo could have expected in June of 2010, that the lowest value of the Endo credit would have been $62 million.

Now, that's less than the 102 million, but it is far greater than the saved litigation costs of about $3 million.

Now, he also calculated --

JUDGE CHAPPELL: I thought the lowest value would be zero.

MR. LOUGHLIN: Your Honor, the expectation --

JUDGE CHAPPELL: There's a big difference between zero and 62 million.

MR. LOUGHLIN: That's true, Your Honor.

But based on -- but based on --

JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero?

MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero. In fact, Impax --

JUDGE CHAPPELL: It sounds like this is all theory to me except what was actually done and what happened. Do we really need someone to sit in the chair and tell us to speculate? We know what happened. Let's talk about facts.

MR. LOUGHLIN: Your Honor, yes. The facts are that they got $102 million. That is a fact. That is far greater than their litigation -- their saved litigation costs, which were expected to be three million.

But respondent criticizes us because there was a theoretical possibility of zero. Their own witness, Mr. Mengler, understood there was a theoretical possibility of zero, but he believed it was so trivial that it wasn't worth worrying about during the

settlement negotiations. And he was right. They ended up making $102 million.

But because respondent has criticized us that there was a possibility of zero, our expert looked at that. And what he determined was that based on the information that Impax and Endo knew at the time, if you just look at the sales that Opana was earning in June of 2010 and compare that to -- take that as the peak sale, then the most likely scenario was about $62 million and -- under the Endo credit, assuming the Endo credit kicked in.

But he also looked at values under various scenarios that could occur where original Opana ER stayed on the market and Impax earned its value through selling generic Opana ER through the no-AG provision.

And what he found under various scenarios were that the no-AG provision was worth at least 16 million to 53 million, again, all well above saved litigation costs of $3 million.

Now, respondent can try to justify this payment as being in exchange for a service that Impax was performing for Endo, but there's been no Impax or Endo witness who has tried to justify the no-AG provision or the Endo credit provision as being connected to any

service provided by Impax; rather, it was a straight cash payment.

Now, you may hear Impax witnesses try to justify the Endo credit as being part of what they call a carrot-and-stick strategy to convince Endo to keep marketing and promoting original Opana ER rather than launch a reformulated product.

But that doesn't justify the large payment, Your Honor. It doesn't change that the large payment induced Impax to accept a settlement that prevented the risk of competition until January 1, 2013.

Now, it may demonstrate that Impax preferred to get its payment in the form of a no-AG rather than the Endo credit, but that doesn't change anything. That doesn't change the fact that this was a large payment and it had the same effect on competition in terms of preventing a risk of competition.

Now, as I mentioned, you're going to hear from respondent's expert Dr. Sumanth Addanki. And Dr. Addanki opines that the Endo credit payment was not large. He doesn't do any calculations of the Endo credit. He doesn't do any calculations of the potential no-AG provision.

Instead, he says that there is a theoretical possibility that Endo could launch its reformulated

product just before January 1, 2013, reduce Opana ER sales to just above 50 percent, which is the trigger for the Endo credit, and in that way, Endo wouldn't have to pay any Endo credit and the value of the no-AG provision wouldn't be worth anything to Impax.

Now, as I mentioned, the problem with this hypothetical is that it's inconsistent with the evidence. What the evidence will show is that Endo did not want to launch its reformulated product just before January 1, 2013; it wanted to launch as soon as it could.

Here's an e-mail from April of 2010 from Endo indicating that the product launch for its EN3288 product, which is the reformulated Opana ER, the schedule was to launch in March 2011, but it could be as early as December 2010.

And the reason that Endo wanted to launch its reformulated Opana ER as early as it could is that because it wanted to get it into the market in advance of generic entry. It wanted to have time for a smooth transition of sales from original Opana ER to the new product before generic versions of the original Opana ER came on the market and destroyed that market.

This is the testimony from Brian Lortie. Brian Lortie is the former president of Endo's branded

division, and he was Endo's designated corporate representative to testify about Endo's plans for the reformulated Opana ER. And he makes clear that Endo wanted to get its reformulated product on the market as soon as it could to have time for a smooth transition.

What it says:

"QUESTION: Because Endo wanted to get the product out sooner rather than later; correct?

"MR. LORTIE: Yes, our interest was to be able to smoothly transition from old product to new product.

"QUESTION: As soon as you could?

"MR. LORTIE: As soon as we could, but also in a way that recognized that we wanted as smooth a [sic] possible transition for patients that were on the old product and transitioning to the new one."

That smooth transition --

JUDGE CHAPPELL: Who are you sic'g there, the witness or the transcriber?

MR. LOUGHLIN: I don't remember, Your Honor, what the witness actually said at this point.

JUDGE CHAPPELL: Well, are you thinking he meant to say "as," A-S?

MR. LOUGHLIN: I think he meant to say "as," "as smooth as possible."

In any event, what the evidence will show is that this kind of smooth transition that Endo wanted takes months.

So that if Endo waited to launch its reformulated product until just before generic entry, as Dr. Addanki has suggested it would, it would risk not being able to shift enough patients to the reformulated product before the generics took over the market. That would risk destroying the entire value of the reformulation project that Endo had spent so much time developing.

Now, that scenario is also inconsistent with the evidence from Impax' perspective. And as I mention --

JUDGE CHAPPELL: Wait a minute. I kept waiting on the connection.

So what's your position, that the agreement in this case delayed the crushproof introduction or didn't delay it or had nothing to do with it because Endo did what they wanted to do with the crushproof version? What's your position on that?

MR. LOUGHLIN: No, the agreement did not delay Endo's reformulation. What happened was that Endo ended up getting FDA approval later than it expected to get. It got it -- rather than getting it in 2011,

it got it in I think early 2012.

JUDGE CHAPPELL: That's why I don't understand what -- what point were you trying to make telling me about the entry dates, telling me what the witness said, what was the point? Because I missed it.

MR. LOUGHLIN: The point was that in order for this hypothetical scenario of there being a zero payment under the Endo credit and no value to the no-AG provision, the scenario that Dr. Addanki, respondent's expert, lays out is that Endo -- for that to happen, Endo would have to launch its reformulated product as late as it could. It would have to delay -- voluntarily delay launching its reformulated product until just before January 1, 2013.

That way, what would happen is the sales of original Opana ER would go down, but not enough to trigger the Endo credit. But at the same time, because it had now launched its reformulated product, Endo wouldn't want to launch an AG; and therefore, the no-AG wasn't going to be worth anything either.

And my point is, the evidence doesn't support that scenario. Endo's testimony, Endo's evidence, its documents show that it wanted to get on the market as soon as it could. It wanted to get on the market so that it could switch the market to the reformulation

well in advance of the launch by Impax in January 2013.

JUDGE CHAPPELL: And as I asked, the facts are Endo did market that product as soon as they could per FDA; correct?

MR. LOUGHLIN: Exactly. They did. They launched as soon as they could. They did not wait --

JUDGE CHAPPELL: And because they did, it degraded the market, which kicked in one of the provisions of the agreement, and payment had to pass.

MR. LOUGHLIN: Exactly, Your Honor. That's correct.

Now, Your Honor, another proposed justification that you may hear from Impax is a topic that actually came up at last Thursday's pretrial conference, and this is the license to future patents that Impax got in the settlement.

But you are not going to see any documents and you're not going to hear any testimony saying that the license justifies the payment that Impax got from Endo. And that's because Impax got both the license and the payment.

Now, presumably Endo would have given Impax the license without the payment. And as a result, the license cannot justify the payment. And that is the

issue.

The Supreme Court makes clear in Actavis that the antitrust defendant must justify the payment. It says, "An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason."

And the Third Circuit made the same point in Lipitor, 868 F.3d 231 at 256 to 57.

JUDGE CHAPPELL: You mean they show it unless someone strikes affirmative defenses before the trial begins? Is that what you mean?

MR. LOUGHLIN: They -- yes, Your Honor --

JUDGE CHAPPELL: Thank you.

MR. LOUGHLIN: -- that's what I mean.

JUDGE CHAPPELL: Thank you.

MR. LOUGHLIN: Now, the challenged term here, Your Honor, is the payment. And of course, we're not challenging the license itself. We're challenging the payment. And that's what needs to be justified.

The Supreme Court made that even clearer stating that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; and one who makes such a

payment may be unable to explain and to justify it...."

In other words, the Supreme Court is making clear that settlements without reverse payments are fundamentally different from settlements with reverse payments; and therefore, it is the payment that needs to be justified.

Now, respondent may try to justify the $10 million side deal payment as being in exchange for the development and co-promotion agreement. This is the $10 million that Endo paid upon signing for co-promote rights to a Parkinson's disease treatment that Impax had in preclinical development stage.

And I talked, Your Honor, about the fact that they paid $10 million for this product despite the fact that they were going to pay the same amount of money for a Phase III final-stage product, they paid the exact same amount, despite the fact that now they were talking about an early-stage product upon which they had very little information.

And in connection with that side deal, complaint counsel will present the testimony of Dr. John Geltosky. Dr. Geltosky is a pharmaceutical consultant who spent decades doing business development deals in the pharmaceutical industry.

And he will testify that these facts, the

facts that I laid out regarding the settlement -- or excuse me -- the negotiations and terms of the co-promotion deal are inconsistent with the way that pharmaceutical companies evaluate and negotiate bona fide licensing or co-promotion deals.

The evidence will also show that Endo viewed the side deal as protecting Opana revenues.

This is an Endo document from July of 2010, just after the settlement. And Endo explained that it has done a license deal with Impax for a development-stage asset. And it notes that the side deal adds significant top-line revenue for Opana.

It's not mentioning top-line revenue from the side deal. It's saying that it's going to provide additional top-line revenue for Opana, in other words, because of the settlement and the fact that Impax' generic was now guaranteed not to be on the market for two and a half years.

Now, as the court heard last Thursday, one of the fundamental issues that would come up in this case is a dispute between the parties' economic experts regarding how you assess whether the settlement had any anticompetitive effect and when those effects occurred.

Complaint counsel's expert Professor Noll will

testify that the relevant anticompetitive effect of the settlement is that Endo made a large payment to Impax to induce Impax to accept the January 1, 2013 entry date and thereby prevented the risk of competition before January 1, 2013.

As a result, the relative -- excuse me -- the relevant anticompetitive effect occurred between June 2010 and January 1, 2013.

We believe that opinion testimony from Professor Noll is consistent with Actavis.

And again, this is the language from Actavis saying that "[T]he large payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm."

Now, in contrast to complaint counsel's expert Professor Noll, you're going to hear from respondent's expert Dr. Sumanth Addanki, who says that to show that the settlement is anticompetitive, complaint counsel must prove that absent the settlement, Impax would have won the patent case against Endo and actually marketed its product before January 1, 2013.

And respondent has a patent lawyer expert, Mr. Anthony Figg, who will testify that Impax likely would have lost the patent case.

But the problem with Dr. Addanki's theory and with Mr. Figg's testimony is that they are both inconsistent with Actavis.

Indeed, in that case the Supreme Court expressly said that "[I]t is normally not necessary to litigate patent validity to --

JUDGE CHAPPELL: Hold it right there.

Are you telling me that Actavis says absolutely nobody gets into whether the patent was valid or not? Because right there you just said "normally not necessary." That's wiggle room right there. You disagree?

MR. LOUGHLIN: Your Honor, to --

JUDGE CHAPPELL: It's not an absolute. And if you think it is, you're going to be disappointed.

MR. LOUGHLIN: No, Your Honor. But the difference in what Actavis is saying is that there's a difference between proving a violation by the FTC and proving a violation and injury by private plaintiffs.

JUDGE CHAPPELL: I agree with you there.

MR. LOUGHLIN: Right.

JUDGE CHAPPELL: But I don't -- but there's nowhere in that decision where they say patents don't matter, nobody talks about the patent, nobody gets into whether it's valid or not. That's not in there.

MR. LOUGHLIN: Well, Your Honor, there are a number of places where the Supreme Court indicates that to decide the antitrust case and whether there's a violation you do not need to prove the patent merits. And in fact, it says that the fact that there's a large payment --

JUDGE CHAPPELL: I'm not saying the government has to prove patent merits. I'm saying patent merits may become an issue. I'm not attributing the fact they have to be proven to anyone.

MR. LOUGHLIN: Your Honor, I agree with you that patent merits will become an issue because respondent will make it an issue. But our position is that this court does not need to address the patent merits to decide an antitrust case and that, under Actavis, the Supreme Court is directing the court not to consider the patent merits --

JUDGE CHAPPELL: I understand your position.

MR. LOUGHLIN: Yep.

JUDGE CHAPPELL: What's next?

MR. LOUGHLIN: What's next, Your Honor, is remedy.

Now, when Endo sued Impax for patent infringement in 2007, as I mentioned, it got a 30-month stay before the FDA could approve Impax'

generic. It got that 30-month stay pursuant to the Hatch-Waxman Act.

Just before that 30-month stay expired, Endo bought another 30-month stay. Endo bought it from Impax through this settlement.

Impax got $112 million, and Endo avoided the risk of generic entry on the most popular dosages of Opana ER for 30 months, from June of 2010 to January 1, 2013.

Endo avoided the risk of competition from Impax, and because of Impax' 180-day exclusivity, it avoided the risk of competition on those five dosages from any other generic.

That is the anticompetitive harm in this case. And that harm occurred between the settlement in June of 2010 and Impax' generic entry in 2013.

As I mentioned at the beginning, we ask the court to find that as a result the settlement violated section 5 of the FTC Act.

And we also ask the court to issue an order prohibiting Impax from entering reverse payment settlements in the future. That is ongoing, future relief that we are requesting. And it is important relief.

It is important because, as I mentioned, Impax

is a generic pharmaceutical company. Its business is to file ANDAs and to challenge patents. And it will find itself in patent litigation with branded pharmaceutical companies again.

And Impax' current CEO testified in this case that he always hopes to get no-AG agreements. He was asked, "...would you hope to get what is frequently known as a no-AG clause?" And he said yes. He said, "Well, I think the best way to answer that would, [sic] be having grown up in the industry and knowing when the law was passed, it was not supposed to have an AG, I would like to always try to maintain that, wherever possible."

Now, Your Honor, we believe that it is appropriate for this court to issue an order telling Impax that if they want to settle patent lawsuits, they can, but they cannot do so with reverse payments of the sort used in this case.

And that's what this case is about, Your Honor.

Thank you.

JUDGE CHAPPELL: Are you ready?

MR. HASSI: I am, Your Honor.

JUDGE CHAPPELL: Go ahead. We may take a break before you finish, but get started.

When the government provides the documents we've discussed, give them to Lawman, the bailiff. He'll provide them to me.

MR. LOUGHLIN: Thank you, Your Honor.

(Pause in the proceedings.)

JUDGE CHAPPELL: Go ahead.

MR. HASSI: Your Honor, it won't surprise you to know that I have slides as well, if I could --

JUDGE CHAPPELL: Pass them out. I don't need one.

Before we get started, let's put up a test slide and make sure the system is working.

All right. Go ahead.

MR. HASSI: Thank you, Your Honor.

Good afternoon.

Your Honor, for patients with chronic pain, there's only one source of oxymorphone ER today, Impax. No other company, branded or generic, supplies oxymorphone ER today. Endo stopped selling it, as we talked about earlier this morning.

JUDGE CHAPPELL: Are you talking about an extended-release version?

MR. HASSI: Yes, Your Honor. Which is I think the only thing we'll be talking about in this case.

I may from time to time switch between

"oxymorphone," and by that I mean oxymorphone HCl ER, and I may say "Opana." I'll try to say "reformulated" if I mean the reformulated. Otherwise, I mean Opana ER or its generic variant.

JUDGE CHAPPELL: And when you and complaint counsel say "reformulated," we're talking about the so-called crushproof version.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: Right, Mr. Loughlin?

MR. LOUGHLIN: Yes, Your Honor.

JUDGE CHAPPELL: Thank you.

MR. HASSI: Now, Endo has used its patents to keep other ANDA filers -- and there were several. Your Honor asked this morning. You'll see that it wasn't just Impax. It wasn't just Impax and Actavis. It was Impax and Actavis and Watson and Amneal, and there were a number of generic filers that filed around the same time as Impax.

Impax was first to file on the five most popular strengths. Actavis --

JUDGE CHAPPELL: But nobody else had the -- no one else qualified for the 180-day exclusivity period?

MR. HASSI: Your Honor, Actavis qualified for 180 days on two strengths, the 7.5 and the 15 milligram. They're sometimes referred to as the

weaning strengths. They're used when titrating people off the drug, and so they're less popular.

Impax was the sole first filer on the five strengths, the 5, 10, 20, 30 and 40 milligram strengths.

JUDGE CHAPPELL: Did Actavis market those two strengths?

MR. HASSI: Actavis did for a period of time market those strengths, yes, Your Honor.

JUDGE CHAPPELL: Did Actavis have a deal with Endo?

MR. HASSI: Actavis did not have a deal with Endo. Actavis marketed those strengths after -- so Impax came on the market in 2013, got its 180 days of exclusivity. After that point, Actavis came to market with those -- with those strengths that had been on since 2011 in the two strengths that it was first to file on, but it came on the five additional strengths in the summer of 2013 and then was kicked off the market by the -- a court in the Southern District of New York and removed the product from the market in 2016 and is not on the market today.

JUDGE CHAPPELL: We've heard this 180-day period is very valuable to the generic. Do you agree?

MR. HASSI: I do agree, yes, Your Honor.

JUDGE CHAPPELL: How does that work out with the FDA, your client being the first filer? If something had gone wrong with Impax, does someone else who filed on the same day or around that time -- do they then step in and get the 180-day exclusivity window?

MR. HASSI: Your Honor, I believe it's simply, if something goes wrong, Impax forfeits it. I don't believe someone else gets it. I will check because I'm not as up on those regulatory rules to answer that question.

But I know there are conditions under which, for example, if Impax --

JUDGE CHAPPELL: I'm sure there will be someone in the chair during the trial who can tell us that.

MR. HASSI: Your Honor, Margaret Snowden, who will testify either this afternoon or tomorrow, is an in-house lawyer for Impax and is the person I would go to to answer that question. And I'm sure she'd be happy to answer it to the extent she can.

JUDGE CHAPPELL: We're going to have to get into the weeds about some of these processes.

MR. HASSI: Understood, Your Honor. And we'll try to provide those answers as best we can.

But, Your Honor, as I said, Impax is the only source of oxymorphone ER today. And the reason it's the only source and the reason it's able to sell that product today is because in 2010 it entered into a settlement with Endo.

That settlement allowed Impax to enter on a date certain. It was allowed to enter on a date certain before the patents that it was litigating with Endo expired.

And in that settlement, it acquired a license to future patents, so not just the two patents that were at issue in that litigation but to the patents that Endo has subsequently acquired and the patents that have kept others off the market today.

And so Impax, as I mentioned, came on the market in 2013 and has been selling ever since.

Other generic filers -- there were a number of them -- settled with Endo but on different terms. None of them got that same broad license, and none of them is on the market today.

As you will hear in this case, Endo acquired a number of additional patents. It has prosecuted those patents, and it's prosecuted them successfully. Judges in New York --

JUDGE CHAPPELL: When you say none of them are

on the market today, were some of these other generic filers -- did they market the drug for a while?

MR. HASSI: Only Actavis, Your Honor. Actavis is the only company that ever came onto the market and sold Opana for a period of time.

JUDGE CHAPPELL: And why are they not on the market?

MR. HASSI: Because they lost a patent challenge to Endo and a judge ordered them off the market, and then they lost a second patent challenge to Endo, and they lost -- in the same litigation, a third patent was upheld.

So there are two separate sets of litigation, four total patents. Those have been upheld, and the last one expires in 2029, and so Actavis is currently under injunction through 2029.

JUDGE CHAPPELL: So it sounds like the reasons why your client is the only one on the market are many and varied, but we're going to hear about them during the trial.

MR. HASSI: That's correct, Your Honor. And I would say that they all stem from the settlement that is at the heart of this trial.

In other words, but for that settlement, Impax would have been sued in those cases, indeed it was sued

in those other cases on the reformulated, and would be enjoined today, and so Impax would not be selling Opana ER today. Nobody would be selling Opana ER today.

Now, complaint counsel would like you to find the settlement anticompetitive because it included a payment from Endo to Impax, and in the hypothetical world that complaint counsel conjures up, that payment must somehow have been bad for consumers.

They don't explain which consumers. They don't explain, other than the window that we heard this morning, sometime between June in 2010 and January of 2013, when Impax would have come to market.

They eschew all that. They don't think they need to prove that under the rule of reason. They just want to say that somehow if Impax had continued to litigate -- because let's face it. That's the only option they had. It was settle or continue to litigate -- somehow if Impax had continued to litigate, the world would have been a better place for consumers.

JUDGE CHAPPELL: What about this $10 million apparently payment for nothing as I've heard?

MR. HASSI: Your Honor, you will hear a lot about that. We certainly don't think it's a payment

for nothing. That drug is --

JUDGE CHAPPELL: Do you agree with what complaint counsel said, that your client basically slipped in a second product in the middle of the night?

MR. HASSI: Not at all, Your Honor. The product -- Endo expressed an interest in what was then called 066.

JUDGE CHAPPELL: Well, let's get down to basics on this.

Is it true that when the agreement was signed, the information regarding the product had not been provided to Endo? It was not identified at the time it was signed?

MR. HASSI: Your Honor, the product had been identified. Information had been provided to Endo at its request. There wasn't as much information about the product that was at that point under formulation as its predecessor.

Its predecessor, by the way, is on the market today. It's a drug called Rytary. Endo expressed an interest initially in Rytary, but Impax wasn't looking for a partner on Rytary.

So, yes, Endo wanted that product and any follow-ons. And Impax says, We're not going to give

you Rytary. We won't -- we will talk to you about the follow-ons.

And that's what IPX -- what was ultimately called IPX-203 is. It's a follow-on to Rytary. It's under development today. It's in Phase II trials today, and Impax has a lot of hope -- we're going to bring Michael Nestor, the head of the brand company, who is going to talk to you about that product, and you'll hear from Bryan Reasons, who complaint counsel is going to call, the CFO -- that's the hope of the brand side of the company.

JUDGE CHAPPELL: I saw a slide here that said there was a trigger.

Did Phase II trigger a $4 million payment?

I mean, is that -- is this still in effect?

MR. HASSI: Your Honor, no. The agreement was ultimately abandoned by Endo.

What happened is, over a period of time -- so the drug was in formulation at the time that the parties were discussing and entered into this agreement. Impax worked on that for a long time, and they had some other issues with the FDA that caused them to pause their work on it for a period of time.

When they ultimately reached a formulation that they thought met the profile they were seeking --

and I'm getting into science that's a little bit beyond me here -- but the profile they were looking to meet in terms of why this drug would be an improvement over what is now being sold as Rytary, they offered that to Endo and they said, Look, in the four corners of the definition of our agreement, this isn't exactly what we agreed upon. It's a slightly revised version of that, and it has to do with an esterized product.

And Mr. Cobuzzi from -- Dr. Cobuzzi from Endo, who is a scientist who did this deal for Endo and, by the way, did his Ph.D. thesis on Parkinson's, he can explain this far better than I can.

But the definition -- the definition changed a little bit. And Endo -- Impax presented it to Endo. Endo looked at this. And this was in 2015, so five years -- for five years Impax had been working on it.

They presented it to Endo. Endo looked at it and Endo said it looked interesting. They talked about entering into -- revising the deal to change the definition for this new product. And then at some point in late 2015 Endo came back and said, You know what, we don't want to do it, and so Endo dropped out.

JUDGE CHAPPELL: Is there a document reflecting the termination of that side agreement?

MR. HASSI: There is, Your Honor. And I

believe you'll hear testimony from Ms. Snowden about it, the lawyer for --

JUDGE CHAPPELL: Is that document on the joint exhibit we're going to get to later today?

MR. HASSI: It is, yes, Your Honor.

So, Your Honor, complaint counsel wants you to assume that maybe Impax would have won the litigation. They don't really talk about the patents, as Your Honor pointed out. We will.

We think that the patents here are important, not just the patents that were at issue in the lawsuit but the after-acquired patents and the license that Impax got.

