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1	FEDERAL TRADE COMMISSION				
2	I N D E X				
3	IN THE MATTER OF IMPAX LABORATORIES, INC.				
4	TRIAL VOLUME 1				
5	PUBLIC RECORD				
6	OCTOBER 24, 2017				
7					
8	WITNESS:	DIRECT	CROSS	REDIRECT	RECROSS VOIR
9	KOCH	211	267		
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12	EXHIBITS	FOR ID	IN EVID	IN CAMERA	STRICKEN/REJECTED
13	CX				
14	(none)				
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16	RX				
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1 correct?

2 MR. LOUGHLIN: Yes, Your Honor.

3 JUDGE CHAPPELL: The patent holder is Endo.

4 MR. LOUGHLIN: Yes.

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

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

9 (Audio difficulty.)

10 JUDGE CHAPPELL: You were telling me about
11 Endo.

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

15 JUDGE CHAPPELL: A consent decree.

16 MR. LOUGHLIN: Yes, Your Honor.

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

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

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

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

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

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

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

12 JUDGE CHAPPELL: Is anything in writing?

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

15 JUDGE CHAPPELL: Iae61BDC 4.2 tlfxyat agree L0hAs part of t

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1 JUDGE CHAPPELL: Thank you.

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

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

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

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

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

1 anticompetitive effects are outweighed by
2 procompetitive effects.

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

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

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

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

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

21 MR. LOUGHLIN: Okay.

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

25 MR. LOUGHLIN: I will work on that,

1 Your Honor.

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

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

8 MR. LOUGHLIN: Your Honor, may I approach?

9 JUDGE CHAPPELL: Yes.

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

12 Go ahead.

13 MR. LOUGHLIN: Thank you, Your Honor.

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

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

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

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

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

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

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

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

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

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1 rule of reason. Do I have that right?

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

4 MR. LOUGHLIN: Yes, Your Honor.

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

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

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

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

19 JUDGE CHAPPELL: We agree there.

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

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

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1 It had validated its commercial manufacturing
2 process.

3 It had produced pills for a commercial launch.

4 It had prepared the packaging for a launch.

5 It had created sales forecasts.

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

8 And it had spent millions of dollars on these
9 preparations.

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

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

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

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

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

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

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

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

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

18 But that marketing exclusivity only prevents
19 the FDA from approving other generics during the
20 180-day exclusivity period. It doesn't stop a brand
21 from launching its own generic during that period, and
22 that is known as an authorized generic.

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

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

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

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

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

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

19 JUDGE CHAPPELL: Yes.

20 MR. LOUGHLIN: It's the pharmacist.

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

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

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

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

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

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

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

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

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1 \$28.5 million in profit in the first six months on the
2 market, in other words, during the 180-day exclusivity
3 period.

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

7 And the reason for those different forecasts
8 are two.

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

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

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

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

1 said, "I'd love that."

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

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

9 It was important because Endo understood that
10 getting tentative FDA approval meant that Impax likely
11 would get final approval in June of 2010 when the
12 30-month stay related to the patent litigation
13 expired.

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

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

18 Now, this is from 2009 when Endo is projecting
19 generic entry in July of 2011. And what you'll see is
20 that sales go from \$205 million in 2010 down to
21 \$32 million in 2011. That's a decline of 84 percent.

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

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

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

8 JUDGE CHAPPELL: You mean an at-risk launch.

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

11 And in May --

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

16 MR. LOUGHLIN: Yes. So --

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

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

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

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

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

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

9 Under the Hatch-Waxman Act, the FDA has a --
10 the Hatch-Waxman Act provides a 30-month stay under
11 which the FDA cannot approve the generic product. And
12 you're right, under this case, it did take about
13 30 months for the case to get from filing to trial,
14 just about 30 months.

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

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

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

1 Opana ER, the product at issue in this case.

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

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

6 At this time Endo was in the process of trying
7 to extend the life of Opana ER by reformulating it. It
8 was trying to create what it claimed was a
9 tamper-resistant formula. And in May of 2010 it was
10 close to filing an NDA with the FDA for a
11 tamper-resistant formulation and expected to launch in
12 2011.

13 JUDGE CHAPPELL: Let me ask you a question.

14 You said that Endo had projected to lose
15 \$20 million a month in sales if a generic launched.

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

20 JUDGE CHAPPELL: Without the competition.

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

25 JUDGE CHAPPELL: All right. Regarding that,

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

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

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

15 MR. LOUGHLIN: Yes, Your Honor.

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

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

24 JUDGE CHAPPELL: You mean for the branded
25 drug.

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

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

6 JUDGE CHAPPELL: Wait a second.

7 That wasn't what I asked you.

8 MR. LOUGHLIN: Okay.

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

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

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

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

24 JUDGE CHAPPELL: And cooperation of
25 physicians.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 And what that shows is that Endo understood

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

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

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

14 JUDGE CHAPPELL: This is a projection.

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

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

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

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

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

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

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

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

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

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

25 JUDGE CHAPPELL: But if you were entering into

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

3 MR. LOUGHLIN: Absolutely.

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

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

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

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

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

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

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

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

9 JUDGE CHAPPELL: But he was told that.

10 MR. LOUGHLIN: He was told it.

11 JUDGE CHAPPELL: No dispute there?

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

14 JUDGE CHAPPELL: All right.

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

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

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

21 MR. LOUGHLIN: Yes.

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

25 MR. LOUGHLIN: I agree.

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

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

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

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

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

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

1 June 3, 2010, reporting on the current status of the
2 negotiations with Endo. And the current proposal was
3 that they enter on January 1, 2013, and they had a
4 provision that if the units, meaning the units of
5 Opana ER, Endo's Opana ER, declined by more than
6 50 percent at launch that a make-whole provision would
7 kick in to protect Impax.

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

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

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

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

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

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

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

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1 Endo projected that every month that a generic stayed

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1 of the agreement.

2 MR. LOUGHLIN: Correct.

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

5 MR. LOUGHLIN: That's correct. Under those
6 two provisions, the Endo credit was not paid until
7 90 days after January 1, 2013, after Endo -- after
8 Impax entered the settlement. That's correct.

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

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

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

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

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

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

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

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

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

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

1 in the form of Endo credit.

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

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

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

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

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

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

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

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

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

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

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

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

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1 And what Impax was projecting in
2 May of 2010 was that if it launched generic Opana ER
3 in June of 2010, it would earn a total of about
4 \$53 million in net sales between 2010 and 2012. It
5 earned twice that by agreeing not to sell during that
6 time period.

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

10 And Impax' current CFO testified that the Endo
11 credit increased Impax' profitability by about
12 50 percent in 2013.

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

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

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

25 JUDGE CHAPPELL: Isn't that why it was only

1 \$10 million?

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

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

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

11 The parties had negotiated \$10 million -- a
12 \$10 million upfront payment on that Phase III product
13 with \$5 million in milestones.

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

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

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

1 basically an agreement where Impax was going to --
2 Endo was going to pay the same \$10 million upfront
3 payment plus additional milestones, and yet at this
4 point Impax hadn't provided any information, any
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1 correct? If you meet these conditions, you get to
2 Phase II, we pay the \$4 million; right?

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

5 MR. LOUGHLIN: No.

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

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

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

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

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

19 MR. LOUGHLIN: You're right.

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

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

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

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

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

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

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

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

22 MR. LOUGHLIN: No.

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

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

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

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

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

17 Is it the government's position that
18 \$10 million is both large and unjustified?

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

4 Go ahead.

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

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

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

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

1 Impax.

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

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

10 And you're going to hear that Impax gave up its

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

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

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

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

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

16 MR. LOUGHLIN: Okay.

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

20 MR. LOUGHLIN: Okay.

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

23 MR. LOUGHLIN: Okay.

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

1 justifications for the payment.

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

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

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

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

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

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

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

1 In other words, Your Honor, as I mentioned,
2 the harm is to the competitive process. We don't know
3 the outcome of that process in any particular case.
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1 generic can come into the market without risk of
2 infringement. It just can't do that with a reverse
3 payment -- or it can't do that without a large reverse
4 payment. That is what Actavis says.

5 JUDGE CHAPPELL: You mean large and
6 unjustified.

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

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

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

19 MR. LOUGHLIN: Understood, Your Honor.

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

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

25 But what the Supreme Court is saying in this

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

6 And other courts have held the same.

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

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

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

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

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

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

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

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

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

25 The only product that constrained the market

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 As I mentioned, the payment had two

1 components.

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

5 The second is the side deal payment, the
6 \$10 million upfront payment as part of the side deal.

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

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

16 MR. LOUGHLIN: One of those --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2 But based on -- but based on --

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

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

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

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

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

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

3 But because respondent has criticized us that
4 there was a possibility of zero, our expert looked at
5 that. And what he determined was that based on the
6 information that Impax and Endo knew at the time, if
7 you just look at the sales that Opana was earning in
8 June of 2010 and compare that to -- take that as the
9 peak sale, then the most likely scenario was about
10 \$62 million and -- under the Endo credit, assuming the
11 Endo credit kicked in.

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

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

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

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Now, as I mentioned, you're go

respondent's expert Dr. Sumanth Addank

Dr. Addanki opines that the Endo credi

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potential no-AG provision.

Instead, he says that there is a theo

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

7 What it says:

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

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

12 "QUESTION: As soon as you could?

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

17 That smooth transition --

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

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

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

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

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

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

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

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

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

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

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

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

6 MR. LOUGHLIN: Exactly. They did. They

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1 issue.

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

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

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

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

15 JUDGE CHAPPELL: Thank you.

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

17 JUDGE CHAPPELL: Thank you.

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

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

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

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

7 Now, respondent may try to justify the
8 \$10 million side deal payment as being in exchange for
9 the development and co-promotion agreement. This is
10 the \$10 million that Endo paid upon signing for
11 co-promote rights to a Parkinson's disease treatment
12 that Impax had in preclinical development stage.