They also want you to assume that Impax would have launched at risk. They sort of cavalierly throw out there that this little, conservative company would have taken this huge risk, betting the company, putting their jobs at stake, and launched this product, launched this product at risk.

And we're going to demonstrate why that assumption is false. We're going to demonstrate to you why that's not reasonable to suggest.

JUDGE CHAPPELL: So even though the FDA approved entry, there's no safe harbor or no protection if you launch and you're later found to be an

infringer?

MR. HASSI: That's correct, Your Honor.

JUDGE CHAPPELL: Why is that?

MR. HASSI: That's as a matter of law because there are patents.

In other words, there are a couple of barriers here. The FDA -- FDA and FDA approval is a barrier to entry. Everyone agrees to that. And ultimately Impax passed that barrier.

JUDGE CHAPPELL: But it's no safe harbor for infringement.

MR. HASSI: It is not safe harbor. It doesn't speak to the patents. If there are patents, that's what was at issue in the litigation, and so Impax, had it launched at risk against those patents --

JUDGE CHAPPELL: This is not my first rodeo involving one of these cases.

MR. HASSI: Understood, Your Honor.

JUDGE CHAPPELL: Doesn't the generic company certify or make some declaration to the FDA that we've got a generic equivalent, biosimilar or whatever, that does not infringe? Isn't that some representation you're making to the FDA in the beginning?

MR. HASSI: All of these Hatch-Waxman cases start with the generic company saying either their

product -- either the patents are invalid or our product doesn't infringe it. And that triggers -- under Hatch-Waxman, that triggers the right of the brand to say, Oh, yes, it does, and to commence a patent litigation.

And the idea behind Hatch-Waxman was that allowed -- before that, generic companies would have to launch at risk and sort of dare the patent company to sue them. Now they can file a Paragraph IV. They don't actually have to go out at risk and risk damages, and they can have the litigation during that 30-month period and a court can decide who's right about the patents.

But what you're not going to hear from complaint counsel --

JUDGE CHAPPELL: But theoretically in that 30-month period.

MR. HASSI: Theoretically in that 30-month period.

And it won't surprise you to know that typically the brand company tries to delay how long it takes to get to trial and the generic company wants to get there as soon as possible so that at the end of that 30-month period they can be in a position to launch.

JUDGE CHAPPELL: Was the settlement in this case blessed by a district court judge?

MR. HASSI: I believe it was, but I'll have to check, Your Honor.

I mean, in other words, it was -- I -- well, I take that back.

It was in litigation at the time. I don't know that the parties needed court approval for the settlement so much as they entered into a settlement, told the judge, and the judge originally paused the trial and then ended the trial.

I don't know that -- and I would have to check as to whether the settlement required court approval. It wasn't a class action --

JUDGE CHAPPELL: Well, when I say "blessed by," I don't mean it had to have court approval, I meant did it get court approval. Was it submitted by the parties to the judge when the litigation ended?

MR. HASSI: I don't know the answer to that, Your Honor. I will have to check.

JUDGE CHAPPELL: I will expect somebody to have that answer at some point on the witness stand.

MR. HASSI: Yes, Your Honor. Again, I'm going to put a lot on Ms. Snowden's plate, but she was one of the in-house lawyers at the time of the litigation and

settlement and --

JUDGE CHAPPELL: Snowden?

MR. HASSI: Snowden, yes, Your Honor.

JUDGE CHAPPELL: No relation?

MR. HASSI: I'm sorry?

JUDGE CHAPPELL: No relation?

MR. HASSI: I don't know the answer to that, Your Honor, but I hope not.

Last night she was Simpson. We were trying to get her checked into a hotel and we put the reservation under another name, so maybe we'll just call her Simpson for these purposes.

But, Your Honor, going back to the idea of a launch at risk, it's a risky proposition, particularly for a small company like Impax. And we're going to show you that it was too big a risk here, that there wasn't really a period of time where, as complaint counsel suggests, there would have been product sold either at risk or falling away. It's all hypothetical, theoretical. Consumers were better off in the real world.

And Your Honor, there's no evidence that there was a payment here for delay. That's -- when you said this is not your first rodeo, I'm sure Your Honor is aware that the FTC has been calling these cases

pay-for-delay for fifteen years or more now.

And it seems like, from what we heard this morning, you don't have to prove pay-for-delay anymore, it's just pay now. They want to say that if there's a payment going from the brand to the generic, it's per se illegal and it's all over.

We think you have to look at this under the rule of reason, and we think you have to balance the procompetitive aspects of the settlement against any purported anticompetitive effects, and we think that that requires showing anticompetitive effects.

And so while you'll hear theories as to -- from experts, that Impax would have entered the market, you're not going to hear any fact witness testify that Impax would have entered the market or that Impax would have won the underlying litigation.

Now, Your Honor is familiar with the rule of reason, and you know that complaint counsel must first prove, before getting to the rule of reason, a large and unjustified payment. And we've talked about that this morning.

The evidence at trial will show Impax did not.

If complaint counsel were to show under the settlement that Impax received a large and unjustified payment, then we apply the rule of reason, as Actavis

said. And I think that's the one thing from Actavis that we can all agree about is the rule of reason applies here.

JUDGE CHAPPELL: Hold on a second.

Josett, would you like for him to slow down a little?

THE REPORTER: I sure would.

MR. HASSI: I will try, Your Honor.

JUDGE CHAPPELL: That's kind of an indirect request.

MR. HASSI: Your Honor, I'm sorry. I realize I'm keeping people from their lunch.

So as the Supreme Court said in Actavis, complaint counsel must then prove their case as in other rule of reason cases. And the conventional rule of reason approach requires courts to engage in a thorough analysis of the relevant market and the effects of the restraint in that market.

Now, the challenged restraint here is the settlement. I heard the payment referred to as the restraint this morning. I'm not sure how a payment restrains anybody.

If we're really just talking about the payment here, not, for example, the entry date, which was in that same agreement, I think we can all just go home.

But I think what you're going to hear is and you did hear at other times, at times they say you've got to justify the payment and other times they say, well, no, no, you've got to tie the payment -- we're going to tie the payment to the entry.

THE REPORTER: You have to slow down. You're not slowing down.

JUDGE CHAPPELL: That's a direct request.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: Speaking of relevant market, Mr. Loughlin didn't spend a lot of time on it, but the government's position is the product market here is the drug you sell. They've got experts to tell us you can't take somebody off that drug, et cetera, et cetera.

I believe you're going to disagree on what the relevant market is?

MR. HASSI: We are absolutely going to disagree on what the relevant market is, Your Honor.

The relevant market is long-acting opioids. And there are -- and particularly extended-release ones, but there are a number of drugs in this category, and you'll see that there is competition at multiple levels. There's competition for insurance companies. There's competition for patients. There's

competition for prescribers, the doctors that prescribe this drug.

You're going to hear that this drug isn't particularly special as compared with those other long-acting opioids. It's a pain relief drug, Your Honor.

The number one indication -- excuse me. The number one use for this is lumbago, lower back pain, which a number of us suffer from. I don't have to take opioids; it's not that bad.

But there are lots of uses for this drug. There's no unique use for this drug. And we absolutely are going to contest the relevant market.

JUDGE CHAPPELL: So your position is, rather than patients who are going to be prescribed this opioid, it is perhaps patients who are going to be prescribed an opioid?

MR. HASSI: An opioid, yes, Your Honor.

In other words, OxyContin, for example, Purdue Pharma's, that's the blockbuster in this. It's a multibillion-dollar market. Purdue Pharma's OxyContin is by far the largest seller in the market. Endo calculated at the time their market share at about 3.4 percent of its American market, so yes, there are lots of choices.

JUDGE CHAPPELL: And today, OxyContin has what percentage of this market?

MR. HASSI: I don't know the market shares today. We can get you that, Your Honor. But OxyContin is still a big player in this market. There have been a number of other entrants into the market.

JUDGE CHAPPELL: What does your client consider to be the number one competitor to this drug that's in dispute?

MR. HASSI: I would have to ask my client, Your Honor. I think OxyContin is the one that gets focused on the most. But, again, initially the company wanted to be an AB-rated generic. That never happened because Endo moved the market to the reformulated.

But as Your Honor points out, under the rule of reason -- so first complaint counsel has to show a large and unreasonable payment. If they do that, we go to the rule of reason. And the first thing we'll talk about under the rule of reason is the product market. And then we'll talk about whether there was an effect in the relevant market.

JUDGE CHAPPELL: You said "unreasonable payment." Do you mean unjustified?

MR. HASSI: You know, the Supreme Court uses

both terms, "large and unreasonable" and "large and unjustified." I take them to mean the same thing, but I can't speak to why they used both terms. I think -- I think -- my recollection is Actavis uses both terms.

Your Honor, Impax is a small drug company. It was founded in 1995 by Dr. Larry Hsu, and he's going to testify in this case. And Impax makes money by selling generic drugs, not from settlements.

Patent settlements may be the way that Impax comes to market often and it was, as I talked about, the main purpose of the Hatch-Waxman Act and that was to foster generic competition, but that's -- patent litigation is often a vehicle that allows Impax to come to market.

It, as we talked about, files a Paragraph IV challenge and following that Paragraph IV challenge enters into litigation typically with the brand company and waits to see, typically, what the result of that litigation is before deciding whether or not to launch at risk or to launch.

And that's what Impax did here. It filed with the FDA, and it challenged Endo's patents in that Paragraph IV filing. And it spent nearly two and a half years litigating with Endo so that it could sell generic Opana ER.

And on the eve of trial -- and actually, trial started -- the parties enter into settlement negotiations.

And you're going to hear from witness after witness that Impax' first interest in those settlement negotiations was to get an early entry date.

That's what they want to do. They want to come to market and they want to sell.

But they want to come to a robust market, so an early entry date alone isn't enough. They want to know that, for example, they're not going to get kicked back off the market by after-acquired patents. And they want to know that there's going to be a robust market to enter into, that the brand isn't going to move the market to in this case a reformulated drug.

And so Impax began -- the first negotiations over the settlement were about the entry date. And Impax pushed on that issue and pushed on that issue. And as Your Honor noted this morning, the first date offered by Endo was a March 10, 2013 date, and that date moved up to a February 1, 2013 date and ultimately became a January 1, 2013 date.

So Impax tried and successfully got earlier and earlier dates. It never agreed to a later date, and it

was always pushing.

JUDGE CHAPPELL: The patent expiration date would be when?

MR. HASSI: September 10, 2013 -- oh, in September 2013, around the 10th. It might have been the 9th and the --

JUDGE CHAPPELL: Same year.

MR. HASSI: Same year, yes, Your Honor.

Indeed, there was a -- you'll hear, again from Ms. Snowden, in the early settlement discussions, in the very first call that she had, there was a discussion about dates. And the discussion went as follows:

Endo laid out that their expectation was that you would take the patent expiration date, which was September '13, and take the earliest possible entry date that Endo -- that Impax could achieve following a litigation to a final decision and split those dates.

And Ms. Snowden suggested, Well, what about June 2010, what about the fact that we could enter at that point? And Endo laughed it off. Endo said, You don't enter at risk. Impax doesn't do that.

And she brought up the one example from five years earlier where Impax once launched at risk. And Endo was very familiar with that because Endo had been

in that case, too.

And Impax didn't launch at risk after a successful district court decision. They entered after a successful district court decision, after another generic had entered, after it was up and briefed in front of and argued in front of the Federal Circuit, and they launched for a very short period of time and settled and got out of the market.

By the way, that was on OxyContin, which we've talked about this morning, another long-acting opioid.

You're going to hear in this case from Larry Hsu, the CEO, that an entry date was his first priority.

And you're going to hear from Chris Mengler, the lead negotiator and the president of the generic division --

JUDGE CHAPPELL: But you ended up January 2013 versus September 2013 with no risk. Why not just wait eight or nine months? If you're going to go to January 2013, why don't you wait eight or nine months when there's no risk?

MR. HASSI: Several reasons, Your Honor.

First, January -- I mean, the objective is to sell early, and so -- to enter early, and January is earlier than September.

JUDGE CHAPPELL: Who brought up March 2013?

MR. HASSI: Endo raised it in the first term sheet. They offered -- they offered March --

JUDGE CHAPPELL: Because at this point, 2013, we're way past any exclusivity period. All that stuff is long gone.

MR. HASSI: No, Your Honor. The exclusivity period starts ticking when Impax first enters the market.

JUDGE CHAPPELL: When did that run in this case? The 30-month --

MR. HASSI: So in this case it ran starting in January of 2013 when they launched and for 180 days.

JUDGE CHAPPELL: So the date -- so January was when, based on the 30-day delay, the 180-day would have begun to run.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: And you -- it turned out you got in the market at the beginning of that period.

MR. HASSI: We got in the market in January 2013, yes, Your Honor.

JUDGE CHAPPELL: All right. So due to the 30-day [sic] delay, had you waited until the patent expired in September, you would have lost the 180 days, due to the 30-month delay.

MR. HASSI: Due to the 30-month, if Impax had waited until September of 2013 to launch, that's right, they would not have been exclusive at that point. They would have forfeited or lost their exclusivity, and other ANDA filers could enter at the same time.

JUDGE CHAPPELL: All right.

MR. HASSI: Now, you're not -- you're going to hear from Chris Mengler, who was the lead negotiator for Impax, that he did his best and pushed for a January 1 -- pushed for the earliest entry date he could and ultimately got to a January 1, 2013 entry date.

You're not going to hear from anybody from Endo or from Impax that an earlier date was offered by Endo. You're not going to hear that, for example, Endo offered an earlier date and Impax said, well, what if you pay us instead and there was a quid pro quo. That didn't happen in this case.

Impax took the earliest date it could get, it pushed on the date, and it got to January 1, 2013.

And you're going to hear -- the only people you're going to hear from that suggest that an earlier date was available are experts hypothesizing that they think that based on their review of the record somehow you could have had an earlier date.

So in the real world -- and we think that's what should count here -- Impax tried to get an earlier date and failed.

And I would ask Your Honor, as you're considering this case, to consider it from the perspective of Impax, because you heard a lot about what Endo knew this morning and what Endo was thinking and what Endo could have done and Endo paying Impax to end the risk of entry. Impax is the -- Impax is the party that's before you.

Impax knew what its options were and what they weren't. It couldn't just -- it could not just enter. In other words, it had to get FDA approval, and it had to deal with the patents.

And the way to deal with the patents is either to win the litigation -- and you're not going to hear that they necessarily would have won the litigation -- or they could enter at risk and take those risks. And again, those are large.

JUDGE CHAPPELL: Just to be clear, there's some inconsistency, right, in your position?

When your client was in the patent litigation, your claim was that the Endo patent was invalid; correct?

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: And what I'm hearing today, you're making the opposite claim, that it was a strong and valid patent.

MR. HASSI: Your Honor, what I will tell you today is what you will hear principally from Mr. Figg, our patent expert. The outcome was uncertain, absolutely. And I think all the -- the experts agree on that, the outcome of the patent litigation. We're not going to say that Impax necessarily would have lost.

What Mr. Figg will tell you is that shortly before the trial started, the judge who was trying that -- who was slated to try that case issued her Markman opinion, and the Markman opinion sided with Endo.

So I think the best we can say at this point -- and this is what Mr. Figg will tell you -- is that it was more likely than not that Impax would have lost.

But again, it's taking a risk. It's rolling the dice.

If Impax goes forward with the litigation and loses, it doesn't get to enter. It doesn't get to sell the drug.

JUDGE CHAPPELL: I read something in probably

your pretrial brief about new patents going into 2029. How does that work? If this patent expired in 2013, what has been changed for a valid patent to go into 2029?

MR. HASSI: Your Honor, Endo acquired additional patents and acquired those patents, some of them, between June of 2010 and January of 2013, and so had we not settled, in 2013 -- if we waited for September 2013, for example -- and I'll show you a demonstrative in a little bit. They acquired five additional patents in that period of time -- we would have had to launch at risk against all five of those patents.

JUDGE CHAPPELL: So rather than reapplying or changing something, they acquired more patents.

MR. HASSI: They did both, Your Honor.

JUDGE CHAPPELL: And they've used these patents to block other opioid generics?

MR. HASSI: They have, Your Honor. They've blocked all of the other ANDA filers who filed against Opana ER and, for that matter, all of the ANDA filers who filed against the reformulated, including Impax.

Because what you'll hear is Impax got a license to Opana ER, it didn't get a license that would cover the reformulated product, and so Impax has been a

defendant in some of those litigations, and Impax is enjoined by those same patents along with the other ANDA filers.

JUDGE CHAPPELL: Is anyone selling the crushproof or reformulated version at this time?

MR. HASSI: No, Your Honor. The only one who ever sold it was Endo, and they were asked this summer by the FDA to leave the market, and as of September 1, they're off the market.

JUDGE CHAPPELL: Voluntary recall.

MR. HASSI: Voluntary recall, yes, Your Honor.

Your Honor, before we talk about the effects, I want to talk about the three payment terms that you heard about this morning.

Complaint counsel points to three provisions, two of them in the agreement and one in the separate development and co-promotion agreement, and say that those were payment terms --

JUDGE CHAPPELL: Wait a second.

Are you saying three, number three being the $10 million deal?

MR. HASSI: The third being the $10 million that was part of the development and co-promotion agreement, yes, Your Honor.

In other words, to be specific, I'm speaking

to the -- what's been called the no authorized generic -- they say that was a payment term -- the Endo credit -- they say that was a payment term, and they put the two together and say it's a guaranteed payment term -- and then you have the development and co-promotion agreement.

So starting with the no authorized generic, complaint counsel bears the burden of showing that that's a large and unexplained or unjustified payment.

And what you heard this morning is Endo offered it in the very first term sheet.

Now, would Impax be interested, as an academic matter, in a no authorized generic? As the CEO will testify, it's better to have one than not.

I mean, in some circumstances, that can be a good thing, a no authorized generic. Here, not necessarily. And the evidence will show that Endo was not planning on launching an authorized generic.

Now, that's in contrast to what you heard this morning, and I want to explain.

Endo did consider launching an authorized generic if Impax were to launch at risk. But we're not talking about a launch at risk here in the settlement. If Impax settles, it's not launching at risk.

And Endo was planning on reformulating, and launching an authorized generic would be inconsistent with that.

JUDGE CHAPPELL: So your position is Endo was never considering selling an authorized generic.

MR. HASSI: Not exactly, Your Honor. Impax --

JUDGE CHAPPELL: Because we saw a chart earlier today.

MR. HASSI: Exactly, Your Honor, and allow me to explain.

So at the point in time before they entered into settlement, before they entered into settlement talks, Endo was concerned that Impax might launch at risk, and it modeled what happens if we launch at risk and should we consider launching -- if Impax launches at risk, should Endo consider launching an authorized generic.

And under those circumstances, it is possible that Endo would have launched an authorized generic. But what's in front of Your Honor is a settlement, so Impax didn't launch at risk. Endo didn't launch an authorized generic -- Endo didn't launch an authorized generic.

It would be inconsistent with what its plan was. Its plan was not to have Impax launch at risk.

Its plan was to --

JUDGE CHAPPELL: No, no. That's two different things. You just now said they didn't launch, but you told me earlier they did never plan to launch. Which is it?

MR. HASSI: Your Honor, they did not plan to launch so long as they could get -- go forward with their plan and --

JUDGE CHAPPELL: But you concede they took steps in line with launching an AG.

MR. HASSI: They did take steps to prepare, in the event that Impax or another generic launched at risk, to respond with an authorized generic. They did, Your Honor.

However, their plan was not to have to launch an authorized generic but instead to launch a reformulated product, to move the market to that reformulated product, and not to have to -- not to launch an authorized generic at all. And that's what it did.

It moved to a new product. That new product -- it would have been inconsistent to launch an authorized generic.

And if we could --

JUDGE CHAPPELL: Whose idea was the prong of

the agreement where your client got payment if the market degraded?

MR. HASSI: So Impax proposed a market degradation trigger. And by that I mean a provision that -- what Impax said is, Look, if the market drops by, say, 50 percent, we get to enter the market at that point in time instead of waiting until January 1, 2013.

JUDGE CHAPPELL: And at the time the deal was done, your client suspected another product coming, but you had been told there would not be another product coming; is that correct?

MR. HASSI: That is correct, Your Honor.

JUDGE CHAPPELL: If Endo planned to launch the other product, why would they put a term in that agreement, knowing they were going to have to pay your client because they were going to degrade the market?

MR. HASSI: Your Honor, I don't think -- and the testimony is they never expected to have to make a payment under that term. They didn't expect -- I mean, they didn't expect to make a payment under the Endo credit.

They expected to move the market to reformulated, and there was, as you heard this morning, a way to do it without triggering that Endo credit

provision. And that would have made that Endo credit provision valueless.

So if I could go back, on the authorized generic -- if you could bring up the Brian Lortie slide.

So you heard about Mr. Lortie this morning. He's an Endo senior vice -- senior vice president who was -- the senior vice president of Endo Pain Solutions, so he was responsible for this drug. And here's what he said.

MR. ANTALICS: Your Honor, the visuals are not working.

JUDGE CHAPPELL: Okay. The monitor is working.

MR. HASSI: Ours are flashing, which is a little disconcerting.

If yours is working, Your Honor, I will shut this one off.

JUDGE CHAPPELL: Mine appears to flash when I look away, but not while I'm looking.

MR. HASSI: Your Honor, so this is testimony from Brian Lortie. He's the senior vice president of Endo Pain Solutions.

And what he testified to is, it would be morally very difficult to justify at the same time

having a crushable authorized generic product and a noncrushable branded product.

And indeed, what Endo did ultimately was file a citizens petition with the FDA and tried to convince the FDA that original Opana ER was removed from the market for safety reasons.

And Impax challenged that citizens petition, and when Endo didn't get a response quickly enough from the FDA, they sued the FDA.

And if we could bring up, Robert, the next slide.

So this is --

JUDGE CHAPPELL: Could it be that some higher power is suggesting we take a break to fix this?

MR. HASSI: Your Honor, I won't disagree with that. I'm finding the flashing very disconcerting.

JUDGE CHAPPELL: Lawman, you're going to get somebody on this; right?

THE BAILIFF: Yes, sir. Yes, Your Honor.

JUDGE CHAPPELL: Let's go ahead and take our lunch break, although be advised that during the trial we generally won't break for lunch this early, we'll be breaking later in the day, but we will take a morning break. We'll get into some of those particulars later.

We're going to take our lunch recess. We'll reconvene at 1:45.

We're in recess.

(Whereupon, at 12:39 p.m., a lunch recess was taken.)

A F T E R N O O N  S E S S I O N

(1:51 p.m.)

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

MR. HASSI: Thank you, Your Honor.

Your Honor, before the lunch break, we were talking about the no authorized generic.

So when we had the technical problems, I was introducing Mr. Lortie, who is the senior vice president of Endo Pain Solutions. And he testified -- Your Honor had asked about whether they might launch an authorized generic.

He testified it would have been morally very difficult to justify at the same time -- it would be morally -- "It would have therefore been morally very difficult to justify at the same time having a crushable authorized generic product on the market. From my opinion, it would have been very difficult to take [these] two positions. So, fundamentally, we intended to replace one product with the other, and that would be the only product that we had on the market."

JUDGE CHAPPELL: Who's Lortie?

MR. HASSI: Lortie is Endo's senior vice president of Pain Solutions. He's one of the

people that would have been the executive making the decision about whether or not Endo would launch an authorized generic.

And so what he's saying is, is we can't be going out there with a reformulated that we're saying is crush-resistant, it's better for people because it's less susceptible to abuse, and at the same time be selling an authorized generic of the drug that we're replacing on grounds that it was less safe.

And indeed, that's what they told the FDA. They filed a citizens petition with the FDA. And in that citizens petition -- if you could bring that up -- they told the FDA -- they asked the FDA to rule that Opana ER was removed for safety. And this is from their citizens petition that they filed with the FDA.

JUDGE CHAPPELL: Who's "they"? You say "they filed."

MR. HASSI: They -- I'm sorry, Your Honor. Endo. Again, we're talking about whether or not Endo would have launched an authorized generic.

Endo not only wouldn't have launched an authorized generic, they told the FDA that Opana ER should not be on the market, it's not safe. They said --

JUDGE CHAPPELL: So this is dated

August 10, 2012.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: What date was the -- the agreement that's the gist of this lawsuit, what date was the agreement signed?

MR. HASSI: June 8, 2010.

JUDGE CHAPPELL: Signed in 2010, generic entry January 2013.

MR. HASSI: Yes, Your Honor.

This is -- Impax would argue that the purpose or that Endo's reason for doing this was to keep Impax from launching its generic at all, and so what they did is they went to the FDA, Endo did, went to the FDA and said to the FDA, we think you should rule that the reason old Opana ER came off the market in favor of reformulated Opana ER is because old Opana ER, because it's not crush-resistant, isn't safe.

And so they said, "The presence of both Opana ER CRF," the crush-resistant, "and generic, non-crush-resistant oxymorphone formulations on the market simultaneously would allow abuse or diversion to continue, limiting the potential benefits that can be provided by Opana ER CRF."

JUDGE CHAPPELL: So if I understand this, your position is that Endo's intent -- and again, we're

talking about Endo, Endo's intent.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: Your take is that Endo went to the FDA in an attempt to purposely in effect cannibalize to end the ER so that everyone has to have the crushproof.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: Opioid.

MR. HASSI: Yes, Your Honor. They wanted -- they wanted -- they wanted to be selling the only version of Opana and they wanted it to be the crushproof. And they didn't want Impax to come on with a generic, and they didn't want to sell their own authorized generic of the non-crush-resistant.

JUDGE CHAPPELL: And this is disputed?

MR. HASSI: This is disputed.

The complaint counsel says that there was -- this no-authorized-generic provision had value.

Our point is, they put that -- they put that provision in the first agreement, "they" Endo, offered that first provision in the first agreement. It was never really discussed. It was in the final agreement, but it really didn't have value, because Endo was giving the sleeves off its vest. Endo wasn't going to launch an authorized generic, so promising to not

launch an authorized generic is a promise with no value.

JUDGE CHAPPELL: And let me talk about some dates.

You say the agreement was finalized June 2010.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: Does that also include what's been called I guess the side agreement, same time, same date?

MR. HASSI: The development and co-promotion agreement was signed a day earlier on June 7.

JUDGE CHAPPELL: And there was a $10 million payment when?

MR. HASSI: The $10 million payment was made shortly thereafter. I want to say it was within five days, but it may have been taken a little longer for the payment to --

JUDGE CHAPPELL: Other than that payment, when did even one penny come from Endo to your client after that agreement was signed in June 2010?

MR. HASSI: The Endo credit was paid I believe at the end of the first quarter of 2013.

JUDGE CHAPPELL: So nothing kicked in until your client was on the market.

MR. HASSI: Not only did it not kick in, Your Honor, what you're going to hear from Endo is it wasn't estimable and it wasn't payable, they didn't know, until 2012.

In the midst of these events related to the reformulation and the market switch, which you're going to hear about, they had a supply chain crisis. That supply chain crisis is what triggered the need to make the Endo payment. That happened in 2012.

JUDGE CHAPPELL: But if the government is right that this was a payment to stay out of the market or a payment not to compete, does the timing even matter?

MR. HASSI: The timing matters in the sense that was it an expected payment. Your Honor asked this morning about did they understand, did the parties understand that there might not be a payment here.

Impax understood that there might not be a payment. And neither party valued this as a payment. Neither party said, gee, we're going to get this from the Endo credit or we're going to get this from the no authorized generic. You're not going to see any estimates of Impax calculating this is what this is

worth to us, this is what we're going to get out of the settlement agreement.

These simply weren't payments. They weren't intended that way.

JUDGE CHAPPELL: Once the payments were coming in based on these two provisions we've discussed, were there disputes about the amount? You know, were accountants on both sides getting together reconciling? How did the amount get determined in the -- how did it really happen?

MR. HASSI: So there was --

JUDGE CHAPPELL: I'm not talking about argument or allegation. You know, I'm not expecting, you know -- what's the evidence going to show us as far as how did the amount get determined under the terms of the agreement, and was it ever in dispute between the two parties?

MR. HASSI: I would say there was confusion, but no, there was not a dispute over the calculation of the payment. I think both parties had to look at it really hard, and what you're going to see is both parties trying to figure out how much do we owe and, on Endo's case, why do we owe this. It sort of came as a surprise you're going to see in their accounting documents. But ultimately there was agreement on the

amount and the amounts paid in 2013.

JUDGE CHAPPELL: Well, just triggering terms like "market share," these are not scientific, quantifiable terms.

MR. HASSI: There was data identified.

So, for example, one of the things that's interesting about the Endo credit is the sales in the fourth quarter were based not on Endo's internal records. One of the triggering events was did the fourth quarter drop below this 50 percent high threshold. And that was based not on Endo's internal records, but it was based on third-party data, IMS data.

JUDGE CHAPPELL: And I haven't committed the agreement to memory, at least not yet, but you're telling me there were terms in there that identified what source to go to to determine or agree on a market share regarding the payment.

MR. HASSI: The parties had worked out how to calculate this and what the data -- what data would be relied on to calculate it, yes, Your Honor.

JUDGE CHAPPELL: All right. Let's get back to the petition. What happened?

MR. HASSI: So back to the petition, the last thing that they said or the last portion I've put up

that Endo said to the FDA is: "The new formulation reduces the risk of an immediate release of a potentially lethal dose of oxymorphone in these situations."

This isn't a company -- this is a company telling the FDA that you should remove Opana ER from the market. This is not a company that's planning on offering Opana ER.

Indeed, when they lost the petition, the citizens petition with the FDA, which Impax intervened in, Endo sued the FDA to get a decision. Impax intervened in that. In other words, Impax was fighting to have the opportunity to come to market.

And ultimately the FDA sided with Impax that old Opana ER, original Opana ER, was not removed for safety reasons. And Endo -- and this is now May of 2013. Endo releases a press release, and they say, "We are extremely disappointed and disagree with today's decision and believe that the approval of [the] non-abuse-deterrent formulations of long-acting opioids will contribute to a significant increase in prescription drug abuse." And that was the CEO saying that.

And I make this point, Your Honor, both to say that not only was this a company that wasn't going to

launch an authorized generic of Opana ER, you -- you asked Mr. Loughlin this morning, and he said, Well, Endo could come back on now with original Opana ER.

And the question is, would Endo, having made these kinds of statements to the public market about original Opana ER being unsafe, being removed from the market for safety, realistically ever come back and sell that drug again? The answer has got to be no.

JUDGE CHAPPELL: What happened in the market before the recall? Did this reformulated drug take off like wildfire? Did it capture a lot of the market?

MR. HASSI: Your Honor, in part because of the supply disruptions, what you see is -- so stepping back a second, one of the reasons that the Endo credit was triggered, recall the calculation has a quarterly high, so how much was being sold in the highest quarter before the end of 2012, and that spiked because this product was growing and growing at a faster rate than Endo, Impax or any of the analysts projected.

So it's growing really fast. And then Endo wasn't making the product itself. Novartis was making it for Endo.

So Endo had Novartis contract-manufacturing

Opana ER. And Novartis got a letter from the FDA in the end of 2011 and was basically told, You're going to have to stop producing product at that factory.

And so Novartis went to Endo and said, We can't make your Opana ER anymore. And Endo went to the FDA and said, We've been working on this reformulated; we're going to speed up the process. And they worked with the FDA to launch reformulated, but that created what you'll hear from Endo's CFO was a supply chain crisis.

And that supply chain crisis affected Endo's ability to move -- I think "smoothly" was the word that -- complaint counsel put up a slide this morning. They wanted to smoothly transition. It was not a smooth transition. It was a forced transition because of this supply chain disruption.

And what the FDA said to Endo at the time is, When you start bringing on the reformulated, you've got to stop selling the old Opana ER. We don't want you to create confusion.

And so they went -- they went full stop on old Opana ER and started selling the reformulated. But I think -- and this is -- it's subject to interpretation because it's data, but the data shows sales -- Endo's sales of Opana went down significantly during that

period of time and didn't quite recover.

And one possibility for that is prescribing physicians were looking and saying, if we start prescribing this to patients and all of a sudden there's this supply -- and we've heard about this supply disruption, I don't want to start prescribing Opana to a patient and then -- and then have them -- that not be available anymore.

JUDGE CHAPPELL: Which Opana?

MR. HASSI: Opana ER. Opana ER.

So the reformulated is just coming out. Opana ER is no longer being supplied. And doctors are saying --

JUDGE CHAPPELL: And did I hear you say that the reason Opana ER was no longer being supplied was that because the FDA told Endo to do that, or was there another reason?

MR. HASSI: There were two reasons, Your Honor.

The first is Novartis couldn't make it anymore, and so Endo was trying to figure out what they do about the fact that they don't have a source of supply. They're not manufacturing this pill.

And second is, what the FDA said is, once you start selling reformulated during the supply chain

crisis, we don't want you also selling the old version, Opana ER.

JUDGE CHAPPELL: What year was this taking place?

MR. HASSI: This was in 2012, Your Honor.

And as a result, the sales dropped off -- of Opana ER dropped off entirely during that year.

JUDGE CHAPPELL: One of the things I want the parties to think about and I hope you can agree to are some issues you can put on a joint exhibit in a stipulation. And one of them is going to be a timeline, things you can agree on, this came to market at this point, this came off the market at this point, things that we're not fighting about. And that can be a joint exhibit that we can all refer to posttrial so we don't have to go digging through and citing fifteen transcript cites for certain points that aren't disputed.

MR. HASSI: I think there's a lot of agreement particularly on the timeline, Your Honor, and I think we will endeavor to do that.

JUDGE CHAPPELL: Not something that I need now. It's something we're going to need at the end of the case.

MR. HASSI: Understood, Your Honor.

In terms of timelines, I think one of the things that I wanted to point out with respect to the no authorized generic -- if we could pull up the next slide -- so as I mentioned, the no authorized generic was in the very first proposal, the very first term sheet from Endo to Impax. And that had a no-authorized-generic provision, and it had a March 10, 2013 entry date.

That no authorized generic was in the next proposal, which had a February 1, 2013 entry date.

And the final agreement had the same no-authorized-generic provision, and the entry date was even earlier, January 1, 2013.

And so what you see from the negotiating history is, far from the no-authorized-generic provision being a payment for delay, it was in there from the beginning and Impax managed, notwithstanding that, to negotiate an earlier and then an even earlier licensed entry date, so it was not a payment for delay.

I'd like to turn now to the Endo credit. And we've talked a little bit about it, but I want to make some additional points.

First, as was indicated, Impax had a concern -- it didn't know, but it had a concern that

Endo might reformulate. And in part, that concern came out of what was happening in the related OxyContin space.

So OxyContin is another form of long-acting opioid, and Purdue came up with what was purportedly a safer version of OxyContin. And the generics were removed by the FDA from the market or encouraged by the FDA to leave the market.

And so, in that related market, what Impax saw was the branded moving to a new drug, one that was purportedly safer, and the AB-rated substitution, the opportunity for Impax to sell, going away.

And there had been statements that Endo had made to Wall Street that suggested that maybe they had some kind of a plan. And Impax was worried about that plan. And Impax was worried that they might reformulate, and so they asked Endo.

You'll hear from Mr. Mengler. He asked Alan Levin, Endo's chief negotiator, point blank, are you guys going to move the market. And Alan said no. Excuse me. Mr. Levin said no.

And Mr. Mengler came back and came up with this idea of acceleration triggers, which we talked about this morning. And the idea was, if the market dipped a certain amount, then Impax would get to enter

even earlier than January 1, 2013.

And Endo rejected that. They rejected it flat-out.

And again I say, you have to look at this case from the perspective of Impax. Did Impax ask for an accelerated trigger? The answer is yes. But when Endo says no, there's not much we can do. We can go back and litigate the case and take -- roll the dice with the litigation, or we can try something else.

Well, in this case they had a discussion -- and if you can bring up Ms. Snowden's testimony.

Ms. Snowden, who you'll hear from I suspect at this point not today but tomorrow, is a lawyer who was involved in the negotiations. And this is her testimony about those negotiations and specifically about the genesis of the Endo credit.

She says: "So I remember a phone call. Chris" -- and that's a reference to Mr. Mengler -- "was sort of leading the negotiations on [the] Impax side. I think it was Alan Levin on the Endo side. And Chris was insisting that we have protection in the event that they, you know, moved the market to a next-generation product. And Alan, I think, said, 'Oh, don't worry. We are not going to do that. We are going to grow the product. We are going to put

all of this effort into it. By the time you launch in 2013, it's going to be an even bigger generic opportunity than it is now. You should pay us.' And Chris" -- and again that's Impax' Mr. Mengler -- "said, 'If you are right and that's what happens, we will be happy to pay you a royalty. But if you are not right and that is not what happens, we need some protection in the contract to preserve our generic market.' And then somewhere that became this," and that's a reference to the Endo credit.

And this is where it was referred to this morning as a carrot-and-stick approach. The idea is, what Endo suggested is, Look, we don't have plans to move the market. We plan to grow the market. And if we grow the market, you benefit as an AB-rated substitutable generic.

And so they'd been asking at that point for a royalty and they said, If we grow the market, pay us a royalty. And Impax' Mr. Mengler said, Fine, if you grow the market, I'll pay you a royalty. But if you degrade the market, I need some protection for my company.

As Your Honor has pointed out, he's just being a businessman. He's trying to figure out how to protect their opportunity here. He's not looking for a

payment for delay. He's looking for what happens if Endo moves the market.

JUDGE CHAPPELL: Did I understand you to just say that one of the provisions, depending on what happened in the market, could have required Impax to pay Endo?

MR. HASSI: Absolutely, Your Honor.

So that was the royalty provision, and what you'll see in the final settlement agreement is a royalty provision. If Endo grew the market sufficiently so that when Impax entered in 2013 it entered a robust market, it would pay -- Impax would pay Endo a royalty. There would be no Endo credit. Impax would be paying money to Endo in the form of a royalty. And that's why this was referred to as a carrot and stick.

Now, there's no evidence that either company assumed Endo would have to make a payment to Impax. Neither company booked a credit. Neither company booked a reserve. And Mr. Levin, Endo's CFO, testified about this point.

So he was the principal negotiator for Endo. He was also the chief financial officer.

And he said: "I don't believe we anticipated that anyone would need to make a payment under the Endo

credit.

"... at the time we put this agreement together, I don't believe we anticipated that Endo would have to make any payment under this provision."

And again, later, "As I said, it was not our expectation that a payment would have to be made."

And there was reference this morning to some calculations that were made to determine on the Endo side as to what this payment might be, what it might be worth. We've never seen those calculations, and I don't expect that we will.

If you'd go to the next slide.

JUDGE CHAPPELL: Are you talking about the expert's calculations?

MR. HASSI: No, Your Honor. There was reference I believe -- and I could be wrong -- in Mr. Loughlin's opening about Mr. Cuca, who I think you're going to hear from, making calculations to determine the magnitude of the Endo credit. And we've never seen those -- we've never seen any such calculations, and I'm not sure that we will.

JUDGE CHAPPELL: Is he wrong?

MR. LOUGHLIN: Mr. Cuca testified that he did -- he performed those calculations. They have not been produced in this case. We have not seen them.

That is his testimony, and we expect he will say it on the stand in this courtroom, Your Honor.

JUDGE CHAPPELL: This Cuca, he's an Endo man?

MR. LOUGHLIN: He is an Endo witness, a former Endo employee.

JUDGE CHAPPELL: All right.

MR. HASSI: And we'll hear what Mr. Cuca has to say -- "Cuca." I don't know if I'm pronouncing it correctly -- we'll hear from him.

This is what Mr. Levin, his boss, the chief financial officer, said.

"You don't have any recollection of anybody at Endo running calculations to try to determine how much the Endo credit might cost Endo based on the version of the Endo credit in CX 324?" That's one of the exhibits in this case.

He answered, "Well, as I said, it's not clear to me that Endo would need to make a payment under this provision. But to your question, I don't recall anyone running any calculations."

Again, "Do you recall anyone running calculations at Endo regarding any version of the Endo credit?

"ANSWER: I don't recall."

So we'll hear what Mr. Cuca has to say, but

we've not seen any calculations of the value of the Endo credit.

Now -- if we could go to slide 3 -- as we were saying, two years later, in 2012, Endo had a supply chain crisis. They had this issue with Novartis. And it was in 2012 that they first realized that there might be a payment due under the Endo credit.

And again, this is the chief financial officer --

JUDGE CHAPPELL: You're saying Novartis was an exclusive supplier for Endo?

MR. HASSI: I'm saying the product was manufactured by Novartis for Endo, yes, sir. And to my knowledge, Endo did not have another source.

Now, the reformulated was being made by a different company, and so that's why they were able to make the switch to the reformulated when Novartis was having manufacturing/regulatory issues with the FDA.

But it was -- it came as a surprise. And the Endo credit came as a surprise. And you'll hear about that. This is what Mr. Levin said. And you'll see this memo in a minute, but this is from an accounting memo.

He's testifying about an accounting memo where they had to justify this payment in 2012 because, not

surprisingly, when you haven't booked a reserve and all of a sudden think that you're going to have to pay $102 million, people start asking questions. And this was -- that memo was to their auditors.

"And [the] memo concludes 'that is,'" we should have reverted -- "'that is, should we have reverted back to the old formulation, it was probable that the quarterly peak'" -- that's one of the terms in the Endo credit -- "'would have been achieved in 2012. There would have been some level of demand cells in Q4 2012, an estimate of which would have been random speculation prior to March 2012.' Is that another way of saying" -- and I apologize for the long question. I think it was mine -- "Is that another way of saying that even Endo was not in a position to determine what the Endo credit might be prior to March 2012 or the payment due under the Endo credit might be prior to March 2012?

"Yes."

Mr. Levin had no idea before March 2012 what the payment might be. In GAAP accounting terms, it wasn't reasonable. It wasn't estimable.

Now, it's worth pointing out that complaint counsel generally suggests that we should be looking at the settlement as of the time it was

entered into and ignore -- ignore what we've been calling the real world after that.

But this is one place, the Endo credit, where they do want to look at the world after the settlement agreement. They want to look all the way forward to 2013 in terms of what was actually paid instead of what the parties' expectations were at the time they entered into the agreement. And the reason for that is simple. There was no expectation of a payment at the time they entered into the agreement.

Complaint counsel also suggests and you heard this morning that they twin the no-AG payment -- the no-AG and this Endo credit and put them together and call them a guaranteed no-AG payment or a guaranteed 180-day payment.

Now, a guarantee usually means something that ensures a particular outcome. Impax wasn't guaranteed a payment here. There were, as complaint counsel admitted this morning, scenarios under which nothing gets paid.

In other words, if Endo draws down sufficiently -- not sufficiently to hit the trigger in the fourth quarter of 2012, but there's no market left in the first quarter of 2013, the Endo credit doesn't get paid, the no authorized generic isn't worth

anything, and Impax doesn't get anything.

And that's a scenario that they don't account for, their experts don't account for, no one accounts for.

So the value is uncertain. And indeed, what one normally does in these cases where the value is uncertain is calculate an expected value.

And if you could bring up -- so you heard about complaint counsel's expert Professor Noll, formerly of Stanford University. This is from his report.

And he talks in footnote 276 -- if you can blow that up at the bottom of the page -- of what an expected value is. He says an "Expected value is the probability-weighted sum of the values of all possible outcomes."

In other words, you take what are the possible outcomes, you multiply them by the probabilities and you add them together.

But you won't see any expected value calculations here. You won't see that Professor Noll or anyone else calculated the value of the possibility that Endo pays nothing under the Endo credit and the no authorized generic is worthless.

Professor Noll is just going to dismiss that,

but he's not going to do any scientific work, he's not going to do any studies, he's not going to calculate any expected value, and he testified as much in his deposition.

I asked him, "And you intertwined the exclusivity provision" -- that's the no-AG -- "and the Endo credit provision. You didn't calculate an expected value for these two provisions together, did you?

"No.

"Nor separately; right?

"No."

You're not going to hear expected value calculations from their expert, or if you do, we'll all be hearing it for the first time, because it wasn't in his report and he didn't have them at the time of his deposition.

So these things could have been worthless, but complaint counsel wants you to ignore that. They want you to look at the payments made years after the settlement was entered into and calculate back a net present value or say the parties should have known it could have been worth -- we saw some numbers this morning -- 62 million or whatnot.

But it was a contingent payment. And the

contingencies were outside of the control of Impax and outside of the control of Endo. I'm speaking here specifically of the Endo credit.

It had two terms that neither party could control. One was this idea of a quarterly peak, Endo's highest quarterly sales of Opana in the period after the settlement was signed. And the second were the sales to consumers. And again, this is based on IMS data, so based on sales in the channel, not based on what Endo was selling, in the fourth quarter of 2012.

And so there were scenarios where, if Endo started to withdraw original Opana ER in the third quarter of 2012, as it planned to do, and gradually drawn down, the Endo credit would have been worthless, and they would have been switching the market away from the generic opportunity such that the no authorized generic would likewise have been worthless.

And we see this, as I said, once in 2012 the Endo credit became reasonable and estimable. As I mentioned before, that accounting team at Endo wrote a memo to justify why they were going to have to make this payment and why it was reasonable and estimable.

And so this is that memo. It's in evidence. It's RX 95. And it describes the accounting

considerations related to the payment.

So if you could go -- it talks about the fact that -- in the first paragraph, that Endo had a number of different scenarios in terms of when they were going to launch reformulated Opana ER, and that was going to happen at this point in time as early as August of 2012, as used in the budget, or as late as October of 2012. And neither of those dates would have likely triggered the Endo credit.

And then it goes on to say, on December 9, 2011, the company received FDA approval for the new crush-resistant, so you asked about that date before -- on December 9, 2011, the company received FDA approval for the crush-resistant.

But just later that month, on December 20, 2011, Endo was notified by Novartis that they were temporarily shutting down their Lincoln, Nebraska facility for a period of three to four weeks. And that's what caused what Mr. Levin referred to as a supply chain crisis.

And so Endo had to work with the FDA to switch to the reformulated drug, which again was being manufactured in a different facility.

And if we could go to the next slide.

So as I mentioned, "In February, the FDA

informed us," here being Endo, "that in order to prevent confusion in the marketplace, on a strength-by-strength basis, once any tablets of CRF were sold, we could no longer sell any tablets of the old formulation. As a result of this FDA guidance, we needed to be certain that we could successfully manufacture and launch CRF prior to relinquishing our alternative strategies on the old formulation."

So again, on a dose-by-dose basis, if they launched a 10 milligram of the CRF, they had to stop selling the 10 milligram of old Opana ER.

And if we could go to the third slide.

JUDGE CHAPPELL: What do you mean, "they had to"?

MR. HASSI: I mean, the FDA told them, gave them guidance that said you cannot sell both at the same time, so when I say "they had to," to comply with the regulator, the FDA, they had to.

JUDGE CHAPPELL: Isn't that exactly what Endo asked for with the citizen petition and were denied?

MR. HASSI: Ironically, it is, Your Honor.

In other words, I think Endo asked for more, though, with the citizens petition. Recall that the citizens petition would have also kept Impax off the market.

The FDA -- now, at this point in time, there were no generics on the market. It's not clear what the FDA's position would have been at the time as to, for example, Impax' Opana ER.

JUDGE CHAPPELL: Based on --

MR. HASSI: We don't know.

JUDGE CHAPPELL: -- what Novartis did, did they indeed shut down and fail to produce for this period?

MR. HASSI: What -- I don't -- I don't -- I believe they shut down. They certainly stopped providing Opana ER to Endo. I can't speak to exactly what Novartis did in terms of shutting the facility down, et cetera. They had to comply with the FDA, and the point is they stopped supplying Opana to Endo, and Endo had this supply chain crisis.

JUDGE CHAPPELL: Do I understand you to say Novartis' shutdown was ordered by the FDA?

MR. HASSI: Novartis' shutdown was ordered by FDA, yes, Your Honor.

JUDGE CHAPPELL: For what reason?

MR. HASSI: I think it had to do with manufacturing issues at the Lincoln facility.