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

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

25 And he will testify that these facts, the

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

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

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

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

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

25 Complaint counsel's expert Professor Noll will

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

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

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

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

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

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

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

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

7 JUDGE CHAPPELL: Hold it right there.

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

13 MR. LOUGHLIN: Your Honor, to --

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

16 MR. LOUGHLIN: No, Your Honor. But the
17 difference in what Actavis is saying is that there's a
18 difference besaying iBent wm2

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

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

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

18 JUDGE CHAPPELL: I understand your position.

19 MR. LOUGHLIN: Yep.

20 JUDGE CHAPPELL: What's next?

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

23 Now, when Endo sued Impax for patent
24 infringement in 2007, as I mentioned, it got a
25 30-month stay before the FDA could approve Impax'

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

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

6 Impax got \$112 million, and Endo avoided the
7 risk of generic entry on the most popular dosages of
8 Opana ER for 30 months, from June of 2010 to January 1,
9 2013.

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

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

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

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

25 It is important because, as I mentioned, Impax

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

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

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

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

21 Thank you.

22 JUDGE CHAPPELL: Are you ready?

23 MR. HASSI: I am, Your Honor.

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

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

4 MR. LOUGHLIN: Thank you, Your Honor.

5 (Pause in the proceedings.)

6 JUDGE CHAPPELL: Go ahead.

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

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

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

13 All right. Go ahead.

14 MR. HASSI: Thank you, Your Honor.

15 Good afternoon.

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

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

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

25 I may from time to time switch between

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

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

8 MR. HASSI: Yes, Your Honor.

9 JUDGE CHAPPELL: Right, Mr. Loughlin?

10 MR. LOUGHLIN: Yes, Your Honor.

11 JUDGE CHAPPELL: Thank you.

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

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

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

23 MR. HASSI: Your Honor, Actavis qualified for
24 180 days on two strengths, the 7.5 and the
25 15 milligram. They're sometimes referred to as the

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

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

6 JUDGE CHAPPELL: Did Actavis market those two
7 strengths?

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

10 JUDGE CHAPPELL: Did Actavis have a deal with
11 Endo?

12 MR. HASSI: Actavis did not have a deal with
13 Endo. Actavis marketed those strengths after -- so
14 Impax came on the market in 2013, got its 180 days of
15 exclusivity. After that point, Actavis came to market
16 with those -- with those strengths that had been on
17 since 2011 in the two strengths that it was first to
18 file on, but it came on the five additional strengths
19 in the summer of 2013 and then was kicked off the
20 market by the -- a court in the Southern District of
21 New York and removed the product from the market in
22 2016 and is not on the market today.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 JUDGE CHAPPELL: When you say none of them are

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 for nothing. That drug is --

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

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

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

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

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

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

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

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

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

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

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1 infringer?

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

3 JUDGE CHAPPELL: Why is that?

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

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

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

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

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

18 MR. HASSI: Understood, Your Honor.

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

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

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

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

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

16 JUDGE CHAPPELL: But theoretically in that
17 30-month period.

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

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

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

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

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

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

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

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

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

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

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

1 settlement and --

2 JUDGE CHAPPELL: Snowden?

3 MR. HASSI: Snowden, yes, Your Honor.

4 JUDGE CHAPPELL: No relation?

5 MR. HASSI: I'm sorry?

6 JUDGE CHAPPELL: No relation?

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

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

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

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

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

4 JUDGE CHAPPELL: Hold on a second.

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

7 THE REPORTER: I sure would.

8 MR. HASSI: I will try, Your Honor.

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

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

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

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

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

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

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

8 JUDGE CHAPPELL: That's a direct request.

9 MR. HASSI: Yes, Your Honor.

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

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

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

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

1 competition for prescribers, the doctors that prescribe
2 this drug.

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

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

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

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

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

19 In other words, OxyContin, for example,
20 Purdue Pharma's, that's the blockbuster in this. It's
21 a multibillion-dollar market. Purdue Pharma's

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

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

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

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

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

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

25 MR. HASSI: You know, the Supreme Court uses

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

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

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

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

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

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1 was always pushing.

2 JUDGE CHAPPELL: The patent expiration date
3 would be when?

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

7 JUDGE CHAPPELL: Same year.

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

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

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

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

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

1 in that case, too.

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

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

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

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

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

22 MR. HASSI: Several reasons, Your Honor.

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

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

6 JUDGE CHAPPELL: All right.

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

13 You're not going to hear from anybody from
14 oxbte.

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

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

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

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

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

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

25 JUDGE CHAPPELL: I read something in probably

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

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

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

7 JUDGE CHAPPELL: Because we saw a chart earlier
8 today.

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

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

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

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

1 Its plan was to --

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

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

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

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

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

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

24 And if we could --

25 JUDGE CHAPPELL: Whose idea was the prong of

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

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

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

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

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

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

13 JUDGE CHAPPELL: Okay. The monitor is
14 working.

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

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

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

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

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

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

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

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

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

12 So this is --

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

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

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

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

20 JUDGE CHAPPELL: Let's go ahead and take our
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1 We're going to take our lunch recess. We'll
2 reconvene at 1:45.

3 We're in recess.

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

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1 August 10, 2012.

2 MR. HASSI: Yes, Your Honor.

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1 talking about Endo, Endo's intent.

2 MR. HASSI: Yes, Your Honor.

3 JUDGE CHAPPELL: Your take is that Endo went to
4 the FDA in an attempt to purposely in effect
5 cannibalize to end the ER so that everyone has to have
6 the crushproof.

7 MR. HASSI: Yes, Your Honor.

8 JUDGE CHAPPELL: Opioid.

9 MR. HASSI: Yes, Your Honor. They wanted --
10 they wanted -- they wanted to be selling the only
11 version of Opana and they wanted it to be the
12 crushproof. And they didn't want Impax to come on with
13 a generic, and they didn't want to sell their own
14 authorized generic of the non-crush-resistant.

15 JUDGE CHAPPELL: And this is disputed?

16 MR. HASSI: This is disputed.

17 The complaint counsel says that there was --
18 this no-authorized-generic provision had value.

19 Our point is, they put that -- they put that
20 provision in the first agreement, "they" Endo, offered
21 that first provision in the first agreement. It was
22 never really discussed. It was in the final agreement,
23 but it really didn't have value, because Endo was
24 giving the sleeves off its vest. Endo wasn't going to
25 launch an authorized generic, so promising to not

1 launch an authorized generic is a promise with no
2 value.

3 JUDGE CHAPPELL: And let me talk about some
4 dates.

5 You say the agreement was finalized
6 June 2010.

7 MR. HASSI: Yes, Your Honor.

8 JUDGE CHAPPELL: Does that also include what's
9 been called I guess the side agreement, same time, same
10 date?

11 MR. HASSI: The development and co-promotion
12 agreement was signed a day earlier on June 7.

13 JUDGE CHAPPELL: And there was a \$10 million
14 payment when?

15 MR. HASSI: The \$10 million payment was made
16 shortly thereafter. I want to say it was within five
17 days, but it may have been taken a little longer for
18 the payment to --

19 JUDGE CHAPPELL: Other than that payment, when
20 did even one penny come from Endo to your client after
21 that agreement was signed in June 2010?

22 MR. HASSI: The Endo credit was paid I believe
23 at the end of the first quarter of 2013.

24 JUDGE CHAPPELL: So nothing kicked in until
25 your client was on the market.

1 worth to us, this is what we're going to get out of the
2 settlement agreement.

3 These simply weren't payments. They weren't
4 intended that way.

5 JUDGE CHAPPELL: Once the payments were coming
6 in based on these two provisions we've discussed, were
7 there disputes about the amount? You know, were
8 accountants on both sides getting together
9 reconciling? How did the amount get determined in
10 the -- how did it really happen?

11 MR. HASSI: So there was --

12 JUDGE CHAPPELL: I'm not talking about
13 argument or allegation. You know, I'm not expecting,
14 you know -- what's the evidence going to show us as far
15 as how did the amount get determined under the terms of
16 the agreement, and was it ever in dispute between the
17 two parties?

18 MR. HASSI: I would say there was confusion,
19 but no, there was not a dispute over the calculation
20 of the payment. I think both parties had to look at
21 it really hard, and what you're going to see is both
22 parties trying to figure out how much do we owe and, on
23 Endo's case, why do we owe this. It sort of came as a
24 surprise you're going to see in their accounting
25 documents. But ultimately there was agreement on the

1 amount and the amounts paid in 2013.

2 JUDGE CHAPPELL: Well, just triggering terms
3 like "market share," these are not scientific,
4 quantifiable terms.

5 MR. HASSI: There was data identified.

6 So, for example, one of the things that's
7 interesting about the Endo credit is the sales in the
8 fourth quarter were based not on Endo's internal
9 records. One of the triggering events was did the
10 fourth quarter drop below this 50 percent high
11 threshold. And that was based not on Endo's internal
12 records, but it was based on third-party data, IMS
13 data.

14 JUDGE CHAPPELL: And I haven't committed the
15 agreement to memory, at least not yet, but you're
16 telling me there were terms in there that identified
17 what source to go to to determine or agree on a market
18 share regarding the payment.

19 MR. HASSI: The parties had worked out how to
20 calculate this and what the data -- what data would be
21 relied on to calculate it, yes, Your Honor.

22 JUDGE CHAPPELL: All right. Let's get back to
23 the petition. What happened?

24 MR. HASSI: So back to the petition, the last
25 thing that they said or the last portion I've put up

1 that Endo said to the FDA is: "The new formulation
2 reduces the risk of an immediate release of a
3 potentially lethal dose of oxymorphone in these
4 situations."

5 This isn't a company -- this is a company
6 telling the FDA that you should remove Opana ER from
7 the market. This is not a company that's planning on
8 offering Opana ER.

9 Indeed, when they lost the petition, the
10 citizens petition with the FDA, which Impax intervened
11 in, Endo sued the FDA to get a decision. Impax
12 intervened in that. In other words, Impax was fighting
13 to have the opportunity to come to market.

14 And ultimately the FDA sided with Impax that
15 old Opana ER, original Opana ER, was not removed for
16 safety reasons. And Endo -- and this is now May of
17 2013. Endo releases a press release, and they say, "We
18 are extremely disappointed and disagree with today's
19 decision and believe that the 1rT8ca0elealyke]
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1 launch an authorized generic of Opana ER, you -- you
2 asked Mr. Loughlin this morning, and he said, Well,
3 Endo could come back on now with original Opana ER.

4 And the question is, would Endo, having made
5 these kinds of statements to the public market about
6 original Opana ER being unsafe, being removed from the
7 market for safety, realistically ever come back and
8 sell that drug again? The answer has got to be no.

9 JUDGE CHAPPELL: What happened in the market
10 before the recall? Did this reformulated drug take
11 off like wildfire? Did it capture a lot of the
12 market?

13 MR. HASSI: Your Honor, in part because of the
14 supply disruptions, what you see is -- so stepping
15 back a second, one of the reasons that the Endo credit
16 was triggered, recall the calculation has a quarterly
17 high, so how much was being sold in the highest
18 quarter before the end of 2012, and that spiked
19 because this product was growing and growing at a
20 faster rate than Endo, Impax or any of the analysts
21 projected.

22 So it's growing really fast. And then Endo
23 wasn't making the product itself. Novartis was making
24 it for Endo.

25 So Endo had Novartis contract-manufacturing

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1 period of time and didn't quite recover.

2 And one possibility for that is prescribing
3 physicians were looking and saying, if we start
4 prescribing this to patients and all of a sudden
5 there's this supply -- and we've heard about this
6 supply disruption, I don't want to start prescribing
7 Opana to a patient and then -- and then have them --
8 that not be available anymore.

9 JUDGE CHAPPELL: Which Opana?

10 MR. HASSI: Opana ER. Opana ER.

11 So the reformulated is just coming out.
12 Opana ER is no longer being supplied. And doctors are
13 saying --

14 JUDGE CHAPPELL: And did I hear you say that
15 the reason Opana ER was no longer being supplied was
16 that because the FDA told Endo to do that, or was there
17 another reason?

18 MR. HASSI: There were two reasons,
19 Your Honor.

20 The first is Novartis couldn't make it
21 anymore, and so Endo was trying to figure out what
22 they do about the fact that they don't have a source
23 of supply. They're not manufacturing this pill.

24 And second is, what the FDA said is, once you
25 start selling reformulated during the supply chain

1 crisis, we don't want you also selling the old version,
2 Opana ER.

3 JUDGE CHAPPELL: What year was this taking
4 place?

5 MR. HASSI: This was in 2012, Your Honor.

6 And as a result, the sales dropped off -- of
7 Opana ER dropped off entirely during that year.

8 JUDGE CHAPPELL: One of the things I want the
9 parties to think about and I hope you can agree to are
10 some issues you can put on a joint exhibit in a
11 stipulation. And one of them is going to be a
12 timeline, things you can agree on, this came to market
13 at this point, this came off the market at this point,
14 things that we're not fighting about. And that can be
15 a joint exhibit that we can all refer to posttrial so
16 we don't have to go digging through and citing fifteen
17 transcript cites for certain points that aren't
18 disputed.

19 MR. HASSI: I think there's a lot of agreement
20 particularly on the timeline, Your Honor, and I think
21 we will endeavor to do that.

22 JUDGE CHAPPELL: Not something that I need now.
23 It's something we're going to need at the end of the
24 case.

25 MR. HASSI: Understood, Your Honor.

1 In terms of timelines, I think one of the
2 things that I wanted to point out with respect to the
3 no authorized generic -- if we could pull up the next
4 slide -- so as I mentioned, the no authorized generic
5 was in the very first proposal, the very first term
6 sheet from Endo to Impax. And that had a
7 no-authorized-generic provision, and it had a
8 March 10, 2013 entry date.

9 That no authorized generic was in the next
10 proposal, which had a February 1, 2013 entry date.

11 And the final agreement had the same
12 no-authorized-generic provision, and the entry date was
13 even earlier, January 1, 2013.

14 And so what you see from the negotiating
15 history is, far from the no-authorized-generic
16 provision being a payment for delay, it was in there
17 from the beginning and Impax managed, notwithstanding
18 that, to negotiate an earlier and then an even earlier
19 licensed entry date, so it was not a payment for
20 delay.

21 I'd like to turn now to the Endo credit. And

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1 Endo might reformulate. And in part, that concern
2 came out of what was happening in the related
3 OxyContin space.

4 So OxyContin is another form of long-acting
5 opioid, and Purdue came up with what was purportedly a
6 safer version of OxyContin. And the generics were
7 removed by the FDA from the market or encouraged by the
8 FDA to leave the market.

9 And so, in that related market, what Impax saw
10 was the branded moving to a new drug, one that was
11 purportedly safer, and the AB-rated substitution, the
12 opportunity for Impax to sell, going away.

13 And there had been statements that Endo had
14 made to Wall Street that suggested that maybe they had
15 some kind of a plan. And Impax was worried about that
16 plan. And Impax was worried that they might
17 reformulate, and so they asked Endo.

18 You'll hear from Mr. Mengler. He asked
19 Alan Levin, Endo's chief negotiator, point blank, are
20 you guys going to move the market. And Alan said no.
21 Excuse me. Mr. Levin said no.

22 And Mr. Mengler came back and came up with
23 this idea of acceleration triggers, which we talked
24 about this morning. And the idea was, if the market
25 dipped a certain amount, then Impax would get to enter

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1 payment for delay. He's looking for what happens if
2 Endo moves the market.

3 JUDGE CHAPPELL: Did I understand you to just
4 say that one of the provisions, depending on what
5 happened in the market, could have required Impax to
6 pay Endo?

7 MR. HASSI: Absolutely, Your Honor.

8 So that was the royalty provision, and what
9 you'll see in the final settlement agreement is a
10 royalty provision. If Endo grew the market
11 sufficiently so that when Impax entered in 2013 it
12 entered a robust market, it would pay -- Impax would
13 pay Endo a royalty. There would be no Endo credit.
14 Impax would be paying money to Endo in the form of a
15 royalty. And that's why this was referred to as a
16 carrot and stick.

17 Now, there's no evidence that either company
18 assumed Endo would have to make a payment to Impax.
19 Neither company booked a credit. Neither company
20 booked a reserve. And Mr. Levin, Endo's CFO, testified
21 about this point.

22 So he was the principal negotiator for Endo.
23 He was also the chief financial officer.

24 And he said: "I don't believe we anticipated
25 that anyone would need to make a payment under the Endo

1 credit.

2 "... at the time we put this agreement
3 together, I don't believe we anticipated that Endo
4 would have to make any payment under this provision."

5 And again, later, "As I said, it was not our
6 expectation that a payment would have to be made."

7 And there was reference this morning to some
8 calculations that were made to determine on the Endo
9 side as to what this payment might be, what it might be
10 worth. We've never seen those calculations, and I
11 don't expect that we will.

12 If you'd go to the next slide.

13 JUDGE CHAPPELL: Are you talking about the
14 expert's calculations?

15 MR. HASSI: No, Your Honor. There was
16 reference I believe -- and I could be wrong -- in
17 Mr. Loughlin's opening about Mr. Cuca, who I think
18 you're going to hear from, making calculations to
19 determine the magnitude of the Endo credit. And we've
20 never seen those -- we've never seen any such
21 calculations, and I'm not sure that we will.

22 JUDGE CHAPPELL: Is he wrong?

23 MR. LOUGHLIN: Mr. Cuca testified that he
24 did -- he performed those calculations. They have not
25 been produced in this case. We have not seen them.

1 That is his testimony, and we expect he will say it on
2 the stand in this courtroom, Your Honor.

3 JUDGE CHAPPELL: This Cuca, he's an Endo man?

4 MR. LOUGHLIN: He is an Endo witness, a former
5 Endo employee.

6 JUDGE CHAPPELL: All right.

7 MR. HASSI: And we'll hear what Mr. Cuca has to
8 say -- "Cuca." I don't know if I'm pronouncing it
9 correctly -- we'll hear from him.

10 This is what Mr. Levin, his boss, the chief
11 financial officer, said.

12 "You don't have any recollection of anybody at
13 Endo running calculations to try to determine how much
14 the Endo credit might cost Endo based on the version of
15 the Endo credit in CX 324?" That's one of the exhibits
16 in this case.

17 He answered, "Well, as I said, it's not clear
18 to me that Endo would need to make a payment under this
19 provision. But to your question, I don't recall anyone
20 running any calculations."

21 Again, "Do you recall anyone running
22 calculations at Endo regarding any version of the Endo
23 credit?"

24 "ANSWER: I don't recall."

25 So we'll hear what Mr. Cuca has to say, but

1 we've not seen any calculations of the value of the
2 Endo credit.

3 Now -- if we could go to slide 3 -- as we were
4 saying, two years later, in 2012, Endo had a supply
5 chain crisis. They had this issue with Novartis. And
6 it was in 2012 that they first realized that there
7 might be a payment due under the Endo credit.

8 And again, this is the chief financial
9 officer --

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1 surprisingly, when you haven't booked a reserve and all
2 of a sudden think that you're going to have to pay

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1 entered into and ignore -- ignore what we've been
2 calling the real world after that.

3 But this is one place, the Endo credit, where
4 they do want to look at the world after the settlement
5 agreement. They want to look all the way forward to
6 2013 in terms of what was actually paid instead of
7 what the parties' expectations were at the time they
8 entered into the agreement. And the reason for that is
9 simple. There was no expectation of a payment at the
10 time they entered into the agreement.

11 Complaint counsel also suggests and you heard
12 this morning that they twin the no-AG payment -- the
13 no-AG and this Endo credit and put them together and
14 call them a guaranteed no-AG payment or a guaranteed
15 180-day payment.

16 Now, a guarantee usually means something that
17 ensures a particular outcome. Impax wasn't guaranteed
18 a payment here. There were, as complaint counsel
19 admitted this morning, scenarios under which nothing
20 gets paid.

21 In other words, if Endo draws down
22 sufficiently -- not sufficiently to hit the trigger in
23 the fourth quarter of 2012, but there's no market left
24 in the first quarter of 2013, the Endo credit doesn't
25 get paid, the no authorized generic isn't worth

1 but he's not going to do any scientific work, he's not
2 going to do any studies, he's not going to calculate
3 any expected value, and he testified as much in his
4 deposition.

5 I asked him, "And you intertwined the
6 exclusivity provision" -- that's the no-AG -- "and the
7 Endo credit provision. You didn't calculate an
8 expected value for these two provisions together, did
9 you?"

10 "No.

11 "Nor separately; right?"

12 "No."