JUDGE CHAPPELL: Nothing to do with the interplay with the crushproof.

MR. HASSI: No, Your Honor, nothing to do with that.

JUDGE CHAPPELL: And did there come a point in time where there was no Opana ER available for patients to be prescribed by doctors?

MR. HASSI: Your Honor, I'm not aware of a point in time where there wasn't any available. I know that, as I mentioned earlier, during this period of time there was a little bit of turmoil and prescribers were shifting people to other drugs.

In other words, OxyContin treats pain. If you were a prescriber at that time, you might have said, because there are issues with Opana, I'm going to prescribe OxyContin instead.

So there were -- it's clear --

JUDGE CHAPPELL: Is there going to be evidence that at some point during this period doctors were prescribing other painkillers in lieu of Opana ER?

MR. HASSI: Your Honor, throughout this period doctors were prescribing other painkillers in addition to Opana ER. Opana ER is never the only painkiller out there.

It's, frankly, a matter -- I think what you're going to hear from both doctor experts who are going to take the stand is, it's a matter of choice by the

physician and it's a matter of what the patient pays for that drug. It's a matter of -- some doctors will tell you it's what they learn -- it's what they learned. In other words, if they were at a teaching hospital where Opana was prescribed, they became familiar with Opana and they prescribe it.

But if you look, for example, in different geographic regions, one drug is more popular than the other. On different formularies one drug is preferred over the other such that insurance companies will charge a higher copay for OxyContin than they will for Opana, and that's one of the areas where these companies compete.

JUDGE CHAPPELL: So someone who testifies during this trial is going to know whether there was a shortage at some point.

MR. HASSI: I believe so, yes, Your Honor.

But in any event, Endo was going through this supply chain crisis, and what they recorded again in this accounting memo is: "The Company recorded a charge in the first quarter of 2012 as the liability became probable in March [of] 2012 when we decided to accelerate CRF and then successfully demonstrated the ability to procure CRF at PMRS with [the] appropriate QA standards."

So in other words, for the first time in 2012 the Endo credit became probable and estimable.

And it goes on to say --

JUDGE CHAPPELL: So are you trying to tell us that the reason one of the provisions kicked in, effecting payment to your client, was this background you're giving us now regarding this issue with the crushproof, the FDA, Novartis and everything else?

MR. HASSI: Yes, Your Honor.

In other words, the point is simply this. Far from being a guaranteed payment that Impax had any control over or even that Endo had control over, it turned out that the payment was triggered by a Novartis issue with the FDA. This wasn't --

JUDGE CHAPPELL: But for someone who doesn't work in this business, they would say, well, there's no way this was all foreseeable, but for someone who's in the business, isn't a lot of this par for the course in drugs coming in and going out, getting approved, getting recalled? Aren't these things foreseeable?

MR. HASSI: I think the point of this memo is Endo is saying, To us, this was not foreseeable. It was not foreseeable. It wasn't -- it wasn't -- as the last paragraph says, "The liability" -- that means the

Endo credit -- "became reasonably estimable during the first quarter of 2012."

They didn't know until March 2012 that they were going to have to make this payment.

And as it goes on to say, "Due to the multitude of uncertainties described above, it was not possible to determine whether or not we could launch CRF," so they didn't know. There's a lot they didn't know. They couldn't predict the future.

And the point is, back in 2010, when the parties signed the settlement agreement, nobody had any idea this was going to happen, but nobody was banking on a payment. It wasn't a naked payment. Impax wasn't expecting to get paid. Endo wasn't expecting to make a payment.

And if we could go to Alan Levin.

And on that point, again, one last time, the CFO of Endo, Alan Levin. And I asked him, "I think we talked about this, but at the time that Endo entered into the Impax settlement, did it expect the fourth quarter 2012 sales to be zero of Opana ER?"

I corrected, "By that I mean Opana ER sales to be zero."

He said, "I can't speak for the company, but I stand by my prior statement that I did not expect that

there would be a payment due under the Endo credit when we signed that transaction."

That's the CFO of Endo, did not expect a payment.

It was a contingent payment. Its value didn't become certain until 2012. And it's not unexplained. It was part of a carrot-and-stick approach, as Ms. Snowden's testimony illustrates, to try and give Impax the chance to enter the most robust market possible.

Now, if we could go to the negotiating history, much like the authorized generic, this was not a payment for delay.

The very first term sheet had no hint of an Endo credit. It did have a royalty provision. But it didn't have any payment going from Endo to Impax in the form of this what became the Endo credit. And it offered a March 10, 2013 date.

The parties started talking about the market acceleration trigger and then about some form of what became the Endo credit. And when that first was introduced, the proposal had moved up. The entry was now, instead of March 10, 2013, Impax -- or excuse me -- Endo was offering Impax a February 1, 2013 licensed entry date.

And in the final agreement, we have the Endo credit as it was finalized, and you have a yet even earlier date, March -- excuse me -- January 1, 2013.

So the negotiating history shows we go from a March entry date with no Endo credit to a January entry date, an earlier entry date, with what complaint counsel is terming a payment to Impax. That's not a payment for delay.

JUDGE CHAPPELL: Well, what about the ten million? I've been told that ten million is large and unjustified.

MR. HASSI: Let's talk about the ten million because --

JUDGE CHAPPELL: Forget these two terms. The ten million, if large and unjustified, is an Actavis problem.

MR. HASSI: Well, Your Honor, whether ten million is large I think is an open -- I think is an open question. I'm not sure anybody is going to take the stand and say, if there were a $10 million payment by itself, that -- I don't -- I think -- my recollection is -- and I'll confirm this -- that Professor Noll said not sure whether he'd call ten million large. He twins it with these other -- he puts it with these other things, but the ten million

alone -- now, we don't necessarily agree with the benchmark that complaint counsel has set about $3 million for Endo's future litigation costs, but ten million isn't really large in this business and in this context.

JUDGE CHAPPELL: Well, not getting into anything proprietary or confidential, market-wise size, market cap, Endo was larger than respondent?

MR. HASSI: Endo was larger than Impax, yes, Your Honor.

JUDGE CHAPPELL: Five times larger? A lot larger?

MR. HASSI: I would have to check --

JUDGE CHAPPELL: Barely larger?

MR. HASSI: -- at the time.

I would say significant and multiples larger, but how many multiples I don't know. Impax was very small.

JUDGE CHAPPELL: Just what I'm getting at is, $10 million might be large, larger to one side of the agreement than the other side of the agreement.

MR. HASSI: I would agree with that, Your Honor.

What's more important is, no one is going to take that witness stand, not even their expert, and

say that that payment was unjustified, that the development and co-promotion agreement was unjustified.

I think what I heard this morning is their expert Mr. Geltosky is going to say it's unusual. It's not unjustified.

This was an arm's length transaction negotiated between Endo and Impax. Endo had an interest in a potential Parkinson's treatment.

Yes, Endo would have preferred to get Rytary and any follow-ons, but what they got was a chance to participate in IPX-203. That drug is still under development, and that drug has considerable potential, and no one is going to take the stand and tell you it doesn't or that it didn't.

So Endo -- Dr. Cobuzzi is going to take the stand, as I mentioned. He's got a Ph.D., and his Ph.D. thesis related to Parkinson's. He's the person who negotiated this on behalf of Endo.

And if we could pull up slide -- Dr. Cobuzzi -- the Cobuzzi e-mail.

So this is the memo that Dr. Cobuzzi sent to the Endo board of directors on June 8. And he tells the Endo board of directors (as read), "To further build on the good news of the day, I want to let you

know that further to the discussion with the Transaction Committee on June 1st the Endo team completed a development and co-promote agreement with Impax."

He went on to say (as read), "This is an exciting opportunity for Endo as it further builds our product pipeline for the future with a drug candidate that fits our commercial footprint."

Now, Endo, what you're going to hear, at the time didn't have its own internal research and development arm.

JUDGE CHAPPELL: But isn't he talking about the first drug, the one that was switched out?

MR. HASSI: No, Your Honor. This is talking about IPX-203.

JUDGE CHAPPELL: How do we know?

MR. HASSI: Because it's on the day and -- and I can --

JUDGE CHAPPELL: I don't see it on the document.

MR. HASSI: It -- this is the -- so this is part of the final agreement, and it's attaching this document called Imperial OEW, which is opportunity evaluation worksheet I believe, evaluating the opportunity of IPX-203. The document is in evidence

and will show you that this relates to IPX-203.

This is the final deal. This is Dr. Cobuzzi saying to his board we've --

JUDGE CHAPPELL: So your position is the evidence will show that he's talking about the test drug or proposed drug that was actually part of the agreement, not the first one that was pulled.

MR. HASSI: That's correct, Your Honor. The first one -- to be clear, the first one wasn't pulled. The first one was Endo expressed an interest -- Endo expressed an interest in what was then being called IPX-66, is now sold on the market as Rytary. There was public information that Impax was developing that drug and developing a drug in the Parkinson's space.

Endo came to Impax -- they talked about it -- even before these parties talked about settlement, there were discussions about this and other drugs.

And Endo came to Impax and said, We're interested in this IPX-66 drug that you're developing. And they asked to enter into a development and co-promotion agreement on that. And what Impax said was, That drug is pretty far along, and we're not looking for a partner in the U.S.

JUDGE CHAPPELL: Endo suggested the first drug.

MR. HASSI: Endo suggested the first drug.

JUDGE CHAPPELL: And the first drug is on the market.

MR. HASSI: And the first drug is on the market.

JUDGE CHAPPELL: Had the deal been about the first drug, it would have been a better investment for Endo.

MR. HASSI: It's unclear, Your Honor, because the next drug hasn't come to the market yet, but if the next drug is really an improvement over the original, it could be worth -- it could be worth significant --

JUDGE CHAPPELL: But that doesn't matter. You told me that that part of the agreement had been vacated.

MR. HASSI: Endo decided not to continue with that part of the agreement, yes, Your Honor.

But there's -- there's no question that they negotiated at arm's length. They asked for IPX-66. Impax wasn't looking for a partner in the United States on IPX-66. They were looking for a partner outside the U.S., and they entered into a deal for sales outside the U.S. because they don't have an ex-U.S. sales force. But they had just built out their sales force

in the U.S., and they wanted to sell this drug. They didn't need a partner in Endo.

But the follow-on drug, there were risks to it and there were costs to it, and they wanted to share some of that risk and share some of that cost and share in some of the potential upside.

JUDGE CHAPPELL: This is Dr. Cobuzzi?

MR. HASSI: This is Dr. Cobuzzi, right.

JUDGE CHAPPELL: A Ph.D. doctor. Is he going to testify in this case?

MR. HASSI: He's going to testify in this case.

JUDGE CHAPPELL: Live.

MR. HASSI: Live, yes, sir. He's going to come here from Ireland to tell you about it, so...

But -- so Endo did make an initial contribution of $10 million.

You're also going to hear, by the way, Your Honor, that while that $10 million was received in the form of a lump-sum payment to Impax, they recognized it over time, over 91 months, over the development of this drug, because they understood it was to defray the costs of development.

And so these two parties entered into a risk-sharing agreement, it was at arm's length, and it

was not a large and unexplained payment.

I want to talk now about the relevant market because --

JUDGE CHAPPELL: You understand that "unexplained" and "unjustified" are not the same thing. Anybody can just explain anything (indicating). But that doesn't mean someone is going to agree it's an actual justification.

MR. HASSI: If Your Honor prefers, I'll try to stick with justification -- "justified."

JUDGE CHAPPELL: I would just advise everybody to be aware, I don't think those two words mean the same thing. One is much broader than the other.

MR. HASSI: Understood, Your Honor.

Well, in any event, if complaint counsel fails to --

JUDGE CHAPPELL: You can explain anything you want, and I can buy it or not buy it, but if I find it to be a justifiable explanation, do you see the difference?

MR. HASSI: I do, Your Honor. And to be clear --

JUDGE CHAPPELL: And the Supremes might have used one or the other interchangeable, but I don't find that works.

MR. HASSI: And to be clear, Your Honor, Impax believes and will show in this case that the development and co-promotion agreement was justified and that the $10 million payment made in connection with that was justified. It was a good opportunity for Endo. They believed as much. They entered into the agreement as part of an arm's length deal.

If I could turn now to the relevant market, because that would be the first step in a rule of reason case.

As I've indicated previously, long-acting opioids are the relevant market.

Complaint counsel has suggested that oxymorphone ER is unique and that Endo has monopoly power. But if that were true, then you'd have to concede that Impax with the only product on the market today is performing a unique role.

We don't think that that's true in the sense that oxymorphone ER is one of several opioids used to treat chronic pain. "ER" stands for extended release, meaning the effect of a dosage is over a twelve-hour period.

If you could pull up the indications slide.

So in the top left is an indication for Opana ER -- and these are all in evidence -- "Opana ER

is in an opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

And if you were to compare that to the other five indications on this page, they are, if not verbatim identical, very similar. And that's because there have been pain treatments, opioids, on the market for a long time, they will be on the market for who knows how long, but there are lots of them. And there are lots of different ways to treat pain.

Each of these products is in the same -- and this is undisputed. Each of these products is in the same therapeutic class, and each is used to treat a very similar and broad range of medical conditions.

You're going to hear from Dr. Addanki, so here's slide 4 from his report. He looked at the data -- and if you could blow up just the first couple lines. What you see is, as I indicated further -- so this is a Share of Use slide for selected long-acting opioids.

And what you have is, for example, across the top of the slide lumbago. Fentanyl is used to treat it in 9.9 percent of the cases. Hydromorphone hydrochloride is used to treat it in 8.6 percent of the

cases.

THE REPORTER: Okay. You have to slow down.

JUDGE CHAPPELL: Okay. We're going to put a bridle on him and some reins, and when he's reading, you're going to pull back, because everybody tends to go fast when they read.

MR. HASSI: I apologize, Your Honor.

JUDGE CHAPPELL: So make note of that.

MR. HASSI: I will, Your Honor.

JUDGE CHAPPELL: Put a sign up if you have to.

MR. HASSI: I think I have one from my last trial with this court.

Morphine sulfate 9.6 percent of the time.

Oxycodone hydrochloride 9.71 percent of the time.

Oxymorphone hydrochloride -- that's what we're talking about here -- 9.25 percent of the time.

And tapentadol hydrochloride 6.58 percent of the time.

There are pages and pages of diagnoses descriptions for which these drugs are prescribed because it's about chronic pain. They're all indicated for chronic pain.

And if we could go to the next slide.

JUDGE CHAPPELL: You're saying these other

painkillers are substitutable, readily substitutable.

MR. HASSI: Interchangeable, substitutable, that's correct, Your Honor.

JUDGE CHAPPELL: And what I would like for someone to tell me here in this trial is, if it is a fact that there was a supply shortage of this drug, how is it that if that's the only market, how is it that other drugs were being prescribed at that time if it's not interchangeable?

MR. HASSI: I think, Your Honor, what you will see is it is interchangeable. And I don't think the doctors disagree.

If you could put up Dr. Savage's testimony.

So you heard Dr. Savage is complaint counsel's expert. And what she said in reference to this issue is:

"'Dr. Michna and I" -- and Dr. Michna is our expert -- "agree that clinically no opioid is ipso facto superior to any other opioid.'

"Correct."

And she went on to explain, "But there is no one best opioid across populations of people."

In other words, a patient comes in with pain, whether that pain is caused by cancer or lower back pain or one of the many other diagnoses for which they

need -- they have chronic pain and need treatment. There's no one opioid that fits that situation. It's not necessarily Opana. It's not necessarily OxyContin.

There are a number of different ways that doctors make that decision. And part of it is based on their experience. Part of it is based on the detailing they may receive from the drug companies. Part of it is based on the insurance coverage that the patient has. Part of it is based on the copayment that the patient makes. And part of it is based on whether the patient has a preference for a particular drug.

And it's true, once someone starts on a course of drugs and it's working, they may stick with that opioid. And they may not want to switch. They may have a preference. But when doctors are making the initial prescribing decision, no one opioid is superior to another, not for any diagnosis and for not -- not for any population of patients.

There's no group you can say, well, if this person walks in the door, if it's a male my age who walks in the door with lower back pain, Opana is going to be the better drug for that. These doctors can't tell you that. And you're not going to hear that.

What you are going to hear --

JUDGE CHAPPELL: Are you prepared to present evidence during your case of the relative cost of these other opioids?

MR. HASSI: I don't think our experts have addressed --

JUDGE CHAPPELL: For example, if a doctor asks me, do you want A, B or C, is one of them going to be twenty times more, even though there might be a generic, it's twenty times more?

MR. HASSI: Your Honor, I don't know that we've addressed the prices in that sense. I think what we do address is and what's relevant to the price to you is insurance coverage and formularies. And indeed, that's one of the ways these companies compete.

So Endo --

JUDGE CHAPPELL: Well, it's a problem with healthcare in general that the patient is not really in the mix negotiating prices. The patient is basically stuck with whatever it is.

MR. HASSI: Your Honor, it's -- I think one of the issues with our healthcare system is the doctors don't necessarily --

JUDGE CHAPPELL: One of many.

MR. HASSI: I'm sorry, Your Honor?

JUDGE CHAPPELL: One of many issues.

MR. HASSI: One of many -- doctors don't necessarily know or pay the price patients don't necessarily know or pay the price. Drugs aren't selected based on price alone.

But insurance companies, the people that buy these drugs on behalf of the patients, they seek to make the drug companies compete on price, and the way they do that is through formularies.

And so drug companies, what you're going to hear, have formularies and they tier these drugs, and so they might put Opana on tier number one, which is their most favored status on the formulary, and for that the patient might have no copay. And they might say to OxyContin, we'll put you on tier one if you offer us a better price than Endo is for Opana.

And they compete that way for a preferred status on the formulary, so they have a -- tier one is going to be for the patient, the patient has no copay, and tier two might be a small copay, tier three might be a higher copay, and tier four might be you've got to get prior approval to even be prescribed the drug.

And what the insurance companies do is pit the drug companies against each other -- and you're going

to hear testimony about that in this case -- where, for example, Endo managed to get OxyContin knocked off a formulary altogether, and Opana was then the preferred long-acting opioid on that formulary. And for those patients, they were therefore more likely to get Opana ER. And that's based on negotiations between the drug companies and health insurers.

JUDGE CHAPPELL: Well, it's no surprise the parties disagree on relevant market, market power. We'll see what shakes out.

MR. HASSI: We will, Your Honor.

If I could mention just quickly two other forms of competition.

One is for the prescribers. As I mentioned, prescribers make a choice whether they're going to write a script for OxyContin or Opana or another drug, and so that's why these folks have sales forces. Purdue sends out a sales force to detail OxyContin. Endo sent out a sales force to detail Opana.

And you're going to hear, there are differences between these drugs. The sales force goes out and touts these differences to say, gee, Opana is better in these circumstances or whatnot, but it's trying to differentiate these drugs so that the prescriber will prefer it over another.

And they also compete for patients, so they compete on this copay level. And when patients have a copay, what you're going to hear is, these companies, Endo included, offer sort of a version of a credit card that could help cover the cost of that copay to convince the patient to get Opana as opposed to, say, for example, OxyContin.

Now, the FTC has looked at this market before.

And if you could bring up the next slide.

And this is from a merger in the long-acting opioid space. And what the FTC ruled in that case -- held in that case is "... the evidence shows that they are particularly close competitors within the larger oral long-acting opioid market." That's what we think the market is here.

It goes on to explain, "Oral long-acting opioids have become the standard of care for the management of moderate-to-severe chronic pain because of their effectiveness, ease of titration and favorable risk-to-benefit ratio. Other oral long-acting opioids are based on distinct chemical compounds, but all of these products have the same mechanisms of action, similar indications, similar dosage forms and similar dosage frequency. The most significant of the other oral long-acting opioids is Purdue Pharma L.P.'s

OxyContin, which is four times larger than Avinza and Kadian, combined. A fourth product, Endo Pharmaceuticals' Opana ER, also competes in this market."

That's the FTC speaking, Your Honor.

So we don't think that -- then finally, I'll just mention briefly that the companies do think they compete, by the way.

So this is an Endo slide speaking to market definition. And if you look at the top of the page, it refers to Opana ER, and it mentions in the market at the time OxyContin, oxycodone CR, Avinza, Kadian, and all other SR morphine. And it shows a sales volume market of about 2.2 billion.

Next slide.

And this is another Endo internal document.

JUDGE CHAPPELL: Go back to that other slide.

MR. HASSI: Could you go back, please, Robert.

JUDGE CHAPPELL: What is Opana ER versus Opana Tablets?

MR. HASSI: I'm sorry, Your Honor?

JUDGE CHAPPELL: The bottom half of the slide says "Opana Tablets." That's different?

MR. HASSI: That may be IR, Your Honor, so that's immediate release as opposed to ER, which is

extended release, so the ER is effective over a twelve-hour period. The IR is a shorter term.

If you look at the bottom line under Opana Tablets in the middle of their market definition, it refers to "all other combination IR oxycodone." Those are immediate-release products compared with extended-release.

JUDGE CHAPPELL: Well, according to this slide, the ER sales volume dwarfs the tablets.

MR. HASSI: I'm sorry. Dwarfs the?

JUDGE CHAPPELL: The sales volume for the ER is much higher, according to this slide. For the entire market size.

MR. HASSI: It's twice the sales --

JUDGE CHAPPELL: It's not important. It's just something I noticed.

MR. HASSI: It's twice the sales volume, yes, Your Honor.

If we could go to the next slide.

And this is another Endo document, evaluating new entrants in this market.

So we heard about a bunch of competitors. This is Endo around the time of 2010 evaluating --

JUDGE CHAPPELL: Am I the only one who's never heard of any of these drugs?

MR. HASSI: I've heard about them since I started on this case, Your Honor, but no. And some of these -- candidly, at least one of these is not on the market.

This was Endo evaluating, if these come on the market, what effect do they have on our share.

And so what you see in the first bar is, at the time, Endo was evaluating its market share at about 8.6 percent.

JUDGE CHAPPELL: At the time, what time? I don't see a date on here.

MR. HASSI: This was I believe it was June 2009, but the document is in evidence and the cover page indicates --

JUDGE CHAPPELL: I saw 2009 on the previous slide, but I don't see a date on this one.

MR. HASSI: I will have to check, Your Honor. It was before the settlement agreement was entered into, so it's designed to be relevant to the market at that time and it's Endo assessing potential new entrants.

But what you see is Opana's share was very small compared to all the others, including the new entrants.

And if we could go to one more slide.

Complaint counsel mentioned that Endo's Mr. Bingol will be testifying in their case. This is from his declaration which was admitted in the patent case that brought the settlement between Endo and Impax together. And he said, "The long-acting opioid market segment consists of several oral tablet products and a patch called Duragesic. ...the LAO market was a well-established and competitive market that consisted of many products that had been on the market for years."

And if you look at the table at the bottom, it calculates Opana ER's market share in March 2010, so this is just a couple months before the settlement, at 3.4 percent of the long-acting opioid market, not exactly the stuff of monopoly power.

Finally, Your Honor, under the rule of reason, complaint counsel has to prove effects. If Endo did have market power, this court is going to have to balance the procompetitive effects associated with the settlement against any purported anticompetitive effects that it had. Was the settlement an anticompetitive constraint or did consumers benefit?

Now, complaint counsel has indicated they have a different way of looking at this, but we'd like to share with you what happened in the real world and how

looking at the events of the past seven years since this settlement was entered into are relevant and how you should take them into account.

And as Justice Brandeis wrote for a unanimous Supreme Court 99 years ago, he said: The true test of legality in rule of reason cases focuses on the facts peculiar to the business to which the restraint is applied, its condition before and after the restraint was imposed, and the nature of the restraint and its effect, actual or probable. That was Board of Trade of City of Chicago, a 1918 case, unanimous Supreme Court, Justice Brandeis writing.

The purported restraint here is the settlement agreement. And we agree with the Supreme Court that you should look at the effects before the agreement was entered into and after the agreement was entered into to determine whether the settlement was pro- or anticompetitive.

And so to do that, we have to compare what the settlement actually -- the effect the settlement actually had in the real world versus what would have happened if Endo and Impax had not settled.

So if we could bring up the slide showing the real world.