13 You're not going to hear expected value
14 calculations from their expert, or if you do, we'll all
15 be hearing it for the first time, because it wasn't in
16 his report and he didn't have them at the time of his
17 deposition.

18 So these things could have been worthless, but
19 complaint counsel wants you to ignore that. They want
20 you to look at the payments made years after the
21 settlement was entered into and calculate back a net
22 present value or say the parties should have known it
23 could have been worth -- we saw some numbers this
24 morning -- 62 million or whatnot.

25 But it was a contingent payment. And the

1 considerations related to the payment.

2 So if you could go -- it talks about the fact
3 that -- in the first paragraph, that Endo had a number
4 of different scenarios in terms of when they were going
5 to launch reformulated Opana ER, and that was going to
6 happen at this point in time as early as August of
7 2012, as used in the budget, or as late as October of
8 2012. And neither of those dates would have likely
9 triggered the Endo credit.

10 And then it goes on to say, on December 9,
11 2011, the company received FDA approval for the new
12 crush-resistant, so you asked about that date before --
13 on December 9, 2011, the company received FDA approval
14 for the crush-resistant.

15 But just later that month, on December 20,
16 2011, Endo was notified by Novartis that they were
17 temporarily shutting down their Lincoln, Nebraska
18 facility for a period of three to four weeks. And
19 that's what caused what Mr. Levin referred to as a
20 supply chain crisis.

21 And so Endo had to work with the FDA to switch
22 to the reformulated drug, which again was being
23 manufactured in a different facility.

24 And if we could go to the next slide.

25 So as I mentioned, "In February, the FDA

1 informed us," here being Endo, "that in order to
2 prevent confusion in the marketplace, on a
3 strength-by-strength basis, once any tablets of CRF
4 were sold, we could no longer sell any tablets of the
5 old formulation. As a result of this FDA guidance, we
6 needed to be certain that we could successfully
7 manufacture and launch CRF prior to relinquishing our
8 alternative strategies on the old formulation."

9 So again, on a dose-by-dose basis, if they
10 launched a 10 milligram of the CRF, they had to stop
11 selling the 10 milligram of old Opana ER.

12 And if we could go to the third slide.

13 JUDGE CHAPPELL: What do you mean, "they had
14 to"?

15 MR. HASSI: I mean, the FDA told them, gave
16 them guidance that said you cannot sell both at the
17 same time, so when I say "they had to," to comply with
18 the regulator, the FDA, they had to.

19 JUDGE CHAPPELL: Isn't that exactly what Endo
20 asked for with the citizen petition and were denied?

21 MR. HASSI: Ironically, it is, Your Honor.

22 In other words, I think Endo asked for more,
23 though, with the citizens petition. Recall that the
24 citizens petition would have also kept Impax off the
25 market.

1 MR. HASSI: No, Your Honor, nothing to do with
2 that.

3 JUDGE CHAPPELL: And did there come a point in
4 time where there was no Opana ER available for patients
5 to be prescribed by doctors?

6 MR. HASSI: Your Honor, I'm not aware of a
7 point in time where there wasn't any available. I
8 know that, as I mentioned earlier, during this period
9 of time there was a little bit of turmoil and
10 prescribers were shifting people to other drugs.

11 In other words, OxyContin treats pain. If you
12 were a prescriber at that time, you might have said,
13 because there are issues with Opana, I'm going to
14 prescribe OxyContin instead.

15 So there were -- it's clear --

16 JUDGE CHAPPELL: Is there going to be evidence
17 that at some point during this period doctors were
18 prescribing other painkillers in lieu of Opana ER?

19 MR. HASSI: Your Honor, throughout this period
20 doctors were prescribing other painkillers in addition
21 to Opana ER. Opana ER is never the only painkiller
22 out there.

23 It's, frankly, a matter -- I think what you're
24 going to hear from both doctor experts who are going
25 to take the stand is, it's a matter of choice by the

1 physician and it's a matter of what the patient pays
2 for that drug. It's a matter of -- some doctors will
3 tell you it's what they learn -- it's what they
4 learned. In other words, if they were at a teaching
5 hospital where Opana was prescribed, they became
6 familiar with Opana and they prescribe it.

7 But if you look, for example, in different
8 geographic regions, one drug is more popular than the
9 other. On different formularies one drug is preferred
10 over the other such that insurance companies will
11 charge a higher copay for OxyContin than they will for
12 Opana, and that's one of the areas where these
13 companies compete.

14 JUDGE CHAPPELL: So someone who testifies
15 during this trial is going to know whether there was a
16 shortage at some point.

17 MR. HASSI: I believe so, yes, Your Honor.

18 But in any event, Endo was going through this
19 supply chain crisis, and what they recorded again in
20 this accounting memo is: "The Company recorded a
21 charge in the first quarter of 2012 as the liability
22 became probable in March [of] 2012 when we decided to
23 accelerate CRF and then successfully demonstrated the
24 ability to procure CRF at PMRS with [the] appropriate
25 QA standards."

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1 Endo credit -- "became reasonably estimable during the
2 first quarter of 2012."

3 They didn't know until March 2012 that they
4 were going to have to make this payment.

5 And as it goes on to say, "Due to the multitude
6 of uncertainties described above, it was not possible
7 to determine whether or not we could launch CRF," so
8 they didn't know. There's a lot they didn't know.
9 They couldn't predict the future.

10 And the point is, back in 2010, when the
11 parties signed the settlement agreement, nobody had
12 any idea this was going to happen, but nobody was
13 banking on a payment. It wasn't a naked payment.
14 Impax wasn't expecting to get paid. Endo wasn't
15 expecting to make a payment.

16 And if we could go to Alan Levin.

17 And on that point, again, one last time, the
18 CFO of Endo, Alan Levin. And I asked him, "I think we
19 talked about this, but at the time that Endo entered
20 into the Impax settlement, did it expect the fourth
21 quarter 2012 sales to be zero of Opana ER?"

22 I corrected, "By that I mean Opana ER sales to
23 be zero."

24 He said, "I can't speak for the company, but I
25 stand by my prior statement that I did not expect that

1 there would be a payment due under the Endo credit when
2 we signed that transaction."

3 That's the CFO of Endo, did not expect a
4 payment.

5 It was a contingent payment. Its value didn't
6 become certain until 2012. And it's not unexplained.
7 It was part of a carrot-and-stick approach, as
8 Ms. Snowden's testimony illustrates, to try and give
9 Impax the chance to enter the most robust market
10 possible.

11 Now, if we could go to the negotiating
12 history, much like the authorized generic, this was
13 not a payment for delay.

14 The very first term sheet had no hint of an
15 Endo credit. It did have a royalty provision. But it
16 didn't have any payment going from Endo to Impax in the
17 form of this what became the Endo credit. And it
18 offered a March 10, 2013 date.

19 The parties started talking about the market
20 acceleration trigger and then about some form of what
21 became the Endo credit. And when that first was
22 introduced, the proposal had moved up. The entry
23 was now, instead of March 10, 2013, Impax -- or
24 excuse me -- Endo was offering Impax a
25 February 1, 2013 licensed entry date.

1 And in the final agreement, we have the Endo
2 credit as it was finalized, and you have a yet even
3 earlier date, March -- excuse me -- January 1, 2013.

4 So the negotiating history shows we go from a
5 March entry date with no Endo credit to a January
6 entry date, an earlier entry date, with what complaint
7 counsel is terming a payment to Impax. That's not a
8 payment for delay.

9 JUDGE CHAPPELL: Well, what about the
10 ten million? I've been told that ten million is large
11 and unjustified.

12 MR. HASSI: Let's talk about the ten million
13 because --

14 JUDGE CHAPPELL: Forget these two terms. The
15 ten million, if large and unjustified, is an Actavis
16 problem.

17 MR. HASSI: Well, Your Honor, whether
18 ten million is large I think is an open -- I think is
19 an open question. I'm not sure anybody is going to
20 take the stand and say, if there were a \$10 million
21 payment by itself, that -- I don't -- I think -- my
22 recollection is -- and I'll confirm this -- that
23 Professor Noll said not sure whether he'd call
24 ten million large. He twins it with these other -- he
25 puts it with these other things, but the ten million

1 alone -- now, we don't necessarily agree with the
2 benchmark that complaint counsel has set about
3 \$3 million for Endo's future litigation costs, but
4 ten million isn't really large in this business and in
5 this context.

6 JUDGE CHAPPELL: Well, not getting into
7 anything proprietary or confidential, market-wise size,
8 market cap, Endo was larger than respondent?

9 MR. HASSI: Endo was larger than Impax, yes,
10 Your Honor.

11 JUDGE CHAPPELL: Five times larger? A lot
12 larger?

13 MR. HASSI: I would have to check --

14 JUDGE CHAPPELL: Barely larger?

15 MR. HASSI: -- at the time.

16 I would say significant and multiples larger,
17 but how many multiples I don't know. Impax was very
18 small.

19 JUDGE CHAPPELL: Just what I'm getting at is,
20 \$10 million might be large, larger to one side of the
21 agreement than the other side of the agreement.

22 MR. HASSI: I would agree with that,
23 Your Honor.

24 What's more important is, no one is going to
25 take that witness stand, not even their expert, and

1 say that that payment was unjustified, that the
2 development and co-promotion agreement was
3 unjustified.

4 I think what I heard this morning is their
5 expert Mr. Geltosky is going to say it's unusual. It's
6 not unjustified.

7 This was an arm's length transaction
8 negotiated between Endo and Impax. Endo had an
9 interest in a potential Parkinson's treatment.

10 Yes, Endo would have preferred to get Rytary
11 and any follow-ons, but what they got was a chance to
12 participate in IPX-203. That drug is still under
13 development, and that drug has considerable potential,
14 and no one is going to take the stand and tell you it
15 doesn't or that it didn't.

16 So Endo -- Dr. Cobuzzi is going to take the
17 stand, as I mentioned. He's got a Ph.D., and his Ph.D.
18 thesis related to Parkinson's. He's the person who
19 negotiated this on behalf of Endo.

20 And if we could pull up slide -- Dr. Cobuzzi --
21 the Cobuzzi e-mail.

22 So this is the memo that Dr. Cobuzzi sent to
23 the Endo board of directors on June 8. And he tells
24 the Endo board of directors (as read), "To further
25 build on the good news of the day, I want to let you

1 know that further to the discussion with the
2 Transaction Committee on June 1st the Endo team
3 completed a development and co-promote agreement with
4 Impax."

5 He went on to say (as read), "This is an
6 exciting opportunity for Endo as it further builds our
7 product pipeline for the future with a drug candidate
8 that fits our commercial footprint."

9 Now, Endo, what you're going to hear, at the
10 time didn't have its own internal research and
11 development arm.

12 JUDGE CHAPPELL: But isn't he talking about the
13 first drug, the one that was switched out?

14 MR. HASSI: No, Your Honor. This is talking
15 about IPX-203.

16 JUDGE CHAPPELL: How do we know?

17 MR. HASSI: Because it's on the day and -- and
18 I can --

19 JUDGE CHAPPELL: I don't see it on the
20 document.

21 MR. HASSI: It -- this is the -- so this is
22 part of the final agreement, and it's attaching this
23 document called Imperial OEW, which is opportunity
24 evaluation worksheet I believe, evaluating the
25 opportunity of IPX-203. The document is in evidence

1 and will show you that this relates to IPX-203.

2 This is the final deal. This is Dr. Cobuzzi
3 saying to his board we've --

4 JUDGE CHAPPELL: So your position is the
5 evidence will show that he's talking about the test
6 drug or proposed drug that was actually part of the
7 agreement, not the first one that was pulled.

8 MR. HASSI: That's correct, Your Honor. The
9 first one -- to be clear, the first one wasn't pulled.
10 The first one was Endo expressed an interest -- Endo
11 expressed an interest in what was then being called
12 IPX-66, is now sold on the market as Rytary. There
13 was public information that Impax was developing that
14 drug and developing a drug in the Parkinson's space.

15 Endo came to Impax -- they talked about it --
16 even before these parties talked about settlement,
17 there were discussions about this and other drugs.

18 And Endo came to Impax and said, We're
19 interested in this IPX-66 drug that you're developing.
20 And they asked to enter into a development and
21 co-promotion agreement on that. And what Impax said
22 was, That drug is pretty far along, and we're not
23 looking for a partner in the U.S.

24 JUDGE CHAPPELL: Endo suggested the first
25 drug.

1 MR. HASSI: Endo suggested the first drug.

2 JUDGE CHAPPELL: And the first drug is on the
3 market.

4 MR. HASSI: And the first drug is on the
5 market.

6 JUDGE CHAPPELL: Had the deal been about the
7 first drug, it would have been a better investment for
8 Endo.

9 MR. HASSI: It's unclear, Your Honor, because
10 the next drug hasn't come to the market yet, but if
11 the next drug is really an improvement over the
12 original, it could be worth -- it could be worth
13 significant --

14 JUDGE CHAPPELL: But that doesn't matter. You
15 told me that that part of the agreement had been
16 vacated.

17 MR. HASSI: Endo decided not to continue with
18 that part of the agreement, yes, Your Honor.

19 But there's -- there's no question that they
20 negotiated at arm's length. They asked for IPX-66.
21 Impax wasn't looking for a partner in the United States
22 on IPX-66. They were looking for a partner outside the
23 U.S., and they entered into a deal for sales outside
24 the U.S. because they don't have an ex-U.S. sales
25 force. But they had just built out their sales force

1 in the U.S., and they wanted to sell this drug. They
2 didn't need a partner in Endo.

3 But the follow-on drug, there were risks to it
4 and there were costs to it, and they wanted to share
5 some of that risk and share some of that cost and share
6 in some of the potential upside.

7 JUDGE CHAPPELL: This is Dr. Cobuzzi?

8 MR. HASSI: This is Dr. Cobuzzi, right.

9 JUDGE CHAPPELL: A Ph.D. doctor. Is he going
10 to testify in this case?

11 MR. HASSI: He's going to testify in this
12 case.

13 JUDGE CHAPPELL: Live.

14 MR. HASSI: Live, yes, sir. He's going to come
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1 was not a large and unexplained payment.

2 I want to talk now about the relevant market
3 because --

4 JUDGE CHAPPELL: You understand that
5 "unexplained" and "unjustified" are not the same thing.
6 Anybody can just explain anything (indicating). But
7 that doesn't mean someone is going to agree it's an
8 actual justification.

9 MR. HASSI: If Your Honor prefers, I'll try to
10 stick with justification -- "justified."

11 JUDGE CHAPPELL: I would just advise everybody
12 to be aware, I don't think those two words mean the
13 same thing. One is much broader than the other.

14 MR. HASSI: Understood, Your Honor.

15 Well, in any event, if complaint counsel fails
16 to --

17 JUDGE CHAPPELL: You can explain anything you
18 want, and I can buy it or not buy it, but if I find it
19 to be a justifiable explanation, do you see the
20 difference?

21 MR. HASSI: I do, Your Honor. And to be
22 clear --

23 JUDGE CHAPPELL: And the Supremes might have
24 used one or the other interchangeable, but I don't find
25 that works.

1 MR. HASSI: And to be clear, Your Honor, Impax
2 believes and will show in this case that the
3 development and co-promotion agreement was justified
4 and that the \$10 million payment made in connection
5 with that was justified. It was a good opportunity for
6 Endo. They believed as much. They entered into the
7 agreement as part of an arm's length deal.

8 If I could turn now to the relevant market,
9 because that would be the first step in a rule of
10 reason case.

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1 painkillers are substitutable, readily substitutable.

2 MR. HASSI: Interchangeable, substitutable,
3 that's correct, Your Honor.

4 JUDGE CHAPPELL: And what I would like for
5 someone to tell me here in this trial is, if it is a
6 fact that there was a supply shortage of this drug, how
7 is it that if that's the only market, how is it that
8 other drugs were being prescribed at that time if it's
9 not interchangeable?

10 MR. HASSI: I think, Your Honor, what you will
11 see is it is interchangeable. And I don't think the
12 doctors disagree.

13 If you could put up Dr. Savage's testimony.

14 So you heard Dr. Savage is complaint counsel's
15 expert. And what she said in reference to this issue
16 is:

17 "'Dr. Michna and I" -- and Dr. Michna is our
18 expert -- "agree that clinically no opioid is
19 ipso facto superior to any other opioid.'

20 "Correct."

21 And she went on to explain, "But there is no
22 one best opioid across populations of people."

23 In other words, a patient comes in with pain,
24 whether that pain is caused by cancer or lower back
25 pain or one of the many other diagnoses for which they

1 need -- they have chronic pain and need treatment.
2 There's no one opioid that fits that situation. It's
3 not necessarily Opana. It's not necessarily
4 OxyContin.

5 There are a number of different ways that
6 doctors make that decision. And part of it is based
7 on their experience. Part of it is based on the
8 detailing they may receive from the drug companies.
9 Part of it is based on the insurance coverage that the
10 patient has. Part of it is based on the copayment
11 that the patient makes. And part of it is based on
12 whether the patient has a preference for a particular
13 drug.

14 And it's true, once someone starts on a course
15 of drugs and it's working, they may stick with that
16 opioid. And they may not want to switch. They may
17 have a preference. But when doctors are making the
18 initial prescribing decision, no one opioid is
19 superior to another, not for any diagnosis and for
20 not -- not for any population of patients.

21 There's no group you can say, well, if this
22 person walks in the door, if it's a male my age who
23 walks in the door with lower back pain, Opana is going
24 to be the better drug for that. These doctors can't
25 tell you that. And you're not going to hear that.

1 What you are going to hear --

2 JUDGE CHAPPELL: Are you prepared to present
3 evidence during your case of the relative cost of these
4 other opioids?

5 MR. HASSI: I don't think our experts have
6 addressed --

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1 to hear testimony about that in this case -- where,
2 for example, Endo managed to get OxyContin knocked off
3 a formulary altogether, and Opana was then the
4 preferred long-acting opioid on that formulary. And
5 for those patients, they were therefore more likely to
6 get Opana ER. And that's based on negotiations between
7 the drug companies and health insurers.

8 JUDGE CHAPPELL: Well, it's no surprise the
9 parties disagree on relevant market, market power.
10 We'll see what shakes out.

11 MR. HASSI: We will, Your Honor.

12 If I could mention just quickly two other
13 forms of competition.

14 One is for the prescribers. As I mentioned,
15 prescribers make a choice whether they're going to
16 write a script for OxyContin or Opana or another drug,
17 and so that's why these folks have sales forces.
18 Purdue sends out a sales force to detail OxyContin.
19 Endo sent out a sales force to detail Opana.

20 And you're going to hear, there are differences
21 between these drugs. The sales force goes out and
22 touts these differences to say, gee, Opana is better in
23 these circumstances or whatnot, but it's trying to
24 differentiate these drugs so that the prescriber will
25 prefer it over another.

1 And they also compete for patients, so they
2 compete on this copay level. And when patients have a
3 copay, what you're going to hear is, these companies,
4 Endo included, offer sort of a version of a credit card
5 that could help cover the cost of that copay to
6 convince the patient to get Opana as opposed to, say,
7 for example, OxyContin.

8 Now, the FTC has looked at this market before.

9 And if you could bring up the next slide.

10 And this is from a merger in the long-acting

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1 extended release, so the ER is effective over a
2 twelve-hour period. The IR is a shorter term.

3 If you look at the bottom line under
4 Opana Tablets in the middle of their market definition,
5 it refers to "all other combination IR oxycodone."
6 Those are immediate-release products compared with
7 extended-release.

8 JUDGE CHAPPELL: Well, according to this slide,
9 the ER sales volume dwarfs the tablets.

10 MR. HASSI: I'm sorry. Dwarfs the?

11 JUDGE CHAPPELL: The sales volume for the ER is
12 much higher, according to this slide. For the entire
13 market size.

14 MR. HASSI: It's twice the sales --

15 JUDGE CHAPPELL: It's not important. It's just
16 something I noticed.

17 MR. HASSI: It's twice the sales volume, yes,
18 Your Honor.

19 If we could go to the next slide.

20 And this is another Endo document, evaluating
21 new entrants in this market.

22 So we heard about a bunch of competitors. This
23 is Endo around the time of 2010 evaluating --

24 JUDGE CHAPPELL: Am I the only one who's never
25 heard of any of these drugs?

1 MR. HASSI: I've heard about them since I
2 started on this case, Your Honor, but no. And some of
3 these -- candidly, at least one of these is not on the
4 market.