And so, Your Honor, this is a depiction of the

real world. We've been talking about other ANDA filers, and those other ANDA filers included Watson, included Actavis and of course Impax.

And what you have is on the far left of the screen June 2010, is that red bubble.

And July 15 is when the 30-month stay would have expired.

January 1, 2013 is the license date.

And so looking at Impax, you see a green bar that showed, as of January 1, 2013, a few days thereafter, Impax came to market and has been selling continuously since then and intends to sell going into the future and that the final patent that Endo has presently, it doesn't expire until 2029.

Watson never came on the market. They filed an ANDA. They have never sold a single dosage of Opana ER.

Actavis was first to file on those two small dosages, the 7.5 and 15 milligram, and so Actavis -- and Actavis got a settlement that allowed them to come on the market in those dosage forms in July 2011. And they came on on July 15, 2011, and they sold for a period of time. But on September 6, 2016, they were enjoined from the market because of Endo's after-acquired patents.

JUDGE CHAPPELL: So did Actavis launch at risk?

MR. HASSI: Actavis launched at risk, Your Honor, in 2013 on the five strengths that Impax was first to file on, so not as against the patents that were at suit in the case between Endo and Impax, but as you'll see, they launched at risk as against other patents that Endo acquired in the meantime.

And so in the summer of 2013, Actavis started selling the five dosage -- the five dosages that Impax was first to file on, and those sales were at risk, and they've since been enjoined from the market.

JUDGE CHAPPELL: But Actavis looks like they were in the market, if I follow your diagram, for, what, four or six years?

MR. HASSI: They were in the market for just over five years, some of that only with -- some of that licensed, not at risk, on the two lower dosage strengths and some of that on all seven dosages for a period of time at risk.

JUDGE CHAPPELL: But the red line you're showing at least for Actavis, that's the after-acquired patents you told us about.

MR. HASSI: That is the result of the after-acquired patents, yes, Your Honor. And I've

got another slide that's a little bit clearer about that.

JUDGE CHAPPELL: Just so the record is clear, even though this is not evidence, is there a dispute on when the 30-month stay ended?

MR. HASSI: No, Your Honor. I believe that's in -- I believe that's in the stipulations that we provided this morning in the JX.

JUDGE CHAPPELL: And what is the date the 30-month stay ended?

MR. HASSI: June -- I'm trying to remember if it's June 14 or June 15, but it's June of 2011.

JUDGE CHAPPELL: 2011.

MR. HASSI: 2010. 2010.

MR. LOUGHLIN: It's June 14, 2010.

JUDGE CHAPPELL: The 30-month stay ended in 2010.

MR. LOUGHLIN: Correct, Your Honor.

JUDGE CHAPPELL: Okay. If that's true, didn't the 180-day exclusivity period begin then?

MR. HASSI: No, Your Honor.

JUDGE CHAPPELL: What delayed the exclusivity period from that point?

MR. HASSI: The 180-day period starts when Impax first launches. Indeed, that's one of the issues

with a launch at risk.

So in other words, until Impax starts selling, that 180-day period doesn't kick in. Once Impax sells even one dose, the 180-day clock starts ticking.

And so I was referencing that with respect to a launch at risk because in a launch at risk, typically the company doesn't sell for all time. They'll sell a small amount to make some money --

JUDGE CHAPPELL: So getting to what I asked earlier, though, then couldn't Impax have waited eight more months to September 2013, not been at risk, and still had the 180 days?

MR. HASSI: No for two reasons, Your Honor.

JUDGE CHAPPELL: It's based on when they first introduced.

MR. HASSI: The 180 days only matters if the patents are -- the patents that were listed in the Orange Book at the time, which were the two patents-in-suit, haven't expired, so if -- the 180 days would have been forfeited essentially if Impax waited until September 2013 to launch.

JUDGE CHAPPELL: This one is complicated because of these after-acquired patents. With one patent at issue, at this point in 2013, September 2013, all generics who had the horsepower

could have brought a generic to market, if they had the formula and could sell it, because there were no longer any patents, or at least the original patent expired then, so you couldn't have had 180 days because the market opens wide open at that point.

MR. HASSI: Right. Had there been no additional patents, the market would be wide open come September 2013, that's right.

JUDGE CHAPPELL: So bottom line, the first generic, the first filer, can take advantage of 180 days provided it's before expiration of the patent.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: It doesn't matter when, and it starts the day they introduce their product, but it needs -- but if you want to really have an exclusive period, it must be before the patent expires.

MR. HASSI: That's correct, Your Honor.

JUDGE CHAPPELL: All right.

MR. HASSI: Now, there were, as I mentioned, other ANDA filers. None of those ANDA filers got the same broad patent license that applied to these after-acquired patents, and none of them were able to come on the market.

Indeed -- so Par, Teva, Amneal, Actavis,

Sandoz, Ranbaxy, those are -- Your Honor asked earlier -- those were all ANDA filers on this drug. They're all enjoined. None of them is on, selling on the market today.

Now, if Impax didn't settle, its option was to keep litigating the patent case and hope to win. And complaint counsel is not going to tell you that they have any particular insight as to what the outcome of that case would have been. Their expert and our expert agrees the outcome was uncertain.

Now, as I mentioned earlier, the one caveat on that is our expert will tell you that Impax had lost the Markman hearing, which is a pivotal point in patent litigation. The judge had sided with Endo, and that was a blow to Impax and would have made it harder for Impax to win that case. Still, the outcome is uncertain, but more likely than not Impax was going to lose at the district court as a result of that.

But complaint counsel wants you to believe that notwithstanding that, if Impax had chosen --

JUDGE CHAPPELL: You've got to remember, this isn't argument, this is opening statement.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: You're getting real close to the line.

MR. HASSI: I will try to back off the line, Your Honor.

Your Honor, with respect to whether Impax would have launched at risk, you heard this morning that complaint counsel is going to put on evidence that, for example, Impax prepared launch -- prepared to launch. And what you have to do in this case is distinguish between efforts to prepare for a launch and a decision to launch at risk.

So Impax, as a matter of routine, when it's approaching an opportunity such as the end of a 30-month stay, wants to make sure that they're ready to launch should the opportunity arise.

And so if we could bring up the 10-K.

This is from Impax' annual report, its 10-K for the year 2010. And what it explains is, "When the Company" -- that's Impax -- "concludes FDA approval is expected within approximately six months, the Company will generally begin to schedule manufacturing process validation studies as required by the FDA to demonstrate the production process can be scaled up to manufacture commercial batches."

So as a matter of course, when they know they're six months away from what's sometimes referred to as a launchable date, a date by which one of those

barriers, the barrier of FDA approval, is going to fall, they want to be ready.

And the operation team sets up and makes sure that they can manufacture the drug, and they make what are called process validation batches. And those are -- you're going to hear about that because they did that in this case. And that is to show not only that we can make a couple of tablets, but we can make manufacturing quantities so that we're not going to have an issue down the road when we have to manufacture a whole lot to supply the market.

And the FDA wants to know that the company has evidence of that, so they as a matter of course prepare a certain number of tablets to qualify that with the FDA, and they take that on notwithstanding the fact that they yet don't have FDA approval.

And as it goes on to say (as read), "Consistent with industry practice, the Company may build quantities of pre-launch inventories of certain products pending required FDA approval and/or resolution of patent infringement litigation, when, in the Company's assessment, such action is appropriate to increase the commercial opportunity, FDA approval is expected in the near term, and/or the litigation will be resolved in the Company's favor."

So there are a number of barriers still in Impax' way in the spring of 2010. One of those is FDA approval. But in May of 2010 they get temporary approval, and they know come June they're going to have full FDA approval.

The other barrier is the patents. Endo still has patents, and the parties are still in litigation, and they've got to decide what to do about that. But in the meantime, it makes good commercial sense -- this is a -- this is a valuable drug, and Impax doesn't want to be in the position of forfeiting its first-to-file opportunity. It wants to be ready to launch at the first opportunity when it can do so and do so safely without risk.

And so they did start, and you will see evidence that they did process validation. They ordered API. All the things you heard about this morning, we -- we don't disagree about that. What we disagree about is whether that was preparations to launch as compared to launch at risk.

It's not evidence that the company had ever made a decision or indeed that management had ever made a recommendation to take that risk and launch at risk.

This goes on to explain -- and this is --

again, this is the 10-K, put this out to the market -- "The capitalization of unapproved pre-launch inventory involves risks, including, among other items, FDA approval of product may not occur; approvals may require additional or different testing and/or specifications than used for unapproved inventory, and, in cases where the unapproved inventory is for a product subject to litigation, the litigation may not be resolved or settled in favor of the Company."

So we make this stuff, we make the product, we know it's still subject to litigation, and one of the risks is we don't win the litigation. And what it explains happens then is, "If any of these risks were to materialize and the launch of the unapproved product delayed or prevented, then the net carrying value of the unapproved inventory may be partially or fully reserved."

In other words, sometimes the company makes product and never gets to sell it, and it has to write it off. And that is a risk of doing business for these folks.

But this is product where the margins are very high, and it makes sense to make a couple million dollars worth of product if you can sell it for eight to ten times that.

And so you take the risk, you operationally make the product, but that doesn't mean you've made a decision to take the risk to launch at risk and face potentially significant damages.

And indeed, the contemporaneous record here will show that they hadn't made any decision to go forward with the launch or even to build launch batches.

So this is an e-mail from Joe Camargo, who you're going to hear from in this case. He's one of the operations people responsible for making the drug. And this is May 12. This is just weeks before the settlement. And he says, "... we will not commence the launch inventory build until we receive the direction to do so from senior management."

So they've done process validation, they've taken some steps to be ready, but they're not making launch quantities because they've not gotten the direction to do that yet.

And this is Larry Hsu, the CEO of the company, to his CFO, who I believe is going to be the first witness in this case. And he says, "It's unlikely" -- so again, this is May 9. This is less than a month before the settlement -- "It's unlikely we will launch Opana ER this year (I actually prefer not to launch

this year for obvious reason)." And Mr. Hsu will testify about that as well.

They weren't planning on launching. They wanted to be prepared, and they certainly wanted Endo to think that they were ready, but they weren't going to launch.

Next.

And here's Todd Engle. You'll hear from him as well. He's head of sales and marketing at this point in time in 2010. Again, May 2010, this is -- they now have -- and this is part of the e-mail chain where they've received FDA tentative approval, so that barrier is falling. They know they're going to be able to get FDA approval. But he says, "A launch decision has not been made." He goes on to say, "There has been no decision yet to complete the launch build."

In other words, yes, they wanted to be ready, but they hadn't made decisions to take the next steps towards launching, and they certainly --

JUDGE CHAPPELL: We're getting close to your time limit.

MR. HASSI: I'm sorry, Your Honor?

JUDGE CHAPPELL: We're getting close to your time limit.

MR. HASSI: I understand, Your Honor.

JUDGE CHAPPELL: How much more do you have?

MR. HASSI: It depends on how slowly I go. I'll try to cut through it and get to the end.

Your Honor, a decision to launch at risk for a small company like this is very significant, and it entails very significant risks.

So you used the example this morning, Mr. Loughlin said --

JUDGE CHAPPELL: I'm going to give you to 3:30. I'm allowing for the questions I've asked.

MR. HASSI: Thank you, Your Honor.

JUDGE CHAPPELL: So you've got twenty minutes.

MR. HASSI: I will get it done in that time, and I won't try Josett's patience any more than I already have.

Your Honor, you used the example this morning, Mr. Loughlin said that they're going to show that Endo's revenues were about $20 million a month at this point in time. The way one calculates lost -- excuse me -- the way one can calculate damages in these cases, the damages that a generic company can be exposed to, are the brand's lost profits, so essentially those revenues minus the minuscule cost of manufacturing are what Impax would be on the hook for.

So Impax sells for less than the brand but has

to, if it pays damage -- pay the damages that the brand sells for, and those can be trebled.

So to use that $20 million example, if Endo is selling $20 million worth of product a month and that's 90 percent profit, that's $18 million a month in profits that they're making.

So if Impax sells a month's worth of drugs, it may owe 18 million or even 18 million trebled for that month in damages, so 18 or even, if my math is right, 54 million in damages.

But recall that Impax is not selling at the same price as the brand. The discount -- the generic typically sells at a discount.

So if it's selling at 60 percent of the brand's price, so instead of 18 million, it's maybe selling $12 million a month, its sales are $12 million. It owes 18 to potentially 54 million dollars in damages. That's what it's risking -- that's on one month's sale.

Now, recall here they've got six months first-to-file exclusivity, and then if they sell one month's worth, they better sell six months' worth, because they're losing their exclusivity, that clock is ticking, if they don't do it, and so that $54 million times six becomes, if my math is right,

$324 million.

That's a lot of money for a company that in its best year in many years, 2010, this company made $880 million in total revenues. That's bet-the-company damages for launching at risk.

So when they ask you to assume that this company would launch at risk, we think the documents and testimony will show otherwise.

I want to skip to -- skip to the procompetitive options slide, the timeline.

So, Your Honor, I want to walk through the real world and the after-acquired patents, so I showed you this slide, and what I want to do now is focus on what might have happened had Impax launched at risk. And we're not saying, to be clear, that Impax would have launched at risk.

Complaint counsel's expert threw out three hypothetical dates, and I just want to walk through what would have happened had it launched on those three hypothetical dates.

And the first hypothetical is that Impax launches at risk after it gets FDA approval in June of 2010.

Well, at that point in time, Impax is in litigation with Endo, and the judge has asked the

parties and asked Impax, Are you going to launch during my trial? And it made Impax essentially promise not to launch during trial.

So if Impax launched while it was waiting for a decision from the judge, the most likely outcome is that the district court enjoins Impax. And again, maybe they get to sell a few pills at risk, but then they get enjoined by the judge. And in this scenario, there goes their 180-day exclusivity, so that significant value to Impax, tens of millions of dollars of value, disappears for the price of a few sales. It's not realistic that Impax would have launched at risk at that point in time.

Scenario number two is they wait and wait and see if they get a favorable district court decision.

So if they get a favorable district court decision, meaning they win at the district court level, notwithstanding the judge's Markman hearing, this is where the after-acquired patents start coming in.

And so in December of 2010, Johnson Matthey gets what's referred to as the '482 patent, and that patent applies to Opana ER, and Johnson Matthey makes both Endo and Impax aware that it's gotten this patent.

Keep going.

And in the first quarter of 2012, Endo acquires that patent, so now Impax is at risk as against the initial patents where maybe it's won a favorable district court decision, but it's at risk against what was originally the Johnson Matthey patent that now Endo had.

JUDGE CHAPPELL: I guess we won't get into how someone gets a patent for a drug that's already patented and on the market.

MR. HASSI: We could show you the patents, Your Honor, but no, I don't think we're going to get into --

JUDGE CHAPPELL: No. I know we're not. I'm just saying, it seems like a ridiculous situation.

MR. HASSI: Well, it probably felt that way to Impax, too, Your Honor, but the fact is, these patents are out there, they're valid, and they've been upheld by district court judges.

Indeed, so in the fourth quarter of 2012, Endo acquires the '122 and '216 patents, and that same month they sue on those new patents and they sue all the other ANDA filers.

JUDGE CHAPPELL: So if I follow this right, the drug was already patented and on the market. Four

other patents were issued that were close enough to where Endo can sue and enjoin people from selling the same drug.

MR. HASSI: Yes, Your Honor. Three at this point. We've got the '482 on here twice, but yes, there are three additional patents here, and Endo did sue on those patents.

And if you can keep going.

Endo acquired two more patents. The '737 and '779 patents were issued in 2014.

Keep going.

And they sued on those patents.

JUDGE CHAPPELL: All of these are basically the same drug.

MR. HASSI: This is all related to both Opana ER, and some of the patents also apply to the crush-resistant.

So Impax wasn't sued on the Opana ER, but it was sued and lost on crush-resistant to Endo on some of these patents.

Keep going.

And that's what these decisions are.

So the Southern District of New York upheld the '122 and '216 patents and enjoined the parties, including this is what led Actavis to have to leave the

market.

A Delaware district judge upheld the '737 and then later the '779 patent, and I believe it's one of those two patents that's valid until 2029. The others may be 2023.

So let's go to the next hypothetical, and that is, suppose we wait for a district court decision and we lose at the district court. Well, Impax doesn't enter at risk. Impax doesn't enter. It just lost. That's what rolling the dice means. That's what continuing the litigation means.

Now, you can wait and hope to win at the appellate court and hope to reverse the district court judge, but the fact is, they were more likely than not to lose at the district court level.

Next.

The third hypothetical that Professor Noll throws out is maybe you wait for an appellate court decision. And in that case, if there's a favorable decision, Impax -- say that comes in in the fall of 2011, and this is assuming that there's no remand, that there's no other issues, and that Impax wins at the appellate court level.

So it gets to come in in 2011. And that's not at risk, except as to the Johnson Matthey patent, which

at this point isn't in Endo's hands, but not long thereafter Endo has acquired that patent. And Endo acquires -- and just speed through the rest -- acquires the additional patents, sues on the additional patents. And one can only assume that Endo was suing -- if Endo was suing Impax on the crush-resistant, if Impax had not settled and didn't have the broad license, they would have sued on Opana ER as well.

And so there's no real option here for Impax to come on and stay on the market. This is why they got the broad license.

Let's go to the next one.

And of course, in hypothetical number three, if Impax loses at the appellate court level, they lose. It's over. They're enjoined until those patents expire.

So one other possibility -- and I think Your Honor hinted at this -- is maybe you wait until September 2013 when the patents expire. Well, that's a fine option if you don't think Endo is going to get any more patents.

Keep going.

But Endo did. And Endo sued on those patents, and so waiting until September 2013 not only loses the 180-day exclusivity, but at that point Impax would have

to launch at risk as to the Johnson Matthey '482 patent, the '122 and the '216 patent, and the additional patents are not far behind.

Next slide.

So if we compare these scenarios to the real world, Your Honor, what you have is no real opportunity for Impax to come to market compared to a real world where Impax settled with Endo, got a broad patent license, came to market, is on the market today, and will be on the market for the foreseeable future.

Now, complaint counsel doesn't want to engage in the kind of traditional balancing that's been the hallmark of the rule of reason, balancing the anticompetitive restraint against procompetitive effects. They want a shortcut. They want pay-for-delay to be just pay. They want to say that if there's value being transferred from the brand to the generic, you should presume that it's anticompetitive.

Now, the Supreme Court rejected that in Actavis, but we're going to ask you over the next few weeks to look at the real world.

We're going to show you how the events unfolded in the real world and how in the seven-plus years since

the settlement was entered into this has had a manifestly procompetitive effect.

We're going to ask you not to ignore those real-world facts, as complaint counsel asked the commission to rule out. They didn't want to hear about this stuff. You shouldn't ignore it.

You shouldn't ignore the fact that Impax got to begin selling Opana ER before the patents Endo was asserting had expired.

We don't think you should ignore the fact that no one, no one ever successfully challenged the two patents that were in suit between Impax and Endo that led to this settlement.

We don't think that you should ignore the fact that by settling, Impax got a license to existing and future patents.

We don't think you should ignore the fact that Endo's after-acquired patents have been upheld by two different judges.

We don't think you should ignore the fact that as a result of those patents, no other generic is on the market.

We don't think you should ignore the fact that because it settled, since January 1, 2013, Impax has been meeting patients' needs for a lower-cost generic

Opana ER and that for at least a year now it's been the only generic Opana ER available to consumers, and finally, since September 1, 2017, it is the only Opana ER available on the market.

Unless Your Honor has any questions, thank you.

JUDGE CHAPPELL: All right. I'm going to make some evidentiary rulings. Then we're going to take a break before we call our first witness. But normally at this time when the opening statements are concluded, a lot of people head for the exit, so I'm going to give you a couple minutes if you want to leave now.

No one? Okay. That's new. All right.

Let's talk about joint exhibits.

And again, we're going to take a break after I'm done here, come back and call the first witness.

I have offered -- or received from the parties JX 2, Joint Revised Stipulation on Admissibility of Exhibits.

Have there been any additional revisions since I received JX 2?

MR. LOUGHLIN: Not since the version you received this morning, Your Honor.

JUDGE CHAPPELL: Okay. And do the parties

jointly offer this exhibit?

Government?

MR. LOUGHLIN: We do, Your Honor.

JUDGE CHAPPELL: Respondent?

MR. HASSI: We do, Your Honor.

JUDGE CHAPPELL: JX 2 is admitted.

(Joint Exhibit Number 2 was admitted into evidence.)

JUDGE CHAPPELL: Stipulations of facts and law. On Monday, I received a joint stipulation, JX 001, and I am pleased to see the parties worked together on this.

Is JX 1 offered as a joint exhibit by the government?

MR. LOUGHLIN: It is, Your Honor.

JUDGE CHAPPELL: By respondent?

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: JX 1 is admitted.

(Joint Exhibit Number 1 was admitted into evidence.)

JUDGE CHAPPELL: I have one other matter I'm going to deal with, and then we'll take a break.

I received a trial brief regarding evidently a discovery issue.

First of all, I'm going to let the parties

know, I do not want to see a trial brief unless I ask for a trial brief. If I want it, I'll let you know.

But since that trial brief was filed, I need to know, do you plan to respond and how long do you need?

MR. HASSI: Your Honor, I'm not sure that there is an issue here.

In other words, the trial brief, as we understand it, addresses questions that were asked to which we asserted a privilege. We don't intend to waive that privilege, and we don't intend to offer evidence related to -- so there were questions about, for example, a model called the Zorn model that Impax creates. We're not planning on putting that Zorn model in, offering it up.

JUDGE CHAPPELL: You don't intend to offer evidence or answers to questions that were objected to and not answered during discovery.

MR. HASSI: That's correct, Your Honor.

JUDGE CHAPPELL: All right. I don't have a motion pending before me now.

Do you want to add anything?

MR. LOUGHLIN: No, Your Honor. The issue is that to the extent that witnesses make representations that call for information that was not disclosed, we

will object and ask Your Honor to rule that those questions cannot be asked.

JUDGE CHAPPELL: When I get an objection, I'll deal with it. But I'll let the parties know, there's a difference in a fact and an opinion. And a fact is not something that needs to be evaluated and analyzed by one side or the other. If someone testifies to a fact, I'm allowing that fact, unless that fact was not allowed in discovery.

Any questions on that?

MR. LOUGHLIN: No, Your Honor.

MR. HASSI: No, Your Honor.

JUDGE CHAPPELL: Is the first witness here?

MR. HASSI: He is, Your Honor.

MR. LOUGHLIN: Yes, Your Honor.

JUDGE CHAPPELL: He's calling the first witness (indicating)?

MR. LOUGHLIN: We're calling the first witness, Your Honor; however, it is Mr. Koch, who is represented by O'Melveny & Myers in this case.

JUDGE CHAPPELL: Okay.

All right. We're going to take about a 15-minute break, may be our last break for the day. Before we do, hold on a second.

(Pause in the proceedings.)

We'll reconvene at 3:45.

We're in recess.

(Recess)

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

Call your first witness.

MR. LOUGHLIN: Your Honor, complaint counsel calls Arthur Koch.

And Your Honor, my colleague Markus Meier will handle the examination of Mr. Koch.

- - - - -

Whereupon --

ARTHUR ANTHONY KOCH, JR.

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

MR. MEIER: Good afternoon, Your Honor.

May it please the court.

My name is Markus Meier, and I'm here on behalf of complaint counsel.

Good afternoon, Mr. Koch.

JUDGE CHAPPELL: Do I recall seeing you, sir, like 15 years ago in court or maybe more?

MR. MEIER: It might have been 16 or 17 years, about then. Whenever you first started, Your Honor.

You saw me in the Hoechst standards case which settled before we went to trial and you saw me a little

bit in the Schering case.

JUDGE CHAPPELL: Schering. That brings back memories.

Okay. Go ahead.

- - - - -

DIRECT EXAMINATION

BY MR. MEIER:

Q. Mr. Koch, would you please introduce yourself by stating your full name.

A. Sure. It's Arthur Anthony Koch, Jr. I spell it K-O-C-H.

Q. Mr. Koch, we met in Philadelphia, Pennsylvania back in June of 2017 when I took your deposition.

A. Yes.

Q. How are you?

JUDGE CHAPPELL: Both of you are going to need to speak up.