5 This was Endo evaluating, if these come on the
6 market, what effect do they have on our share.

7 And so what you see in the first bar is, at the
8 time, Endo was evaluating its market share at about
9 8.6 percent.

10 JUDGE CHAPPELL: At the time, what time? I
11 don't see a date on here.

12 MR. HASSI: This was I believe it was
13 June 2009, but the document is in evidence and the
14 cover page indicates --

15 JUDGE CHAPPELL: I saw 2009 on the previous
16 slide, but I don't see a date on this one.

17 MR. HASSI: I will have to check, Your Honor.
18 It was before the settlement agreement was entered
19 into, so it's designed to be relevant to the market at
20 that time and it's Endo assessing potential new
21 entrants.

22 But what you see is Opana's share was very
23 small compared to all the others, including the new
24 entrants.

25 And if we could go to one more slide.

1 Complaint counsel mentioned that Endo's
2 Mr. Bingol will be testifying in their case. This is
3 from his declaration which was admitted in the patent
4 case that brought the settlement between Endo and Impax
5 together. And he said, "The long-acting opioid market
6 segment consists of several oral tablet products and a
7 patch called Duragesic. ...the LAO market was a
8 well-established and competitive market that consisted
9 of many products that had been on the market for
10 years."

11 And if you look at the table at the bottom, it
12 calculates Opana ER's market share in March 2010, so
13 this is just a couple months before the settlement, at
14 3.4 percent of the long-acting opioid market, not
15 exactly the stuff of monopoly power.

16 Finally, Your Honor, under the rule of reason,
17 complaint counsel has to prove effects. If Endo did
18 have market power, this court is going to have to
19 balance the procompetitive effects associated with the
20 settlement against any purported anticompetitive
21 effects that it had. Was the settlement an
22 anticompetitive constraint or did consumers benefit?

23 Now, complaint counsel has indicated they have
24 a different way of looking at this, but we'd like to
25 share with you what happened in the real world and how

1 looking at the events of the past seven years since
2 this settlement was entered into are relevant and how
3 you should take them into account.

4 And as Justice Brandeis wrote for a unanimous
5 Supreme Court 99 years ago, he said: The true test of
6 legality in rule of reason cases focuses on the facts
7 peculiar to the business to which the restraint is
8 applied, its condition before and after the restraint
9 was imposed, and the nature of the restraint and its
10 effect, actual or probable. That was Board of Trade of
11 City of Chicago, a 1918 case, unanimous Supreme Court,
12 Justice Brandeis writing.

13 The purported restraint here is the settlement
14 agreement. And we agree with the Supreme Court that
15 you should look at the effects before the agreement was
16 entered into and after the agreement was entered into
17 to determine whether the settlement was pro- or
18 anticompetitive.

19 And so to do that, we have to compare what the
20 settlement actually -- the effect the settlement
21 actually had in the real world versus what would have
22 happened if Endo and Impax had not settled.

23 So if we could bring up the slide showing the
24 real world.

25 And so, Your Honor, this is a depiction of the

1 real world. We've been talking about other ANDA
2 filers, and those other ANDA filers included Watson,
3 included Actavis and of course Impax.

4 And what you have is on the far left of the
5 screen June 2010, is that red bubble.

6 And July 15 is when the 30-month stay would
7 have expired.

8 January 1, 2013 is the license date.

9 And so looking at Impax, you see a green bar
10 that showed, as of January 1, 2013, a few days
11 thereafter, Impax came to market and has been selling
12 continuously since then and intends to sell going into
13 the future and that the final patent that Endo has
14 presently, it doesn't expire until 2029.

15 Watson never came on the market. They filed an
16 ANDA. They have never sold a single dosage of
17 Opana ER.

18 Actavis was first to file on those two small
19 dosages, the 7.5 and 15 milligram, and so Actavis --
20 and Actavis got a settlement that allowed them to come
21 on the market in those dosage forms in July 2011. And
22 they came on on July 15, 2011, and they sold for a
23 period of time. But on September 6, 2016, they were
24 enjoined from the market because of Endo's
25 after-acquired patents.

1 JUDGE CHAPPELL: So did Actavis launch at
2 risk?

3 MR. HASSI: Actavis launched at risk,
4 Your Honor, in 2013 on the five strengths that Impax
5 was first to file on, so not as against the patents
6 that were at suit in the case between Endo and Impax,
7 but as you'll see, they launched at risk as against
8 other patents that Endo acquired in the meantime.

9 And so in the summer of 2013, Actavis started
10 selling the five dosage -- the five dosages that Impax
11 was first to file on, and those sales were at risk, and
12 they've since been enjoined from the market.

13 JUDGE CHAPPELL: But Actavis looks like they
14 were in the market, if I follow your diagram, for,
15 what, four or six years?

16 MR. HASSI: They were in the market for just
17 over five years, some of that only with -- some of that
18 licensed, not at risk, on the two lower dosage
19 strengths and some of that on all seven dosages for a
20 period of time at risk.

21 JUDGE CHAPPELL: But the red line you're
22 showing at least for Actavis, that's the after-acquired
23 patents you told us about.

24 MR. HASSI: That is the result of the
25 after-acquired patents, yes, Your Honor. And I've

1 got another slide that's a little bit clearer about
2 that.

3 JUDGE CHAPPELL: Just so the record is clear,
4 even though this is not evidence, is there a dispute on
5 when the 30-month stay ended?

6 MR. HASSI: No, Your Honor. I believe that's
7 in -- I believe that's in the stipulations that we
8 provided this morning in the JX.

9 JUDGE CHAPPELL: And what is the date the
10 30-month stay ended?

11 MR. HASSI: June -- I'm trying to remember if
12 it's June 14 or June 15, but it's June of 2011.

13 JUDGE CHAPPELL: 2011.

14 MR. HASSI: 2010. 2010.

15 MR. LOUGHLIN: It's June 14, 2010.

16 JUDGE CHAPPELL: The 30-month stay ended in
17 2010.

18 MR. LOUGHLIN: Correct, Your Honor.

19 JUDGE CHAPPELL: Okay. If that's true, didn't
20 the 180-day exclusivity period begin then?

21 MR. HASSI: No, Your Honor.

22 JUDGE CHAPPELL: What delayed the exclusivity
23 period from that point?

24 MR. HASSI: The 180-day period starts when
25 Impax first launches. Indeed, that's one of the issues

1 with a launch at risk.

2 So in other words, until Impax starts selling,
3 that 180-day period doesn't kick in. Once Impax sells
4 even one dose, the 180-day clock starts ticking.

5 And so I was referencing that with respect to
6 a launch at risk because in a launch at risk, typically
7 the company doesn't sell for all time. They'll sell a
8 small amount to make some money --

9 JUDGE CHAPPELL: So getting to what I asked
10 earlier, though, then couldn't Impax have waited eight
11 more months to September 2013, not been at risk, and
12 still had the 180 days?

13 MR. HASSI: No for two reasons, Your Honor.

14 JUDGE CHAPPELL: It's based on when they first
15 introduced.

16 MR. HASSI: The 180 days only matters if the
17 patents are -- the patents that were listed in the
18 Orange Book at the time, which were the two
19 patents-in-suit, haven't expired, so if -- the 180 days
20 would have been forfeited essentially if Impax waited
21 until September 2013 to launch.

22 JUDGE CHAPPELL: This one is complicated
23 because of these after-acquired patents. With one
24 patent at issue, at this point in 2013,
25 September 2013, all generics who had the horsepower

1 could have brought a generic to market, if they had
2 the formula and could sell it, because there were no
3 longer any patents, or at least the original patent
4 expired then, so you couldn't have had 180 days
5 because the market opens wide open at that point.

6 MR. HASSI: Right. Had there been no
7 additional patents, the market would be wide open come
8 September 2013, that's right.

9 JUDGE CHAPPELL: So bottom line, the first
10 generic, the first filer, can take advantage of
11 180 days provided it's before expiration of the
12 patent.

13 MR. HASSI: Yes, Your Honor.

14 JUDGE CHAPPELL: It doesn't matter when, and it
15 starts the day they introduce their product, but it
16 needs -- but if you want to really have an exclusive
17 period, it must be before the patent expires.

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

19 JUDGE CHAPPELL: All right.

20 MR. HASSI: Now, there were, as I mentioned,
21 other ANDA filers. None of those ANDA filers got the
22 same broad patent license that applied to these
23 after-acquired patents, and none of them were able to
24 come on the market.

25 Indeed -- so Par, Teva, Amneal, Actavis,

1 Sandoz, Ranbaxy, those are -- Your Honor asked
2 earlier -- those were all ANDA filers on this drug.
3 They're all enjoined. None of them is on, selling on
4 the market today.

5 Now, if Impax didn't settle, its option was to
6 keep litigating the patent case and hope to win. And
7 complaint counsel is not going to tell you that they
8 have any particular insight as to what the outcome of
9 that case would have been. Their expert and our expert
10 agrees the outcome was uncertain.

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1 MR. HASSI: I will try to back off the line,
2 Your Honor.

3 Your Honor, with respect to whether Impax
4 would have launched at risk, you heard this morning
5 that complaint counsel is going to put on evidence
6 that, for example, Impax prepared launch -- prepared to
7 launch. And what you have to do in this case is
8 distinguish between efforts to prepare for a launch and
9 a decision to launch at risk.

10 So Impax, as a matter of routine, when it's
11 approaching an opportunity such as the end of a
12 30-month stay, wants to make sure that they're ready to
13 launch should the opportunity arise.

14 And so if we could bring up the 10-K.

15 This is from Impax' annual report, its 10-K for
16 the year 2010. And what it explains is, "When the
17 Company" -- that's Impax -- "concludes FDA approval is
18 expected within approximately six months, the Company
19 will generally begin to schedule manufacturing process
20 validation studies as required by the FDA to
21 demonstrate the production process can be scaled up to
22 manufacture commercial batches."

23 So as a matter of course, when they know
24 they're six months away from what's sometimes referred
25 to as a launchable date, a date by which one of those

1 So there are a number of barriers still in
2 Impax' way in the spring of 2010. One of those is FDA
3 approval. But in May of 2010 they get temporary
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1 again, this is the 10-K, put this out to the market --
2 "The capitalization of unapproved pre-launch inventory
3 involves risks, including, among other items, FDA
4 approval of product may not occur; approvals may
5 require additional or different testing and/or
6 specifications than used for unapproved inventory, and,
7 in cases where the unapproved inventory is for a
8 product subject to litigation, the litigation may not

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1 this year for obvious reason)." And Mr. Hsu will
2 testify about that as well.

3 They weren't planning on launching. They
4 wanted to be prepared, and they certainly wanted Endo
5 to think that they were ready, but they weren't going
6 to launch.

7 Next.

8 And here's Todd Engle. You'll hear from him
9 as well. He's head of sales and marketing at this
10 point in time in 2010. Again, May 2010, this is --
11 they now have -- and this is part of the e-mail chain
12 where they've received FDA tentative approval, so that
13 barrier is falling. They know they're going to be able
14 to get FDA approval. But he says, "A launch decision
15 has not been made." He goes on to say, "There has been
16 no decision yet to complete the launch build."

17 In other words, yes, they wanted to be ready,
18 but they hadn't made decisions to take the next steps
19 towards launching, and they certainly --

20 JUDGE CHAPPELL: We're getting close to your
21 time limit.

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

23 JUDGE CHAPPELL: We're getting close to your
24 time limit.

25 MR. HASSI: I understand, Your Honor.

1 JUDGE CHAPPELL: How much more do you have?

2 MR. HASSI: It depends on how slowly I go.

3 I'll try to cut through it and get to the end.

4 Your Honor, a decision to launch at risk for a

5 small company like this is very significant, and it

6 entails very significant risks.

7 ~~MR. HASSI~~ MR. Thank2 -2,4.2 -2.035.ore do you have? JUDGE CH4.2

8 MR. wi2 - thrigndone in thisitime,how slowly I go.

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1 \$324 million.

2 That's a lot of money for a company that in its
3 best year in many years, 2010, this company made
4 \$880 million in total revenues. That's bet-the-company
5 damages for launching at risk.

6 So when they ask you to assume that this
7 company would launch at risk, we think the documents
8 and testimony will show otherwise.

9 I want to skip to -- skip to the procompetitive
10 options slide, the timeline.

11 So, Your Honor, I want to walk through the real
12 world and the after-acquired patents, so I showed you
13 this slide, and what I want to do now is focus on what
14 might have happened had Impax launched at risk. And
15 we're not saying, to be clear, that Impax would have
16 launched at risk.

17 Complaint counsel's expert threw out three
18 hypothetical dates, and I just want to walk through
19 what would have happened had it launched on those three
20 hypothetical dates.

21 And the first hypothetical is that Impax
22 launches at risk after it gets FDA approval in June of
23 2010.

24 Well, at that point in time, Impax is in
25 litigation with Endo, and the judge has asked the

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1 other patents were issued that were close enough to
2 where Endo can sue and enjoin people from selling the
3 same drug.

4 MR. HASSI: Yes, Your Honor. Three at this
5 point. We've got the '482 on here twice, but yes,
6 there are three additional patents here, and Endo did
7 sue on those patents.

8 And if you can keep going.

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1 market.

2 A Delaware district judge upheld the '737 and
3 then later the '779 patent, and I believe it's one of
4 those two patents that's valid until 2029. The others
5 may be 2023.

6 So let's go to the next hypothetical, and that
7 is, suppose we wait for a district court decision and
8 we lose at the district court. Well, Impax doesn't
9 enter at risk. Impax doesn't enter. It just lost.
10 That's what rolling the dice means. That's what
11 continuing the litigation means.

12 Now, you can wait and hope to win at the
13 appellate court and hope to reverse the district court
14 judge, but the fact is, they were more likely than not
15 to lose at the district court level.

16 Next.

17 The third hypothetical that Professor Noll
18 throws out is maybe you wait for an appellate court
19 decision. And in that case, if there's a favorable
20 decision, Impax -- say that comes in in the fall of
21 2011, and this is assuming that there's no remand,
22 that there's no other issues, and that Impax wins at
23 the appellate court level.

24 So it gets to come in in 2011. And that's not
25 at risk, except as to the Johnson Matthey patent, which

1 at this point isn't in Endo's hands, but not long
2 thereafter Endo has acquired that patent. And Endo
3 acquires -- and just speed through the rest -- acquires
4 the additional patents, sues on the additional patents.
5 And one can only assume that Endo was suing -- if Endo
6 was suing Impax on the crush-resistant, if Impax had
7 not settled and didn't have the broad license, they
8 would have sued on Opana ER as well.

9 And so there's no real option here for Impax to
10 come on and stay on the market. This is why they got
11 the broad license.

12 Let's go to the next one.

13 And of course, in hypothetical number three, if
14 Impax loses at the appellate court level, they lose.
15 It's over. They're enjoined until those patents
16 expire.

17 So one other possibility -- and I think
18 Your Honor hinted at this -- is maybe you wait until
19 September 2013 when the patents expire. Well, that's a
20 fine option if you don't think Endo is going to get any
21 more patents.

22 Keep going.

23 But Endo did. And Endo sued on those patents,
24 and so waiting until September 2013 not only loses the
25 180-day exclusivity, but at that point Impax would have

1 to launch at risk as to the Johnson Matthey
2 '482 patent, the '122 and the '216 patent, and the
3 additional patents are not far behind.

4 Next slide.

5 So if we compare these scenarios to the real
6 world, Your Honor, what you have is no real
7 opportunity for Impax to come to market compared to a
8 real world where Impax settled with Endo, got a broad
9 patent license, came to market, is on the market
10 today, and will be on the market for the foreseeable
11 future.

12 Now, complaint counsel doesn't want to engage
13 in the kind of traditional balancing that's been the
14 hallmark of the rule of reason, balancing the
15 anticompetitive restraint against procompetitive
16 effects. They want a shortcut. They want
17 pay-for-delay to be just pay. They want to say that
18 if there's value being transferred from the brand to
19 the generic, you should presume that it's
20 anticompetitive.

21 Now, the Supreme Court rejected that in
22 Actavis, but we're going to ask you over the next few
23 weeks to look at the real world.

24 We're going to show you how the events unfolded
25 in the real world and how in the seven-plus years since

1 the settlement was entered into this has had a
2 manifestly procompetitive effect.

3 We're going to ask you not to ignore those
4 real-world facts, as complaint counsel asked the
5 commission to rule out. They didn't want to hear about
6 this stuff. You shouldn't ignore it.

7 You shouldn't ignore the fact that Impax got to
8 begin selling Opana ER before the patents Endo was
9 asserting had expired.

10 We don't think you should ignore the fact that
11 no one, no one ever successfully challenged the two
12 patents that were in suit between Impax and Endo that
13 led to this settlement.

14 We don't think that you should ignore the fact
15 that by settling, Impax got a license to existing and
16 future patents.

17 We don't think you should ignore the fact that
18 Endo's after-acquired patents have been upheld by two
19 different judges.

20 We don't think you should ignore the fact that
21 as a result of those patents, no other generic is on
22 the market.

23 We don't think you should ignore the fact that
24 because it settled, since January 1, 2013, Impax has
25 been meeting patients' needs for a lower-cost generic

1 Opana ER and that for at least a year now it's been the
2 only generic Opana ER available to consumers, and
3 finally, since September 1, 2017, it is the only
4 Opana ER available on the market.

5 Unless Your Honor has any questions,
6 thank you.

7 JUDGE CHAPPELL: All right. I'm going to make
8 some evidentiary rulings. Then we're going to take a
9 break before we call our first witness. But normally
10 at this time when the opening statements are
11 concluded, a lot of people head for the exit, so I'm
12 going to give you a couple minutes if you want to leave
13 now.

14 No one? Okay. That's new. All right.

15 Let's talk about joint exhibits. I'm going to give you 600 seconds.

16

17 I have offhanded -- for received from the parties

18

19

20 There has been any additional evidence, since

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22 MR. LOUGHLIN:

23 received this more in, Your Honor.

24 JUDGE CHAPPELL: Okay.

25

1 jointly offer this exhibit?

2 Government?

3 MR. LOUGHLIN: We do, Your Honor.

4 JUDGE CHAPPELL: Respondent?

5 MR. HASSI: We do, Your Honor.

6 JUDGE CHAPPELL: JX 2 is admitted.

7 (Joint Exhibit Number 2 was admitted into
8 evidence.)

9 JUDGE CHAPPELL: Stipulations of facts and law.
10 On Monday, I received a joint stipulation, JX 001, and
11 I am pleased to see the parties worked together on
12 this.

13 Is JX 1 offered as a joint exhibit by the
14 government?

15 MR. LOUGHLIN: It is, Your Honor.

16 JUDGE CHAPPELL: By respondent?

17 MR. HASSI: Yes, Your Honor.

18 JUDGE CHAPPELL: JX 1 is admitted.

19 (Joint Exhibit Number 1 was admitted into
20 evidence.)

21 JUDGE CHAPPELL: I have one other matter I'm
22 going to deal with, and then we'll take a break.

23 I received a trial brief regarding evidently a
24 discovery issue.

25 First of all, I'm going to let the parties

1 know, I do not want to see a trial brief unless I ask
2 for a trial brief. If I want it, I'll let you know.

3 But since that trial brief was filed, I need
4 to know, do you plan to respond and how long do you
5 need?

6 MR. HASSI: Your Honor, I'm not sure that there
7 is an issue here.

8 In other words, the trial brief, as we
9 understand it, addresses questions that were asked to
10 which we asserted a privilege. We don't intend to
11 waive that privilege, and we don't intend to offer
12 evidence related to -- so there were questions about,
13 for example, a model called the Zorn model that Impax
14 creates. We're not planning on putting that Zorn model
15 in, offering it up.

16 JUDGE CHAPPELL: You don't intend to offer
17 evidence or answers to questions that were objected to
18 and not answered during discovery.

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

20 JUDGE CHAPPELL: All right. I don't have a
21 motion pending before me now.

22 Do you want to add anything?

23 MR. LOUGHLIN: No, Your Honor. The issue is
24 that to the extent that witnesses make representations

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1 will object and ask Your Honor to rule that those
2 questions cannot be asked.