THE WITNESS: Thank you. I'm very well.

BY MR. MEIER:

Q. Is there anything that would affect your ability to give truthful, complete testimony today?

A. Nothing.

Q. Mr. Koch, there should be a binder down to your left there and a bottle of water. I may -- we don't need the binder right now, but I just want to let you

know it's there. It's got some exhibits that I might be asking you about later. And there's also a bottle of water there for you.

A. Thank you.

MR. MEIER: Your Honor, Mr. Koch is a former employee of Impax, and that's the respondent in this case. And under your order of October 18, 2017, Mr. Koch has been deemed an adverse witness and subject to examination by leading questioning, so I intend to avail myself of that ruling.

JUDGE CHAPPELL: Okay.

BY MR. MEIER:

Q. You sat for a deposition in this matter; correct?

A. Yes.

Q. Your deposition was in Philadelphia.

A. Correct.

Q. And your deposition was earlier this year.

A. June. Yes.

Q. And you were represented by Mr. Hassi at your deposition; correct?

A. Yes.

Q. That's the lawyer sitting here to my left (indicating)?

A. Correct.

Q. And you met with Mr. Hassi for about seven hours to prepare for your deposition.

A. Correct.

Q. You reviewed documents while meeting with Mr. Hassi to prepare for your deposition.

A. I did.

Q. You were sent a copy of the transcript and exhibits from an earlier FTC investigational hearing to help you prepare for your deposition.

A. Yes.

Q. And Impax reimbursed you for your time and expenses for testifying at the deposition.

A. Correct.

Q. Impax paid you $500 an hour.

A. Correct.

Q. Impax also paid you for the time you spent preparing for your deposition.

A. It did.

Q. And that was $500 an hour.

A. Correct.

Q. Now, you sat for an investigational hearing during the FTC's investigation in this matter.

A. I did.

Q. And that was held here in Washington, D.C.

A. It was.

Q. And that was a number of years ago.
A. Yes, it was.
Q. And you were represented at that time by lawyers from O'Melveny & Myers; correct?
A. I was.
Q. And the O'Melveny & Myers lawyers were partners of Mr. Hassi; correct?
A. They were.
Q. And that's the law firm representing Impax at the hearing today; correct?
A. Yes.
Q. At the time of your investigational hearing, O'Melveny & Myers represented both you and Impax; correct?
A. That's correct.
Q. And you met with the lawyers before your investigational hearing.
A. I did.
Q. And you met with them for at least a day to prepare for your investigational hearing.
A. That's correct.
Q. In fact, you reviewed some documents when you met with the lawyers from O'Melveny & Myers before your investigational hearing.
A. I did. It was many years ago.

Q. And Impax paid you for your time and expenses for testifying at the investigational hearing.
A. They reimbursed me for my time, yes.
Q. And they paid you $500 an hour?
A. Yes.
Q. Did you meet with the lawyers from O'Melveny & Myers to prepare for your testimony today?
A. I did.
Q. How long did you meet?
A. Probably six or seven hours yesterday.
Q. Did you review documents with the -- Impax' lawyers?
A. I did.
Q. And are you being paid by Impax for the time you spent preparing for your testimony today?
A. They're reimbursing for my time and my expense, yes.
Q. $500 an hour?
A. Correct.
Q. And are they paying for your time testifying today, too?
A. Yes.
Q. And that's $500 an hour.
A. Correct.
Q. Now, Mr. Koch, let's switch subjects and

discuss the time you worked at Impax and a little bit about your professional experience.

You joined Impax in February of 2015.

A. 2005.

Q. I'm sorry. Correct. Thank you. Let me rephrase that.

You joined Impax in February of 2005.

A. That's correct.

Q. And it might have been Valentine's Day in February.

A. I think it was. Yes.

Q. And at the time you joined Impax, you'd already had 30 years of finance, operations and public accounting experience.

A. Correct.

Q. This included service as the chief financial officer of three publicly traded healthcare companies; correct?

A. Yes.

Q. And then you resigned from Impax in June of 2012.

A. I did.

Q. So you were at Impax for just about a little more than seven years.

A. Correct.

Q. All told, you have more than 19 years of experience working in the life sciences industries; correct?

A. Yes, correct.

Q. I'd like to now focus on your duties and responsibilities when you worked at Impax.

While you were at Impax, your job title changed, but you essentially served as the chief financial officer the whole time; correct?

A. That's correct.

Q. And that's for the entire seven years?

A. Yes.

Q. And "chief financial officer" is sometimes abbreviated as "CFO"; correct?

A. It is.

Q. So sometimes today I might say "CFO" and sometimes I might say "chief financial officer," but you'll understand that those are both --

A. I will understand.

Q. During your seven years at Impax, you reported to Impax' chief executive officer.

A. That's correct.

Q. And when you first joined Impax, the CEO was Barry Edwards?

A. That's also correct.

Q. Eventually you reported to Larry Hsu.
A. I did.
Q. And "Hsu" is spelled H-S-U; correct?
A. That's correct.
Q. You reported to Dr. Hsu when he became Impax' CEO.
A. I did.
Q. And broadly speaking, your responsibility as CFO was to manage the financial affairs of Impax; correct?
A. Broadly speaking, yes.
Q. But more specifically, your responsibilities as CFO included financial reporting, budgeting, investor relations, capital planning, resource allocation and IT infrastructure.
A. Correct.
Q. As CFO, you worked very closely with Impax' CEO Dr. Hsu.
A. I did.
Q. You also worked very closely with other members of Impax' management team.
A. Correct.
Q. And these other members of the management team sat on something called the executive committee.
A. Also correct.

Q. The Impax executive committee included the CEO, the president of the brand division, the president of the generics division, the vice president of manufacturing and you.

A. Indeed.

Q. And the Impax executive committee was also sometimes called the G5 because you had five members; correct?

A. That's correct.

Q. You also served on the financial reporting committee and the products development committees at Impax; correct?

A. For both the brand division and the generics division, yes.

Q. Right.

And that product development committee was also sometimes called the new product committee.

A. That's correct.

Q. And as you just said, the company has one for the branded division and one for the generic division.

A. Correct.

Q. And you served on both of those committees.

A. I did.

Q. During your seven years at Impax, Impax had both a branded business unit and a separate generic

business unit.

A. I believe the brand business might have been formed shortly after I got there, but there were brand activities. It may not have been formalized.

Q. So during most of the time you were at Impax, there was a branded --

A. Correct.

Q. -- division and a generic division; correct?

As part of your responsibilities at Impax, you also served as the secretary of Impax' board of directors?

A. For a time, yes, for a portion of the time.

Q. And additionally, as part of your responsibility as CFO, you would regularly attend the Impax board of directors meetings.

A. That's correct.

Q. And you made regular presentations to the board of directors in your capacity as CFO.

A. I did.

Q. And it would be common for you to make presentations to the board of directors at their meetings.

A. Correct.

Q. When you made a presentation to the board of directors, you would always try to be accurate.

A. Always.
Q. And if you saw a mistake in the presentation materials you put together, you'd absolutely try to correct it.
A. Absolutely.
Q. And the Impax board of directors would meet quarterly.
A. Sometimes more frequently ad hoc, but there was a quarterly scheduled, yes.
Q. So they would meet quarterly, and sometimes they'd even meet more often than that.
A. That's right.
Q. And you typically reported the financial results of the company and its performance against the plan to the board; correct?
A. That's correct.
Q. What does "performance against plan" mean?
A. Comparing actual results to budgeted results.
Q. And "budgeted results" would mean what?
A. Each year, we would set an annual budget for the business, and we would compare actual results to the board -- we would compare actual results to those plans to the directors as part of my presentation.
Q. Impax is a publicly traded company.
A. That's correct.

Q. And Impax is listed on the Nasdaq Stock Exchange.

A. Correct.

Q. As part of your job as CFO --

JUDGE CHAPPELL: What's the stock symbol?

THE WITNESS: IPXL. IPXL.

JUDGE CHAPPELL: Has that been consistent since it went public?

THE WITNESS: Yes.

There was a time, though, Your Honor, when we were not registered on the exchange because of a dispute we had with our accountants over revenue recognition, so we lost our registration and had to reregister in 2010.

JUDGE CHAPPELL: You were able to get the same symbol?

THE WITNESS: Yes.

JUDGE CHAPPELL: Thank you.

BY MR. MEIER:

Q. As part of your job as CFO, you would review Impax' filings required by the Securities and Exchange Commission?

A. Yes.

Q. You were responsible for Impax' Sarbanes-Oxley Act compliance?

A. I'm sorry. I couldn't hear that.
Q. Yes.
You were responsible for Impax' Sarbanes-Oxley Act compliance?
A. Yes.
Q. And under Sarbanes-Oxley you had to individually certify the accuracy of financial information you reported for Impax.
A. I did.
Q. You were typically involved in the preparation of Impax' annual reports; correct?
A. Most of the times our annual reports were a wraparound our 10-K, so yes.
Q. And you would review drafts and proposals for inclusion in the annual report.
A. Yes.
Q. And the same with the company's so-called 10-K filing.
A. Correct.
Q. That's a filing you make with the SEC.
A. Yes.
Q. And Impax' financial plans, while you were there, were based on the information available to you at the time; correct?
A. Yes.

Q. And Impax' financial plans reflected the company's best efforts at making estimates.

A. Yes.

Q. In addition to preparing plans, you and the people who worked for you sometimes also prepared forecasts.

A. Correct.

Q. And when you prepared forecasts, you would try to use the best information available to the company at the time.

A. Correct.

Q. And your mandate from the CEO and the Impax board was to be accurate in your planning.

A. Of course.

Q. In your plans at Impax, something called an upside scenario is -- in your plans -- sorry. If I move the microphone closer, it's going to start sliding down the lectern.

JUDGE CHAPPELL: You can raise that entire --

MR. MEIER: Yes.

JUDGE CHAPPELL: -- lectern or whatever it's called. There's a button somewhere that will raise the whole thing.

MR. MEIER: Yes. The problem, Your Honor, is it starts to slope, and if I move the microphone, I

have book here it starts to slope in on. Sorry about that. Let me start that over.

BY MR. MEIER:

Q. In your plans at Impax, something called the upside scenario is a set of assumptions that are the most beneficial to Impax; correct?

A. I wouldn't characterize it as most beneficial. It was better -- it was a more favorable forecast than a base case.

Q. So a base-case scenario wouldn't include many of the if-everything-goes-right assumptions for the company?

A. Correct.

Q. So if I have it correctly, a base-case scenario was more conservative than an upside scenario.

A. Yes.

Q. Mr. Koch, let's shift gathers now and talk about Impax' efforts to develop generic Opana.

Opana ER is a brand product manufactured by Endo Pharmaceuticals or at the time that you were at Impax; correct?

A. Yes.

Q. And Opana ER is an opioid.

A. It is.

Q. Opana ER is used to treat pain.
A. It is.
Q. Opana ER's generic name is oxymorphone hydrochloride extended release.
A. Correct.
Q. One shorthand for generic Opana ER used inside of Impax when you were at the company was oxymorphone.
A. Correct.
Q. Another shorthand you'd use for generic Opana inside Impax was just the initials O, X and M; correct?
A. Correct.
Q. Impax' generic business unit was responsible for developing oxymorphone.
A. A generic for it, yes.
Q. And that was the business unit headed by Chris Mengler at the time you were at Impax.
A. Correct.
Q. While at Impax you were aware of a patent lawsuit by Endo Pharmaceuticals against Impax involving generic Opana ER.
A. I was.
Q. And Endo's lawsuit concerning generic Opana started sometime after you joined Impax.
A. It did.

Q. You testified at your deposition that Impax, quote, had a formulation of generic Opana that the company felt didn't infringe Endo's patents; is that correct?

A. It either felt it didn't infringe or we felt that the patents weren't enforceable.

Q. You were directly involved in negotiating with Endo from the period of about June 4 to about June 8, 2010.

A. Yes. A very short period of time right at the end.

Q. Right at the end of the negotiations.

A. Correct.

Q. And by the time you became involved in the negotiations with Endo in June 2010, the negotiations had already been proceeding for some time.

A. Yes, they had.

Q. You were asked to finish the negotiations with Endo.

A. I was -- yes, I was.

Q. And you picked up where Chris Mengler had left off.

A. I did.

Q. And again, Mr. Mengler was Impax' president of the global pharmaceuticals division at the time.

A. He was, yes.
Q. And the global pharmaceuticals division, that's just the same name -- I'm sorry -- that was Impax' name for the generic business unit.
A. That's right. We called the business unit of the generics division global pharmaceuticals from -- in different contexts over time. Yes.
Q. And like you, Mr. Mengler was a member of Impax' executive committee at the time that he was there.
A. Yes.
Q. And Mr. Mengler had been leading the negotiations with Endo for Impax before you took over.
A. He did. He was.
Q. But you took over to get the project across the finish line; correct?
A. Larry asked me to get a specific set of objectives in the final negotiations. Yes.
Q. Before you personally became involved in actually negotiating with Endo, you were kept regularly apprised of the status of the negotiations as a member of Impax' executive committee.
A. Yes. The committee was regularly updated.
Q. And during the time Mr. Mengler was leading the settlement negotiations with Endo, you would give input

to him on the settlement terms.

A. As would other members of the executive committee. Yes.

Q. As would other members of the executive committee; correct?

A. Yes.

Q. And Meg Snowden, an in-house counsel at Impax, was involved in the negotiations with Endo, too.

A. She was.

Q. And Ms. Snowden worked with you to complete the negotiations.

A. She did.

Q. Larry Hsu, Impax' CEO at the time, was also involved in the settlement negotiations but not directly in the conversations with Endo; correct?

A. Well, his role as CEO, he was ultimately responsible, yes, but he did not have direct contact with Endo.

Q. So Larry Hsu, Impax' CEO at the time, was also involved in the settlement negotiations but not directly.

A. Correct.

Q. You were negotiating with Alan Levin, Endo's chief financial officer.

A. I was.

Q. And you saw the final settlement agreement.
A. I did.
Q. You signed the final settlement agreement.
A. That's correct.
Q. And you signed the final settlement agreement on behalf of Impax.
A. I did.
Q. Do you remember when Impax' settlement agreement with Endo was signed?
A. June -- I don't remember the day. June 2010.
Q. In your 19 years working in the life sciences industry, have you ever heard the term "first-to-file exclusivity"?
A. Yes.
Q. "First-to-file exclusivity" is a term you've personally used?
A. In a general sense, businessman sense, yes.
Q. What does "first-to-file exclusivity" mean in your businessman sense?
A. It's a concept granted to a first filer under the FDA's ANDA regulations for new products, new generic products.
Q. And Impax was the first company to file an ANDA with the so-called paragraph certifications for the 5, 10, 20, 30 and 40 milligram dosages of Opana ER;

correct?

A. Correct.

Q. I'm sorry. Let me try to --

A. Oh, I'm sorry.

Q. I'm going to try to finish my question.

A. I'm sorry.

Q. I'm sorry. My voice probably tailed off there at the end.

JUDGE CHAPPELL: Well, actually, the witness is being friendly and he's anticipating, so just wait for him to finish, then answer.

THE WITNESS: I will.

JUDGE CHAPPELL: Nobody is doing anything wrong. Just one at a time is all she can transcribe here. This might be new to you.

THE WITNESS: Okay.

JUDGE CHAPPELL: If you're lucky.

BY MR. MEIER:

Q. I'm going to do my best to be more cognizant of it, too, so I'm sorry about that. Sometimes maybe my voice trails off at the end.

Right before that happened, I believe I was asking, Impax was the first company to file an ANDA with Paragraph IV certifications for the 5, 10, 20, 30 and 40 milligram dosages of Opana ER; correct?

A. Correct.
Q. And at the time, those dosages comprised over 95 percent of Endo's Opana ER sales?
A. I don't remember the number, but it was a vast preponderance, so I wouldn't dispute it.
Q. And so Impax was eligible for the first-filer exclusivity on those dosages.
A. Correct.
Q. And first-to-file exclusivity is very valuable to a generic company; correct?
A. It is.
Q. Why is first-to-file exclusivity very valuable to a generic company?
A. It's an incentive the FDA came up with to provide an opportunity for a generics company to justify the investment necessary to create generic drugs and giving them six months of runway before another entrant will be reviewed or approved.
Q. Is it the case that generic companies can often make most of their profits during that six-month runway?
A. They can make -- depending on market characteristics -- "most" is hard to characterize. They can make a substantial portion of their profits. But the life of the generic and a great many other

factors enter into determining whether it was most.

Q. So first-to-file exclusivity is very valuable to a generic company because it helps the generic company make more money.

A. Yes, it does.

Q. You are familiar with the term "authorized generic"; correct?

A. I am.

Q. And "the authorized generic" is a term of art used in your industry to describe an arrangement that a brand company enters into with a generic manufacturer to market a generic product of their own brand; correct?

A. Yes.

Q. And in your experience, it's common for a brand to launch an authorized generic.

A. It's hard to characterize it as common. It's not un- -- it's not infrequent or rare. It happens from time to time. But it's hard to know what one means by "common." It happens frequently. It happens often.

Q. As an element of negotiating a settlement agreement with a brand, a no-authorized-generic agreement would be a provision that Impax would typically seek in a settlement; correct?

A. A lot of variables go into that answer because it would depend on the plans by the brand to the extent they were known. It would depend on the brand's prior experience and history.

So it's not a categorical answer, but a general answer is yes.

Q. So as an element of negotiating the settlement agreement with a brand, a no authorized generic would be a provision Impax would seek.

A. Yes.

Q. And Impax would seek a no-AG agreement because the more control over the market a generic has, the more predictable the outcomes will be, so the absence of an authorized generic would mean more control.

A. The absence of an authorized generic would mean --

Q. More control for the generic company.

A. That's correct. Yes.

Q. And control can often lead to higher profits; correct?

A. Yes, it can.

Q. The settlement agreement that you signed on behalf of Impax with Endo included a no-authorized-generic provision; correct?

A. It did.

Q. And a no-authorized-generic term was part of the settlement you signed.

A. Yes.

Q. And Endo agreed not to launch an authorized generic of Opana ER in competition with Impax' generic Opana; correct?

A. That's what "no AG" means. Yes.

Q. In addition to the no-authorized-generic term, another subject of the settlement negotiation with Endo was the date when Impax could enter the market with generic Opana ER; correct?

A. Yes.

Q. And the date was one of the most important elements of the settlement agreement.

A. Yes.

Q. Impax was seeking as soon a launch date as possible as close to the expiration of your 30-month stay as you could get.

A. Correct.

Q. The launch date under the settlement agreement that you eventually entered into was January 1, 2013.

A. Correct.

Q. And Impax agreed to a specific launch date in return for eliminating the uncertainty of the patent litigation with Endo.

A. I'm sorry. Could you repeat that.
Q. Yes, I will.
Impax agreed to a specific launch date in return for eliminating uncertainty of the patent litigation with Endo.
A. Yes. Correct.
Q. Impax got final FDA approval to market generic Opana shortly after entering the settlement agreement with Endo.
A. That's what I remember. Yes.
Q. So you didn't actually get final FDA approval until after you entered the settlement agreement.
A. Correct.
Q. So final FDA approval was sometime after June 8, 2010?
A. Correct. Shortly after but after.
Q. Did it ever occur to you that when Impax agreed not to launch generic Opana until January 2013 it was giving Endo time to switch the market to a reformulated version of Opana?
A. Yes.
Q. It did occur to you?
A. Yes.
Q. So you understood that when you entered the agreement?

A. Well, it was understood when we entered into the negotiations we had developed what we called a carrot and a stick as a way to get more control than just the lost control over that period of time.

Q. Do you remember discussing a negotiation term that was referred to as an acceleration trigger with Impax?

A. There was an acceleration trigger term discussed with Endo. Yes.

Q. But the meaning of this acceleration trigger, that changed over time during the negotiations; correct?

A. Not really.

Q. Oh, it did not?

A. No. We never got an accelerated trigger.

Q. Right.

So -- but when it was first discussed, you were talking about the opportunity for an earlier launch date than the generic entry date Endo proposed.

A. Right.

Q. And Impax' interest in negotiating an acceleration trigger with Endo was because one of the other tools available to a brand is to develop alternative products and switch the market.

A. Correct.

Q. You were concerned about Endo switching the market on you before you had a chance to launch your generic Opana; correct?

A. We were.

Q. And when a branded company does that, the brand tries to switch patients away from the brand product that Impax has the generic to in favor of a line extension or other products that would not be covered by Impax' ANDA.

A. Correct.

Q. But at some point the negotiations with Endo moved away from an accelerated launch date in favor of something that you understood as the make-whole provision; correct?

A. Yes.

Q. You remember a term in the settlement agreement that eventually was called the Endo credit?

A. I'm familiar with that term, but it was not a term used while I was at Impax.

Q. So you remember calling the Endo credit term a make-whole provision when you were at Impax.

A. Correct.

Q. And the make-whole was part of the carrot and stick that I think you mentioned a moment ago that Impax gave to Endo as an incentive to continue to

invest in the products to which Impax had the generic.

A. That's correct.

Q. And in return for Endo giving Impax an agreement to accept the carrot and stick, Impax stopped pursuing an earlier launch date.

A. It stopped pursuing that trigger, yes.

Q. In return for Endo giving Impax an agreement to accept the carrot and the stick, Impax stopped pursuing an earlier launch date; correct?

A. I wouldn't characterize it that way. We met complete resistance to the concept of an earlier launch date. We replaced that concept with another form of insurance we called the carrot and the stick, which was a royalty and downside protection.

Q. You said you wouldn't characterize it that way, but if I showed you your deposition transcript testimony where you actually said that, would that refresh your recollection that you actually did characterize it that way?

A. Yes.

Q. Okay. Could you please pull up the binder, please. And if you look at the tabs, there's one that's the very last one, at the bottom says "DEP."

Do you see that?

A. Yes.

Q. That's your deposition.

And I'd like to call your attention to page 71 lines 15 through 23.

Now, Terri, if you could pull that up, I'd appreciate it. Or let me say "Ms. Martin" since we're in the courtroom.

Do you see line 15?

A. Line 15 that I read says:

"QUESTION: Okay. So what did Impax give Endo."

BY MR. MEIER:

Q. "In return for Endo's agreement to accept the carrot and the stick?" Mr. Hassi then objects. And you say, "What we did was stop pursuing [the] earlier launch date"; correct?

A. I did.

Q. Thank you.

A. But the concept I was describing then and now is not so much we stopped in the absence of anything else, we replaced what we were pursuing as the earlier trigger with this carrot and stick.

Q. So what did Impax give Endo in return for the carrot and the stick?

A. Again, we're twisting this around a little bit. I can straighten it out a little -- I hope I can

straighten it out a little bit by describing what was going through my mind as we were evaluating this settlement.

There was a period of time between the date of our approval and the -- a date-certain launch of January '13. We were worried about the control the brand had over their product during that time, and we were looking for a way to gain -- take back some of that control away from the brand.

The tool that we ultimately pursued was the what I called carrot and stick as an incentive in the form of a carrot to incent them to continue to invest in the product and a stick in the form of a penalty should the market degrade over that period of time.

Q. And the penalty was what eventually was called the Endo credit; correct?

A. That's correct.

Q. And you recall hearing that Impax was eventually paid $102 million by Endo under the terms of the patent settlement agreement.

A. Correct.

Q. And that's the patent settlement agreement you negotiated and signed for Impax on June 8, 2010.

A. Was there a question?

Q. Yes, there was.

The patents -- and that's the patent settlement agreement --

A. Oh, sorry. Yes, it is.

Q. -- that you negotiated and signed for Impax on June 8, 2010; correct?

A. Correct.

Q. In addition to negotiating the settlement agreement with Endo, you negotiated an agreement that became known as the development and co-promotion agreement; correct?

A. I did.

Q. You also signed the development and co-promotion agreement with Endo.

A. I did.

Q. You signed the co-promotion and development agreement with Endo on behalf of Impax.

A. I did.

Q. Impax had not talked to Endo about the development and co-promotion agreement before entering into the patent settlement negotiations.

Let me try that again. I kind of mangled it. I can see that you didn't hear me very well.

A. Okay.

Q. Impax had not talked to Endo about the development and co-promotion agreement before actually

entering into the patent settlement negotiations; correct?

A. That's correct, yes.

Q. The product that was to be the subject of the development and co-promotion agreement eventually became known as IPX-203.

A. It is. Yes.

Q. And Impax hoped that IPX-203 would become a line extension of a product Impax called IPX-066.

A. It is. That's correct.

Q. If successful, IPX-203 would have been a brand product.

A. It would have, yes.

Q. And as far as you know, Endo was the only potential partner Impax was negotiating with concerning IPX-203.

A. That's correct.

Q. At the time of the development and co-promotion agreement, IPX-203 was at a very early stage of clinical development.

A. Yes.

Q. In fact, IPX-203 was preclinical.

A. Yes. Correct.

Q. What does "preclinical" mean?

A. Before human testing.

Q. Had it even been formulated at the time that you had negotiated the agreement with Endo?

A. I don't know that the formulation had been finalized. I think formulation work was underway.

Q. We've been talking about two agreements that Impax entered with Endo in June of 2010, a settlement and license agreement and a development and co-promotion agreement.

You were involved in providing input on the terms and conditions for both of those agreements; correct?

A. I was, yes.

Q. And other members of Impax' executive committee were also involved in giving their input on both agreements.

A. They were.

Q. And both agreements were negotiated at the same time.

A. They were.

Q. Both agreements were completed during the same time.

A. They were.

Q. Sometimes you would talk to the Endo people about the settlement terms and the development terms in the same call.

A. I would.
Q. Most of the negotiations were actually done by telephone; correct?
A. That's correct.
Q. And sometimes the terms for both of the agreements were discussed at the same meetings that you participated in within Impax.
A. I'm sorry.
Q. All right. So you would have meetings internally within Impax.
A. Yes.
Q. Correct?
A. Yes.
Q. Like the G5 meetings?
A. Okay. Yes.
Q. And sometimes the terms for both of these agreements were being discussed at the same G5 meetings.
A. That's correct, yes.
Q. And you were discussing both at the same time?
A. Yes.
Q. And it was the same team negotiating both?
A. The same points of contact negotiating both. Both -- both Endo and Impax had separate teams for each of the projects because one was brand and one was

generic.

Q. Right.

But the teams that were actually doing the negotiations --

A. Yes.

Q. -- on the call was the same people for Impax doing both agreements; correct?

A. The contact, yes. The point of contact was the same.

Q. And the same people for Endo; right?

A. That's correct.

Q. And you and Endo were both trying to get these deals done.

A. We were, yes.

Q. I'd like to now talk to you about something known in the pharmaceutical industry as launch at risk.

You're familiar with the term "launch at risk"; correct?

A. I am.

Q. It's a term you've personally used?

A. Sure. Yes.

Q. It means launching a generic product in the presence of patent litigation with a brand; correct?

A. Yes.

Q. And in your experience in the seven years at Impax, Impax would evaluate at-risk launches from time to time.

A. Infrequently, but yes.

Q. And whether Impax should launch generic Opana at risk was under consideration by Impax in 2010.

A. It was, yes.

Q. But Impax ultimately settled its litigation with Endo before Impax had final FDA approval to launch generic Opana; correct?

A. It did.

Q. Successfully launching oxymorphone was a key company goal for Impax in 2010; correct?

A. At certain points in time during 2010, the February or January-February time frame, yes, it was. That later changed in 2010 as developments unfolded with the negotiations.

Q. All right. Well, successfully launching oxymorphone was a key company goal for Impax in 2010; correct?

A. January-February time frame.

JUDGE CHAPPELL: Hold on a second.

Impax referred to the generic drug as Opana ER?

THE WITNESS: Yes.

JUDGE CHAPPELL: Do you know what Endo referred to the same drug as, the branded drug as?

THE WITNESS: I believe it referred to it as Opana ER also.

JUDGE CHAPPELL: Same name.

THE WITNESS: Yes.

Your Honor, often in a -- it would depend on the context, but we would often refer to the generic name as a matter of -- so we would more often refer to it as oxymorphone, but sometimes we would refer to it as Opana. Both would be used.

JUDGE CHAPPELL: So it's not a problem -- for example, if you were selling generic Lipitor, you couldn't call it Lipitor, could you?

THE WITNESS: No.

JUDGE CHAPPELL: Yet you could call this Opana ER?

THE WITNESS: Not on the market.

JUDGE CHAPPELL: Not on the market.

THE WITNESS: We would call it oxymorphone.

JUDGE CHAPPELL: All right. Thank you.

BY MR. MEIER:

Q. Oxymorphone, just to be clear, that's the actual generic name of the active pharmaceutical ingredient; correct?

A. Yes. But it's formulated with hydrochloride, and there are some other ingredients. The shorthand is "oxymorphone."

JUDGE CHAPPELL: So the prescription bottle would say, if you've got the generic at CVS, it would say "oxymorphone."

THE WITNESS: "HCl."

JUDGE CHAPPELL: "HCl." Okay. Thank you.

BY MR. MEIER:

Q. For hydrochloride?

A. I believe so, yes.

Q. Impax' CEO, Larry Hsu, would communicate the company's key goals to management and staff annually; correct?

A. Yes.

Q. And Dr. Hsu would do this in writing; correct?

A. Yes.

Q. And division heads like you would use the key company goals to make sure you had the plans and resources in place to accomplish those goals.

A. Yes.

Q. And the key company goals were also used as a tool for setting compensation for Impax' employees.

A. Yes.

Q. The key compensation -- the key company goals

were used as a tool in setting the compensation of executives at Impax like you.

A. Correct.

Q. In fact, the key company goals were used as a tool in setting your compensation while at Impax.

A. That's correct.

Q. So, Mr. Koch, would you please look into your binder at Exhibit Number CX 2562. That's the very first tab.

And while you're doing that, I'll just state for the record that this exhibit is included in JX 2 and has been admitted in evidence, and it is not subject to Your Honor's in camera ruling.

JUDGE CHAPPELL: Thank you.

MR. MEIER: And I would ask Ms. Martin to pull this up.

BY MR. MEIER:

Q. The first page is an e-mail from Dr. Hsu; correct?

A. Yes.

Q. And you're one of the people who Dr. Hsu sent the e-mail to. It's the third line down.

Do you see that?

A. I do.

Q. And you're Art Koch; correct?

A. I am.
Q. And the date of this e-mail was January -- I'm sorry -- February 28, 2010; correct?
A. Yes.
Q. And the subject is key -- company key goals 2010.
A. Correct.
Q. And the e-mail says, "Attached please find the finalized 2010 company key goals based on discussion in the off-site meeting."
Do you see that?
A. I do.
Q. Did you participate in the off-site meeting?
A. Yes.
Q. And the next sentence says, "Please use this document in setting your MBOs"; correct?
A. Correct.
Q. And "MBOs" means management by objective?
A. It does.
Q. Now, let's turn to the second page of CX 2562, looking sort of at the very top first.
JUDGE CHAPPELL: Before you do that, where is Impax located?
THE WITNESS: Head office is in Hayward, California. There was a second office on the

East Coast in Doylestown, Pennsylvania.

JUDGE CHAPPELL: Thank you.

BY MR. MEIER:

Q. Looking at the second page of 2562, at the very top, these are the 2010 company key goals for Impax; correct?

A. That's what it says. Yes.

Q. And now if we look to the middle of the page, under the heading Generics Business, do you see the bullet that says, "Successfully manage key marketed products and new product launches"?

A. I do.

Q. And one of those successfully managed key marketed products and new product launches is oxymorphone; correct?

A. I see that. Yes.

Q. That's the generic product we've been talking about today.

A. Yes, it is.

Q. So successfully managing a new product launch of oxymorphone was one of Impax' key company goals in February of 2010.

A. That's what Larry wrote. Yes.

Q. And Impax -- we can take that down now, Ms. Martin.

And Impax took steps in 2010 to prepare to launch generic oxymorphone in 2010.

A. It did, yes.

Q. Impax management asked the manufacturing people to begin to manufacture launch quantities in 2010.

A. Correct.

Q. And this required the purchase of raw materials.

A. Among other things, yes.

Q. And it required the manufacture of pills.

A. Right.

Q. And some of the manufactured generic Opana by the time of the settlement was already manufactured in something called bright stock; correct?

A. Correct.

Q. And bright stock is product that's manufactured, placed in bottles, but hasn't actually been labeled yet.

A. That's correct.

Q. And some of the manufactured generic Opana by the time of the settlement was manufactured as finished goods; correct?

A. Yes.

Q. And "finished goods" means it's manufactured,

in the bottle, and there are labels on the bottles.

A. Very good. Yes.

Q. Okay. All right. I'd like to now shift gears and talk a little bit about your role as secretary of the Impax board of directors.

When you started at Impax in 2005 until sometime about 2011, you were responsible for recording the meeting minutes of Impax' board of directors; correct?

A. Yes.

Q. And your practice was to take notes during the meeting; correct?

A. Yes.

Q. And you would take these notes with a view to making the minutes?

A. Correct.

Q. And then you'd prepare a draft.

A. I would.

Q. And then you would circulate the draft?

A. I would.

Q. And at some point you would publish the minutes.

A. That's correct.

Q. But you would first circulate the draft minutes to the CEO.

A. I would.
Q. And when you were comfortable, you would circulate the minutes to the board of directors.
A. Correct.
Q. And there would be a motion to approve the minutes at the next board meeting.
A. There would.
Q. And this motion would be voted on by the board.
A. And recorded in the minutes.
Q. I'm sorry?
A. And recorded in the minutes.
Q. Okay. And when you say publishing the minutes a moment ago, you mean the minutes would go into the minute book.
A. That's correct.
Q. And the minute book is a record of Impax.
A. It is.
Q. And as secretary of the board, you would actually sign the board-approved minutes?
A. I would.
Q. And you wouldn't sign the minutes unless you believed they were accurate?
A. Correct.
Q. The purpose of the board minutes is to create a

record of the -- the purpose of the board minutes is to create a record to show the deliberations the board considers in the administration of the company.

A. Correct.

Q. The board minutes serve as a permanent corporate record of the company.

A. That's correct.

Q. Do you recall testifying at your deposition that no one at Impax would go to the board of directors and make a recommendation about an at-risk launch without the approval of the executive committee first?

A. Yes.

Q. Mr. Koch, I'd like to show you what's been marked as CX 2663. It's in your binder.

And before pulling that up on the screen, I'd just like to state that 2663 is included in JX 2, it has been admitted in evidence, and that Impax has requested partial in camera treatment for this exhibit, but not for the part I plan to use. And consequently, we've created a blacked-out version that blacks out the in camera part.

With Your Honor's permission, I'd rather not have the courtroom sealed. I've blacked out -- and I represent to Your Honor that we've blacked out the part that they've asked for in camera treatment of

because it's not the part I'm going to be asking about.

JUDGE CHAPPELL: No. That's good. Thanks. Go ahead.

MR. MEIER: Ms. Martin, would you please project the redacted version of CX 2663 which blacks out the in camera portion of this exhibit. Thank you.

BY MR. MEIER:

Q. Mr. Koch, you've seen CX 2663 before; correct?

A. I have, yes.

Q. And CX 2663 is the minutes of the Impax board of directors meeting for May 25 and 26, 2010?

A. It is.

Q. And that's a few weeks before you actually signed the settlement of the negotiations with Endo; correct?

A. It is, yes.

Q. And if we look at the very last page, page 4 of the minutes, that's your signature on page 4 of the minutes; correct?

If we could just pull that up real quickly.

A. Yes, it is.

Q. And that's your signing in your capacity as secretary of the board.

A. Correct.

Q. Going back to page 1, if we look at the second paragraph, this is a paragraph that begins with "Mr. Mengler reviewed."

Do you see that?

A. I do.

Q. And if I understand this correctly, Mr. Mengler was making a presentation to the Impax board of directors at this time.

A. That's -- yes.

Q. That's what you're reporting on in this paragraph; correct?

A. Correct.

Q. And still looking at the second paragraph, there's a sentence toward the bottom before the blacked-out part where it starts with "He expressed the view."

Do you see that?

A. I do.

Q. And it says, "He" -- meaning Mr. Mengler; correct?

A. It is.

Q. -- "expressed the view that oxymorphone was a good candidate for an at-risk launch"; correct?

A. Yes, it does.

Q. And if anyone had expressed disagreement with

Mr. Mengler at that board meeting, you would have included that in the minutes; correct?

A. I would have.

Q. And as far as you know, everyone agreed that oxymorphone was a great market opportunity for Impax; correct?

A. Yes.

Q. You've heard the term "earnings call" before; correct? You can put that down.

A. Yes.

Q. And an earnings -- I'm sorry. Did I say "earnings call"? Yes, I did.

I meant to say, you've heard the term "earnings conference call" before; correct?

A. Yes.

Q. And an earnings conference call is a meeting Impax holds each quarter to review the results of the company's operations with analysts and investors.

A. That's correct.

Q. And it would be typical for you to attend Impax conference calls when you were the CFO.

A. Correct.

Q. And it would be common for you to talk at the earnings conference calls.

A. I made a presentation every time. Yes.

Q. And that was part of your official duties as CFO.
A. Correct.
Q. And you were speaking on behalf of the company when you did that.
A. I was.
Q. And it was part of your job responsibilities to do that.
A. It was.
Q. And you'd make a prepared statement; correct?
A. I would.
Q. And then you'd also answer questions from analysts; correct?
A. Yes.
Q. And Impax' earnings calls are public.
A. They are.
Q. So actually anybody could listen in.
A. That's correct.
Q. And the earnings calls are recorded.
A. They are.
Q. And there are various services out there that prepare written transcripts of earnings calls; correct?
A. That's correct.
Q. And one such transcription service is called

CQ Roll Call, Incorporated; correct?

A. Correct.

Q. And that happens to be the transcription service that Impax used when you were there.

A. That's correct.

Q. Mr. Koch, I'd like to show you what's been marked as CX 2703. It's also in your binder. It's the third tab.

But before I call it up, let me state that, Your Honor, CX 2703 is included in JX 2 and has been admitted in evidence. The exhibit is a public document and is not subject to your in camera ruling.

Ms. Martin, would you please put CX 2703 up on the screen. Thank you.

Mr. Koch, looking at the cover of CX 2703, what is it?

A. It's the cover published by the service describing the Q3 2011 Impax Laboratories Earnings Conference Call - Final, Fair Disclosure Wire, November 1, 2011 Tuesday.

Q. So the date of the conference call would have been November 1, 2011?

A. That's correct.

Q. Let's turn to page 3.

And I'm going to direct your attention to the

bottom of page 3, where it says "Art Koch, SVP of finance," and if Ms. Martin could blow that up for everybody else to see.

When it says "Art Koch, senior vice president of finance, CFO," that's you; correct?

A. Yes.

Q. And is it correct that this is the part of the conference call where you give your prepared remarks?

A. Correct.

Q. Turning now to page 4, towards the bottom, this page -- first of all, this page 4, this is your prepared remarks that you made at this earnings conference call in November of 2011; correct?

A. It is, yes.

Q. Okay. Turning to the bottom, the third from the bottom paragraph that starts with "Total expenses in the third quarter were basically flat," do you see that?

A. I do.

Q. The next sentence says, "We have lowered our patent litigation expense guidance for the full year for 2011 from $13 million to $10 million primarily due to recent settlements."

Do you see that?

A. I do.

Q. And by "recent settlements" you mean recent patent settlements?

A. It's implied. Yes.

Q. And you were telling the investment community at that time that Impax is going to save three million in litigation expenses because of settlements.

A. Yes, that's correct.

Q. And one of those recent settlements was the Endo settlement.

A. It was.

Q. But that was not the only settlement because you used the plural "settlements"; correct?

A. Correct.

Q. So the Endo settlement was one of a number of settlements for which Impax was able to lower its estimate of litigation expenses by $3 million; correct?

A. That's what it says. Yes.

Q. That's what you say.

A. That's what it says.

Q. No. That's what you said at the conference call; correct?

A. Correct.

Q. Turning now to page 13 of the earnings conference call transcript -- and actually, before I

ask you specifically about page 13, I want to point to the bottom of page 12, where it says "Jim Molloy"?

A. I see it.

Q. I'll let Ms. Martin catch up to us.

This is the part of the conference call where the analysts get to ask you questions; correct?

A. Yes.

Q. And Mr. Molloy asked you, "Another question on another -- Endo recently had their conference call talking about the Opana switchout."

Do you see that?

A. I do see that, yes.

Q. What was the Opana switchout?

A. What I took it to mean and what I take it to mean is their intent to switch from the products for which we had generic approval to other forms of the product.

Q. To the Opana tamper-resistant form?

A. Right.

Q. And then on the top of page 14, if we could call that up -- I'm sorry. I'm sorry, Ms. Martin. I misspoke. I meant page 13.

And this is where you answer Mr. Molloy's question; correct?

A. It is, yes.

Q. And you say, "Well, the switchout is a very well-known strategy"; correct?

A. Yes.

Q. And then towards the bottom of that answer in that first paragraph -- and if we could highlight it -- it says, "Fortunately, though."

Do you see that?

A. I see it, yes.

Q. "Fortunately, though, we do have [downside] protection built into the agreement so we should have a reasonable outcome almost no matter what happens"; correct?

A. I see that, yes.

Q. And that's what you said on the conference call that was recorded in 2011.

A. Correct.

Q. Is your answer to the analyst similar to what you called the carrot and the stick earlier today?

A. Well, this is the stick of the carrot and the stick. Yes.

Q. So if Endo did a switchout to Opana tamper-resistant, Impax would be able to realize a payment from Endo; correct?

A. That's correct.

Q. So you had protection that basically Impax

had a reasonable outcome almost no matter what Endo did.

A. That's correct. We viewed it as insurance.

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

JUDGE CHAPPELL: Any cross?

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: Go ahead.

MR. HASSI: Your Honor, may I approach the witness to give him a binder?

JUDGE CHAPPELL: Yes.

I've got a question for Mr. Meier.

Did you mean to ask whether if Endo did a switch to Opana tamper-resistant? Didn't you mean crush-resistant?

MR. MEIER: Well, at the time, it was called tamper-resistant, Your Honor, if you look --

JUDGE CHAPPELL: So that's what you meant to ask?

MR. MEIER: I meant to ask tamper-resistant. That was the question that the analyst had asked. It eventually became -- the name changed from tamper-resistant to crush-resistant.

JUDGE CHAPPELL: All right.

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CROSS-EXAMINATION

BY MR. HASSI:

Q. Good afternoon, Mr. Koch.

You were asked some questions a minute ago. You assist when you were -- you assisted when you were at Impax in the preparation of the 10-K; is that right?

A. Can you step closer to the mike. I can't hear you, Ted.

Q. I'm sorry.

Did you assist in the preparation of the 10-K when you were at Impax?

A. Yes.

Q. Let's take a look in your binder or we can pull it up on the screen at CX 3278.

It's in evidence, Your Honor, and it is not in camera.

It's tab 1 in your binder. Do you have it?

A. I do.

Q. Okay. Do you recognize this document?

A. Sure. Yes.

Q. And what is it?

A. Impax' annual report for 2010.

Q. And you were involved in the preparation of this document?

A. Yes.
Q. And it was filed with the Securities and Exchange Commission?
A. That is correct.
Q. If we could go to page 100, please.
And this -- this page is noted -- it says "Notes to Consolidated Financial Statements."
Can you tell us what the notes to consolidated financial statements are?
A. I'm having trouble finding 100. I'm sorry.
Q. Sorry.
A. Is it the little CX number?
Got it.
Q. Yes.
A. Okay. I'm with you. I'm sorry.
Q. Can you tell the court what notes to financial statements are?
A. They're explanatory notes that are required under generally accepted accounting principles to help readers understand in greater detail the disclosures on the basic financial statements, the balance sheet, income statement and cash flow.
Q. Okay. And about halfway down the page a section starts "Inventory."
Do you see that?

A. I do.

Q. What is "inventory" a reference to in the financial statements of Impax?

A. "Inventory" refers to the carrying value of product held for future sale, and it's usually carried at cost or the -- an estimate of that cost as described in its accounting policies.

Q. If you turn to the next page, page 101, using the CX number -- and Robert, if we could blow up the top of the page -- there's a section that starts on the third line. It says, "When the Company concludes FDA approval is expected within approximately six months, the Company will generally begin to schedule manufacturing process validation studies as required by the FDA to demonstrate the production process can be scaled up to manufacture commercial batches."

Can you start by telling us, what is process validation?

A. It's a concept in manufacturing to show the steps, the manufacturing steps necessary to manufacture the pill, the product, and process validation is the -- a way to demonstrate to the agency that you can -- you've made small batches, now you can make large batches similar to commercial volumes.

Q. In the statement I just read, was that

consistent with Impax' practices in 2010 when you were the CFO?

A. Yes.

Q. With respect to -- strike that.

Why does a company have to do process validation?

A. The FDA requires it.

Q. And would Impax schedule process validation for a product even if it was the subject of active litigation?

A. Yes.

Q. It goes on to say, "Consistent with industry practice, the Company may build quantities of pre-launch inventories of certain products pending required final FDA approval and/or resolution of patent infringement litigation, when, in the company's assessment, such action is appropriate to increase the commercial opportunity, FDA approval is expected in the near term, and/or the litigation will be resolved in the Company's favor."

Was that an accurate statement of Impax' practices in 2010?

A. Yes.

Q. And why would a company build pre-launch inventories of certain products?

A. Because the readiness, the preparedness for launch, sometimes involved long lead items, and it's much less expensive, in terms of the company's financial goals, to prepare a small cost item to be prepared for the launch into a large market.

Q. Can you explain what you mean when you say a small cost item launched?

A. Cost of the pills is very low relative to the market value of the products usually, so it's a small cost.

Q. Did Impax build from time to time pre-launch inventories of products that were still the subject of litigation?

A. Yes.

Q. This statement says that doing so is consistent with industry practice.

As someone who's got twenty-plus years in the life sciences industry, do you think that building launch quantities before approval is consistent with industry practice?

A. Yeah. I believe it's routine, yes.

Q. If Impax builds pre-launch inventories for products that are still the subject of litigation, does that indicate that Impax expects the litigation will be resolved in its favor?

A. It -- it may. It does not always, but it may.
Q. Okay. The statement goes on to say, "The capitalization of unapproved pre-launch inventory involves risks, including, among other items, FDA approval of product may not occur; approvals may require additional or different testing and/or specifications than used for unapproved inventory, and, in cases where the unapproved inventory is for a product subject to litigation, the litigation may not be resolved or settled in favor of the Company. If any of these risks were to materialize and the launch of the unapproved product delayed or prevented, then the net carrying value of unapproved inventory may be partially or fully reserved."
Can you explain that last part about something being partially or fully reserved?
A. Yes. That's an accounting term. Sorry. But it means to write off or reduce the carrying value of the inventory that we're talking about to reflect those risks that were reflected upon.
Q. And one of the risks that's reflected above is losing in litigation; is that right?
A. Yes.
Q. And another risk is not getting FDA approval?
A. Correct.

Q. And when you reserve against a product, what happens to the product?

A. It's destroyed.

Q. Is that just a cost of doing business?

A. It is. Routinely.

Again, it's a small cost and it is a -- the best way to describe it is a cost of doing business in the generic industry.

Q. Do you know whether Impax made process validation batches of oxymorphone?

A. Yes.

Q. And do you know what happened to those process validation batches?

A. I believe they were ultimately destroyed.

Q. When Mr. Meier was asking you questions about product that was made and bright-stocked, was that a reference to process validation batches?

A. It included process validation batches and some manufacturing that was done over and above that. Yes.

Q. Was it unusual for you to have to write off process validation batches such as you did with Opana?

A. No.

Q. How frequently did Impax have to write off unused product or material?

A. We evaluated the reserves for the carrying value of our inventory every quarter, and every quarter we might have to adjust those reserves, write off more product or less product, depending on the circumstances. It was frequently evaluated, though.

Q. You indicated, in response to one of Mr. Meier's questions, you're familiar with an at-risk launch; is that right?

A. I'm sorry?

Q. You're familiar with the concept of an at-risk launch?

A. Yes.

Q. In your time at Impax, did Impax ever launch a product at risk?

A. I recall one.

Q. What product do you recall Impax launching at risk?

A. A generic for OxyContin.

Q. And when did Impax launch a generic for OxyContin at risk?

A. Sometime in 2005 I recall.

Q. And what was -- if it was at risk, does that mean there was litigation ongoing at that point in time?

A. Yes.

Q. Do you recall what the status of that litigation was?

A. I don't recall. Sorry.

Q. Do you recall whether there had been a favorable district court decision for the generics on that product?

A. Yes. Yes, there was -- there had been.

Q. And under what circumstances did Impax launch OxyContin at risk in 2005?

A. We made a very controlled launch of the product, capping the risk of the at-risk launch at 25 million in sales.

Q. How would Impax cap the launch at 25 million in sales?

A. We would only sell -- we would sell $25 million worth of product and then withdraw from the market.

Q. And why would Impax cap its risk in this case at $25 million?

A. Well, because even in the case where we have a favorable ruling from the lower court, there's still risk of the patent litigation, and Impax, being a small company, could not risk -- could not bet the company on any one product and therefore had to cap its risk, you know, given -- tailored to the specific market characteristics.

Q. Do you know whether when you launched OxyContin at risk whether any other generics were on the market at that time?

A. I believe not.

Q. Did Impax have a process for deciding whether to launch a product at risk?

A. Yes.

Q. Can you walk us stepwise through that process?

A. It was probably the most significant effort the company made in making this evaluation. It would begin with an evaluation by the new products committee, who would evaluate the science and the legal from a general perspective as well as the market opportunity, and then, with their recommendation, further diligence would be done by the R&D team into specifics and the legal team into specifics of the litigation.

From there, the division heads of those operations would come to me. We would for -- we would formulate a risk analysis profile for a launch. We would take that to the executive committee. And everywhere along the way, if there were questions, we would go back and respond to those questions.

We would ultimately present it to the executive committee for their approval. If we got their approval, we would take it on to the board of

directors because every at-risk launch is a board-level decision.

Q. If the executive committee was not in favor of recommending a launch at risk, what would happen?

A. Work would stop and we would discontinue the effort.

Q. And if the executive committee were to recommend a launch at risk, did I hear you correctly it would go to the board?

A. We would. That was always a board-level decision.

Q. And how would the executive committee share its recommendation to launch at risk with the board? What format --

A. It would be a very formal presentation of the background, the basis for the conclusion by the executive committee to move forward, and then a draft of a resolution seeking their vote and -- on the matter.

Q. Who would participate in that presentation to the board in the 2010 time frame?

A. It would be legal, the generics president, myself, manufacturing. It would be a team.

Q. You mentioned a limit on the OxyContin risk.

Would as part of its recommendation to the

board the executive committee propose limits on a risk at launch?

A. I'm sorry. I couldn't hear.

Q. You mentioned that when you -- when Impax launched oxy- -- the one time you remember a launch at risk of OxyContin that it was subject to a $25 million limit.

A. Right.

Q. Would management make a recommendation to the board that when it launched at risk it launch subject to certain limits?

A. Yes.

Q. And tell me how management would formulate that.

A. Through a deliberation among the executive committee, we would decide how much of the capital of the company we felt we could put at risk in this type of a launch scenario, and based on that, we would do a calculation of how much market penetration we could absorb.

Q. And would that limit be part of the recommendation that the executive committee would make to the board?

A. Yes.

MR. MEIER: Your Honor, I object. I mean,

Mr. Hassi is starting to lead him into discussions that we were precluded from asking about during depositions and in discovery about the considerations that this company took into account when it would decide whether to do an at-risk launch.

In fact, they kept claiming privilege for that. And I don't see why it's appropriate at this time for Mr. Koch to start explaining how the company went about making those decisions when it's clear that there was legal advice involved in that decision.

MR. HASSI: Your Honor, I'll make three points.

First, I've not asked for and I'm not asking for Mr. Koch to divulge any legal advice.

Second, if complaint counsel can point to one question that was asked of Mr. Koch that I refused to let him answer during deposition, they should do so now, because it's not there. We didn't prevent him from testifying on this, and we shouldn't be barred from that.

Furthermore, with respect to this process of the decision to launch at risk, they asked and we answered a very detailed interrogatory. It's interrogatory number 9. It's in evidence as part of CX 2927. It goes on for pages explaining this idea of

the process of a launch at risk, so we shouldn't be barred from addressing these subjects now.

MR. MEIER: Your Honor, I will agree that I didn't press that issue during the deposition with Mr. Koch, but that's because we had been foreclosed time and time again in the depositions of other witnesses about this issue.

If Your Honor will recall, when I put up that CX 2663 where Mr. Mengler spoke to the board and I told you that there was pieces of it that had been blocked out by -- because of in camera, there was also a piece where Meg Snowden, the general counsel or person in the general counsel's office that you're going to hear from later, that that was redacted for privilege.

After Mr. Mengler made the statement about this would be a great opportunity to launch at risk, they redacted Meg Snowden's comments to the board about that very thing. I think it's inappropriate.

Maybe we haven't quite crossed that line yet, but I think we're getting very, very close to that line, Your Honor.

It's inappropriate to have this businessperson now come up here and try to explain how the company went about thinking about at-risk launch when everybody in this room knows that lawyers were involved in those

decisions and they took legal counsel into account when they made those decisions.

MR. HASSI: Your Honor, this is all based on testimony that Mr. Koch has already given in his deposition.

JUDGE CHAPPELL: All right. Here's my ruling.

Respondent is not allowed to ask questions that were objected to in discovery.

MR. HASSI: Understood, Your Honor.

JUDGE CHAPPELL: Otherwise, the objection is overruled.

MR. HASSI: Thank you, Your Honor.

JUDGE CHAPPELL: If you didn't allow them to answer in discovery, they're not going to be able to answer in court.

MR. HASSI: Understood, Your Honor. And I'm not asking.

And I would just add, with respect to the redaction on --

JUDGE CHAPPELL: And not to put too fine a point on it, but if there is some legal privilege you claimed that you're now waiving, that's not allowed either. If it's privileged, it's privileged.

MR. HASSI: Your Honor, we have no intent to waive the privilege, we're not waiving the privilege,

and I'm not asking questions that were objected to.

JUDGE CHAPPELL: But again I'll say what I said earlier regarding a trial brief that came flying in recently, that facts are facts, and every fact doesn't get to be tested by someone's expert on analysis, on fundamentals and other things. Facts are facts. Witnesses can testify to facts, unless a question was objected to and the question wasn't answered.

MR. HASSI: Thank you, Your Honor.

And I just wanted to add --

JUDGE CHAPPELL: And if you can show me, Complaint Counsel, a question that was asked, what did you do when the light turned green, objection, privilege, that same question won't be allowed. That answer won't be allowed.

MR. MEIER: I understand that, Your Honor. But I'm also suggesting to the court that when it was objected to with other witnesses, it's not appropriate now to bring it in through this witness just -- I didn't ask him -- I stayed away --

JUDGE CHAPPELL: And again, are you telling me it's the same question?

MR. MEIER: No. We'll have to look for the exact same questions, but as I said, Your Honor, the document that I put up earlier shows that they did

exactly that. They redacted out the legal advice that Ms. Snowden gave immediately after Chris Mengler said this is a great opportunity for an at-risk launch. The very next sentence, they blacked it out and they redacted it for privilege.

And I don't think it's appropriate now to have Mr. Koch come in here and sponsor testimony about how they went about thinking about the risk of an at-risk launch when we were prevented from exploring that in discovery.

JUDGE CHAPPELL: The facts regarding when the company has done at-risk launches, when they haven't done at-risk launches, those are facts, and if those facts were disclosed, those are coming in.

MR. MEIER: A hundred percent, Your Honor, a hundred percent. That's different than this discussion that's been going into what the board and what the executive committee was presenting to the board about their assessment of the risk. That's quite a different question than how many times have you launched at risk, what kinds of factors do you generally consider when you launch at risk.

This is very specific advice that was being given to the board that we've been prevented from seeing.

JUDGE CHAPPELL: Did you tell me that these are questions you asked during a deposition?

MR. HASSI: Your Honor, I didn't ask them. Mr. Meier asked them. And I'll read from his deposition.

JUDGE CHAPPELL: I don't need to hear that. If you're telling me this is information that's already been revealed, go ahead. The objection is overruled.

MR. HASSI: It is, Your Honor.

And I just want to add, with respect to the redaction on 2663, obviously that's just speculation in terms of what's under that, what's under that redaction. I don't know. Mr. Meier doesn't know. He's just guessing.

The paragraph goes on to speak about something completely different, and so we don't know -- we don't know what's under there, we're not offering it, and I'm not asking questions about it.

MR. MEIER: Your Honor, I just -- may I respond to that?

JUDGE CHAPPELL: Go ahead.

MR. MEIER: The sentence says, "He expressed the view that oxymorphone was a good candidate for an at-risk launch, and Ms. Snowden discussed," and then everything else is redacted.

MR. HASSI: Well, no. It goes on to say, "Mr. Mengler's presentation also" -- it goes on to talk about something completely different.

MR. MEIER: That's correct. But the part that's been redacted is a comma from Mr. Mengler's statement about it being a good candidate for an at-risk launch --

JUDGE CHAPPELL: It sounded to me what was redacted was what Ms. Snowden said.

MR. MEIER: Precisely.

JUDGE CHAPPELL: Well, if that was redacted, they're not going to be able to ask Ms. Snowden that.

MR. MEIER: Precisely my point, Your Honor. Thank you.

MR. HASSI: And we don't intend to, Your Honor.

BY MR. HASSI:

Q. If a recommendation to launch at risk were presented to the board, what would happen next process-wise?

A. If a recommendation by the executive committee was made to the board, the board would often drill us on whatever interests or questions they had. We would frequently ask that the board appoint a special committee so that we could have time to collect the

answers to their questions and report back to the board those answers and use the special committee as a tool during the evaluation by the board.

Once everybody was satisfied, we would go to the board for a full vote on the draft resolution to go for an at-risk launch.

Q. And if the board authorized an at-risk launch, what form would that authorization take?

A. It would be recorded in the minute book.

Q. Would there be a resolution?

A. Yes. There would be a resolution and a vote, and both would be recorded in the minute book.

Q. If the board authorized the company to launch at risk, would the company necessarily launch at risk?

A. You know, market conditions change on a daily basis, and it's hard to say that by the time we were able to launch at risk even with board approval conditions still warranted it, so nothing about an at-risk launch is set in stone. It's very fluid because of the dynamics of the market and the litigation.

Q. We've been talking about an at-risk launch.

What does the risk in an at-risk launch refer to generally?

A. It's a very serious risk under the patent

litigation that the brand, the patent holder, holds over the generic's head in the form of damages it calculated as lost profits from the sale of their product, which could be greater than the total amount of the selling price of the generic product.

So it's a very significant risk factor for a generic to consider.

Q. What effect might such damages have on a company the size of Impax?

A. Uncontrolled, it could be a bet-the-company, it could take the solvency of the company entirely.

Q. In the time that you were CFO at Impax, how would you describe Impax' attitude towards risk?

A. We were conservative.

Q. Why were you conservative?

A. Well, we had a very rapidly growing business. We didn't want to risk that business on any one particular situation, product, lawsuit, and we were very careful.

Q. I want to talk now about your involvement with the board.

I gather you attended board meetings?

A. Routinely.

Q. And made presentations?

A. I did.

Q. And you were the secretary for the board for a period of time?

A. I was.

Q. And so you took the minutes?

A. I did.

Q. And tell us what was your process for preparing board meeting minutes.

A. I would take notes during the meeting with a view to make the minutes, so the reason I distinguish them, they're not notes of the meeting so much as they're notes of the actions and activities at the meeting.

And once I -- the meeting was over, I would draft a set of those minutes and I would compare my recollection with Larry's recollection. He'd review a draft of the minutes. When we were together, we would send it off to the board in preparation for the next meeting, and they would review and send me any inputs, and then we would submit it to the board for approval.

Q. You mentioned actions and activities.

Can you describe what kinds of information in terms of actions and activities you would include in your meeting minutes?

A. We would -- each of the division heads, business unit leaders, would make presentations on a

review of the recent results and a forward-looking outlook for the next period of time.

I would make a presentation on the financial performance against the company's budget and any updates to that budget we were seeking as a result of changes in condition.

Q. If at a board meeting management made a recommendation to the board to authorize an at-risk launch, is that the kind of thing that you would as the secretary record in the minutes?

A. Very carefully. Yes.

Q. What about if there were a discussion about a launch at risk at the board level? Would you include that in the minutes as the secretary?

A. Yes.

Q. If there were a board vote on a launch at risk, what would you as the secretary do?

A. That would be carried in the minutes.

Q. If a resolution were voted on by the board, would that resolution appear in the minutes?

A. Yes.

Q. And if the board authorized a launch at risk, how would that be reflected in the minutes?

A. The resolution authorizing management would be recorded in the minutes and the vote on that resolution

also recorded.

Q. You were asked some questions -- do you recall that Mr. Mengler made a presentation at the May 2010 board meeting?

A. I do.

Q. Okay. If we can bring up CX 2662. And I'll note for the record this document is in evidence and is not in camera.

And looking at the cover e-mail of 2662, do you recognize this?

A. Yes.

Q. Okay. Who was Mr. Mengler at the time?

A. President of the generics division.

Q. And he's sending this e-mail to a Laura Bisbing.

Can you tell us who Ms. Bisbing was?

A. Laura was my secretary. She was responsible for sending board materials out in advance of the meeting.

Q. Let's take a look at the attachment that Mr. Mengler sent.

Do you recognize this document?

A. Yes.

Q. And what is it?

A. Impax' board of directors meeting presentation

by Chris Mengler, president of global pharmaceuticals or generics division.

Q. If you would flip to page -4, please, Robert.

What was Mr. Mengler's presentation to the board about? What was the purpose of his presentation?

A. As I said, each of the division heads would give a history, a presentation on the recent past and an outlook ahead. This is his presentation on sales and marketing for the division.

Q. Let's turn to page -13 if we could.

What is this? What is this page about?

A. I'm sorry?

Q. What is -- what did Mr. Mengler indicate to the board about oxymorphone at this meeting?

A. He's updating them on the status of the product.

Q. Okay. There's a note toward the bottom. It says under Remaining Issues "Validation Complete."

What does that mean?

A. Well, there are two different bullet points. "Remaining Issues," I don't know what he meant. But "Validation Complete" means we've completed the process validation.

Q. And the next bullet says "Several additional

batches needed for full launch quantities."

What does that mean?

MR. MEIER: Your Honor, I'm going to object.

If they want to ask Mr. Mengler what Mr. Mengler meant in his presentation to the board, that seems appropriate to me, but to come in and bring Mr. Koch in to talk about what Mr. Mengler was saying and what Mr. Mengler was presenting, I think that's inappropriate. And Mr. Mengler will be here I believe tomorrow.

MR. HASSI: Your Honor, Mr. Koch was asked and I want to connect this to the board minutes and a reference in the board minutes about Mr. Mengler's presentation. This is the presentation that Mr. Koch wrote about in those minutes, and we think we're entitled to ask him a few questions related to this.

JUDGE CHAPPELL: Well, the objection is sustained as far as your asking this witness what another witness intended or meant. If you're asking what he heard or what he understood, I'll allow that.

MR. HASSI: Thank you, Your Honor.

BY MR. HASSI:

Q. What did you understand Mr. Mengler to be conveying to the board about additional batches needed for full launch quantities?

A. That the process validation batches weren't sufficient to meet the market demand for a full launch.

Q. Let's go back a page to page 12, please.

What did you understand Mr. Mengler to be conveying to the board with this page of the presentation?

A. He's updating the board on the assumptions used in the generic division forecast, budget.

Q. And at the bottom of the page, there's a notation related to oxymorphone.

What did you understand Mr. Mengler to be telling the board regarding oxymorphone?

A. That in this forecast he was anticipating an at-risk launch.

Q. And do you have an understanding as to why in his forecast he was anticipating an at-risk launch?

A. I think he was trying to give the board his best estimates of what market opportunities lie ahead and that at the time it was uncertain what we would be doing with oxymorphone and he made -- he wanted to include a -- an idea of what an oxymorphone launch would mean.

MR. MEIER: Your Honor, again, I'm going to raise my objection again.

JUDGE CHAPPELL: That objection is sustained. That answer will not be considered.

MR. HASSI: Understood, Your Honor.

MR. MEIER: Your Honor, if I could also be -- I appreciate your ruling, but --

JUDGE CHAPPELL: Well, he was violating what I said earlier in that he was testifying to his interpretation of what another man meant. That's why I'm sustaining it.

MR. MEIER: Thank you very much.

BY MR. HASSI:

Q. Let's go to 2663, which are the board minutes.

And if we could blow up the second paragraph.

Mr. Koch, do I understand you were the author of these minutes?

A. Correct. Yes.

Q. And as the author of these minutes, what did you intend when you wrote, "He expressed the view that oxymorphone was a good candidate for an at-risk launch"?

A. And the simplest way I can describe what I meant is he thought it was a great market opportunity. And that's what I intended to communicate in those words.

Q. What do you mean by "a great market

opportunity"?

A. Oxymorphone was a very rapidly growing product, and we had a tentative approval or we had an application that was going to be successful, and it presented a great opportunity.

Q. Looking at these minutes, was there a recommendation from the executive committee to launch oxymorphone at risk made at this board meeting?

A. There's no discussion of an at-risk launch by any -- I regret that I used the words "at-risk launch." It's confusing the readers. There was no discussion of an at-risk launch.

MR. MEIER: Your Honor, again, this is parts redacted. We don't know what it says. I'm not really sure how Mr. Koch can confidently testify based on this one paragraph when there's all these other redactions on this page.

MR. HASSI: Well, we anticipated Mr. Meier's objection. If Mr. Koch would like to see the unredacted portions that Mr. Meier redacted and appropriately because it's in camera, we've given him an in camera version in his binder that he can look at, and we don't have to project it up on the screen, and he can read the parts that complaint counsel redacted if he needs to assure himself --

JUDGE CHAPPELL: Was he at the meeting?

MR. HASSI: He was, Your Honor. He took the minutes.

JUDGE CHAPPELL: The way I heard the answer, he said that there was no discussion at the meeting. He can certainly tell us that if he recalls it.

MR. MEIER: If he recalls that from the meeting but not from these minutes and this is the --

JUDGE CHAPPELL: Well, I thought it was redacted.

MR. MEIER: But this shows -- the first redaction there where it says "and Ms. Snowden discussed," they redacted that for privilege. That's not redacted for the in camera purpose. That was redacted for privilege.

That's exactly what I was talking about earlier, is that as soon as Mr. Mengler finishes making this statement -- and by the way, it's not a new sentence, it's a continuation of Mr. Mengler's expression -- you have the lawyer Ms. Snowden discussing, and then that's been redacted.

That's not the in camera redaction. That was redacted for privilege, and so we don't know what it says under there. We've never seen what it says under there. We were denied from seeing what's under there.

And I don't know how Mr. Koch can represent from these minutes at -- that he doesn't remember that discussion.

JUDGE CHAPPELL: Is he testifying from memory or from minutes? Or from the document?

MR. HASSI: I would have to ask him, but my question wasn't what Ms. Snowden discussed. My question was what the board discussed.

This sentence -- and it's just one sentence. I mean, Mr. Meier would like to blow this up and make you think that this was a huge discussion, there's a resolution hidden under there, and all this other stuff. It's one sentence about what Ms. Snowden discussed.

I didn't ask the witness that question. I asked him whether the board discussed an at-risk launch, and I'm asking the author of these minutes.

JUDGE CHAPPELL: Based on the question and the answer that I see in the record, he's telling us what occurred at the meeting. He was at the meeting.

The objection is overruled.

You can inquire into that if you'd like when you question the witness.

BY MR. HASSI:

Q. Sir, if the board had discussed an at-risk

launch, would you have reflected -- of oxymorphone at this meeting, would you have reflected that in the minutes?

A. Absolutely.

An at-risk launch is something that, you know, is a very serious undertaking by the company, and if there was a discussion about it by the directors, I would have noted that.

Q. If a resolution had been put before the board with regard to an at-risk launch of oxymorphone at this meeting, would it be reflected in the minutes?

A. Absolutely.

Q. Do you see one reflected in the minutes? And if you need to look at the in camera version, it's in your binder.

A. Yeah, I don't need -- there was no resolution. I would have written the resolution, and there was no resolution for oxymorphone.

Q. If the board was asked to vote about an at-risk launch, would you have noted that in the minutes?

A. Absolutely.

Q. Is there any -- was there any vote taken at that meeting with regard to an at-risk launch of oxymorphone?

A. There was not.

Q. In your time at Impax, was the board of directors of Impax ever asked to vote on an at-risk launch of oxymorphone?

A. No.

Q. Did management ever make a recommendation to the board of directors for an at-risk launch for oxymorphone?

A. We did not.

Q. In your testimony, Mr. Meier asked you whether an at-risk launch was being considered by the management. Do you recall that?

A. I do.

Q. Can you describe what sort of consideration generally management was giving to an at-risk launch at this point in time?

A. We were looking at possible scenarios and at different points in time -- our calendar -- our fiscal year is a calendar year, so in the beginning of the year, we'll make a budget and we'll describe the assumptions included in those budgets. And frequently, almost on a monthly basis, circumstances will change, requiring an update to those budgets.

So at different points in time and I remember in early 2010 we were -- we budgeted, we forecasted, we

modeled an at-risk launch just to scope out the magnitude of what that might look like should we make a decision to go down that road.

At Impax, we were very good at modeling and we were very good at looking at different various scenarios, and we tried very hard to be able to describe the possible outcomes under any number of different assumptions.

So it -- we frequently made forecasts and budgets and projections on differing assumptions and scenarios that changed throughout time.

Q. As the CFO of Impax, why would management -- as a member of the management team, why would management have a presentation made to the board of directors including the assumption of an at-risk launch related to oxymorphone?

A. Chris was a -- is an expert in the generic marketplace, and everyone looked to him for his assessment of product opportunities, product potential. He was a very valuable member of the team.

Here, he's saying -- what I intended to write here is here he's saying, I've made an evaluation of the oxymorphone market, and it's a very attractive, exciting market. The product is growing very rapidly and looks like it will do very well.

So it's his analysis. He's communicating his analysis of the market opportunity.

Q. Why would you share that information with the board of directors if management is not prepared at this time to recommend a launch at risk?

A. Because we were unsure of what direction we were to ultimately take and we didn't want the case -- we didn't want to come back to the board seeking an at-risk launch with them never having heard of it before, so almost at the earliest time we can think of we would scope out for them the market profile. And this -- and that was what Chris was doing here.

Q. I want to jump now to the negotiation of the settlement and the negotiation of the separate development and co-promotion agreement.

You were involved in those negotiations; right?

JUDGE CHAPPELL: It's past 5:30. How much more time do you need with this witness?

MR. HASSI: I would think fifteen minutes to a half an hour, Your Honor.

JUDGE CHAPPELL: Is there going to be redirect?

MR. MEIER: I'm certainly considering it, Your Honor. And I think I would probably need about

ten, ten to fifteen minutes.

JUDGE CHAPPELL: I don't see us finishing before 6:00, so we're going to call it a day.

Is this a good breaking point?

MR. HASSI: It is a good breaking point, yes, Your Honor.

MR. LOUGHLIN: Your Honor, can I ask a question?

Since the witness is on the stand, can I assume that counsel is prohibited from discussing any testimony with the witness until the case is over?

JUDGE CHAPPELL: You two work something out. I don't want to hear things like this at the end of the day. Talk among yourselves, come up with an agreement, and if you can't settle it, let me know in the morning.

Thank you, sir. You can take off. But be back in the morning.

THE WITNESS: Thank you, Your Honor. I will.

JUDGE CHAPPELL: Anything further?

MR. HASSI: Nothing further from respondents, Your Honor.

JUDGE CHAPPELL: Okay. Until tomorrow morning at 9:45 we're in recess.

(Whereupon, the foregoing hearing was adjourned at 5:32 a.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