3 JUDGE CHAPPELL: When I get an objection, I'll
4 deal with it. But I'll let the parties know, there's a
5 difference in a fact and an opinion. And a fact is not
6 something that needs to be evaluated and analyzed by
7 one side or the other. If someone testifies to a fact,
8 I'm allowing that fact, unless that fact was not
9 allowed in discovery.

10 Any questions on that?

11 MR. LOUGHLIN: No, Your Honor.

12 MR. HASSI: No, Your Honor.

13 JUDGE CHAPPELL: Is the first witness here?

14 MR. HASSI: He is, Your Honor.

15 MR. LOUGHLIN: Yes, Your Honor.

16 JUDGE CHAPPELL: He's calling the first
17 witness (indicating)?

18 MR. LOUGHLIN: We're calling the first witness,
19 Your Honor; however, it is Mr. Koch, who is represented
20 by O'Melveny & Myers in this case.

21 JUDGE CHAPPELL: Okay.

22 All right. We're going to take about a
23 15-minute break, may be our last break for the day.
24 Before we do, hold on a second.

25 (Pause in the proceedings.)

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1 know it's there. It's got some exhibits that I might
2 be asking you about later. And there's also a bottle
3 of water there for you.

4 A. Thank you.

5 MR. MEIER: Your Honor, Mr. Koch is a former
6 employee of Impax, and that's the respondent in this
7 case. And under your order of October 18, 2017,
8 Mr. Koch has been deemed an adverse witness and subject
9 to examination by leading questioning, so I intend to
10 avail myself of that ruling.

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1 Q. And you met with Mr. Hassi for about seven
2 hours to prepare for your deposition.

3 A. Correct.

4 Q. You reviewed documents while meeting with
5 Mr. Hassi to prepare for your deposition.

6 A. I did.

7 Q. You were sent a copy of the transcript and
8 exhibits from an earlier FTC investigational hearing to
9 help you prepare for your deposition.

10 A. Yes.

11 Q. And Impax reimbursed you for your time and
12 expenses for testifying at the deposition.

13 A. Correct.

14 Q. Impax paid you \$500 an hour.

15 A. Correct.

16 Q. Impax also paid you for the time you spent
17 preparing for your deposition.

18 A. It did.

19 Q. And that was \$500 an hour.

20 A. Correct.

21 Q. Now, you sat for an investigational hearing
22 during the FTC's investigation in this matter.

23 A. I did.

24 Q. And that was held here in Washington, D.C.

25 A. It was.

1 Q. And that was a number of years ago.

2 A. Yes, it was.

3 Q. And you were represented at that time by
4 lawyers from O'Melveny & Myers; correct?

5 A. I was.

6 Q. And the O'Melveny & Myers lawyers were partners
7 of Mr. Hassi; correct?

8 A. They were.

9 Q. And that's the law firm representing Impax at
10 the hearing today; correct?

11 A. Yes.

12 Q. At the time of your investigational hearing,
13 O'Melveny & Myers represented both you and Impax;
14 correct?

15 A. That's correct.

16 Q. And you met with the lawyers before your
17 investigational hearing.

18 A. I did.

19 Q. And you met with them for at least a day to
20 prepare for your investigational hearing.

21 A. That's correct.

22 Q. In fact, you reviewed some documents when you
23 met with the lawyers from O'Melveny & Myers before your
24 investigational hearing.

25 A. I did. It was many years ago.

1 Q. And Impax paid you for your time and expenses
2 for testifying at the investigational hearing.

3 A. They reimbursed me for my time, yes.

4 Q. And they paid you \$500 an hour?

5 A. Yes.

6 Q. Did you meet with the lawyers from
7 O'Melveny & Myers to prepare for your testimony today?

8 A. I did.

9 Q. How long did you meet?

10 A. Probably six or seven hours yesterday.

11 Q. Did you review documents with the -- Impax'
12 lawyers?

13 A. I did.

14 Q. And are you being paid by Impax for the time
15 you spent preparing for your testimony today?

16 A. They're reimbursing for my time and my expense,
17 yes.

18 Q. \$500 an hour?

19 A. Correct.

20 Q. And are they paying for your time testifying
21 today, too?

22 A. Yes.

23 Q. And that's \$500 an hour.

24 A. Correct.

25 Q. Now, Mr. Koch, let's switch subjects and

1 discuss the time you worked at Impax and a little bit
2 about your professional experience.

3 You joined Impax in February of 2015.

4 A. 2005.

5 Q. I'm sorry. Correct. Thank you. Let me
6 rephrase that.

7 You joined Impax in February of 2005.

8 A. That's correct.

9 Q. And it might have been Valentine's Day in
10 February.

11 A. I think it was. Yes.

12 Q. And at the time you joined Impax, you'd already
13 had 30 years of finance, operations and public
14 accounting experience.

15 A. Correct.

16 Q. This included service as the chief financial
17 officer of three publicly traded healthcare companies;
18 correct?

19 A. Yes.

20 Q. And then you resigned from Impax in June of
21 2012.

22 A. I did.

23 Q. So you were at Impax for just about a little
24 more than seven years.

25 A. Correct.

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1 Q. Eventually you reported to Larry Hsu.

2 A. I did.

3 Q. And "Hsu" is spelled H-S-U; correct?

4 A. That's correct.

5 Q. You reported to Dr. Hsu when he became Impax'

6 CEO.

7 A. I did.

8 Q. And broadly speaking, your responsibility as
9 CFO was to manage the financial affairs of Impax;
10 correct?

11 A. Broadly speaking, yes.

12 Q. But more specifically, your responsibilities as
13 CFO included financial reporting, budgeting, investor
14 relations, and DC's tax affairs?

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1 Q. The Impax executive committee included the CEO,
2 the president of the brand division, the president of
3 the generics division, the vice president of
4 manufacturing and you.

5 A. Indeed.

6 Q. And the Impax executive committee was also
7 sometimes called the G5 because you had five members;
8 correct?

9 A. That's correct.

10 Q. You also served on the financial reporting
11 committee and the products development committees at
12 Impax; correct?

13 A. For both the brand division and the generics
14 division, yes.

15 Q. Right.

16 And that product development committee was also
17 sometimes called the new product committee.

18 A. That's correct.

19 Q. And as you just said, the company has one for
20 the branded division and one for the generic division.

21 A. Correct.

22 Q. And you served on both of those committees.

23 A. I did.

24 Q. During your seven years at Impax, Impax had
25 both a branded business unit and a separate generic

1 business unit.

2 A. I believe the brand business might have been
3 formed shortly after I got there, but there were brand
4 activities. It may not have been formalized.

5 Q. So during most of the time you were at Impax,
6 there was a branded --

7 A. Correct.

8 Q. -- division and a generic division; correct?

9 As part of your responsibilities at Impax, you
10 also served as the secretary of Impax' board of
11 directors?

12 A. For a time, yes, for a portion of the time.

13 Q. And additionally, as part of your
14 responsibility as CFO, you would regularly attend the
15 Impax board of directors meetings.

16 A. That's correct.

17 Q. And you made regular presentations to the board
18 of directors in your capacity as CFO.

19 A. I did.

20 Q. And it would be common for you to make
21 presentations to the board of directors at their
22 meetings.

23 A. Correct.

24 Q. When you made a presentation to the board of
25 directors, you would always try to be accurate.

1 A. Always.

2 Q. And if you saw a mistake in the presentation
3 materials you put together, you'd absolutely try to
4 correct it.

5 A. Absolutely.

6 Q. And the Impax board of directors would meet
7 quarterly.

8 A. Sometimes more frequently ad hoc, but there was
9 a quarterly scheduled, yes.

10 Q. So they would meet quarterly, and sometimes
11 they'd even meet more often than that.

12 A. That's right.

13 Q. And you typically reported the financial
14 results of the company and its performance against the
15 plan to the board; correct?

16 A. That's correct.

17 Q. What does "performance against plan" mean?

18 A. Comparing actual results to budgeted results.

19 Q. And "budgeted results" would mean what?

20 A. Each year, we would set an annual budget for
21 the business, and we would compare actual results to
22 the board -- we would compare actual results to those
23 plans to the directors as part of my presentation.

24 Q. Impax is a publicly traded company.

25 A. That's correct.

1 Q. And Impax is listed on the Nasdaq Stock
2 Exchange.

3 A. Correct.

4 Q. As part of your job as CFO --

5 JUDGE CHAPPELL: What's the stock symbol?

6 THE WITNESS: IPXL. IPXL.

7 JUDGE CHAPPELL: Has that been consistent since
8 it went public?

9 THE WITNESS: Yes.

10 There was a time, though, Your Honor, when we
11 were not registered on the exchange because of a
12 dispute we had with our accountants over revenue
13 recognition, so we lost our registration and had to
14 reregister in 2010.

15 JUDGE CHAPPELL: You were able to get the same
16 symbol?

17 THE WITNESS: Yes.

18 JUDGE CHAPPELL: Thank you.

19 BY MR. MEIER:

20 Q. As part of your job as CFO, you would review
21 Impax' filings required by the Securities and Exchange
22 Commission?

23 A. Yes.

24 Q. You were responsible for Impax'
25 Sarbanes-Oxley Act compliance?

1 A. I'm sorry. I couldn't hear that.

2 Q. Yes.

3 You were responsible for Impax'
4 Sarbanes-Oxley Act compliance?

5 A. Yes.

6 Q. And under Sarbanes-Oxley you had to
7 individually certify the accuracy of financial
8 information you reported for Impax.

9 A. I did.

10 Q. You were typically involved in the preparation
11 of Impax' annual reports; correct?

12 A. Most of the times our annual reports were a
13 wraparound our 10-K, so yes.

14 Q. And you would review drafts and proposals for
15 inclusion in the annual report.

16 A. Yes.

17 Q. And the same with the company's so-called 10-K
18 filing.

19 A. Correct.

20 Q. That's a filing you make with the SEC.

21 A. Yes.

22 Q. And Impax' financial plans, while you were
23 there, were based on the information available to you
24 at the time; correct?

25 A. Yes.

1 Q. And Impax' financial plans reflected the
2 company's best efforts at making estimates.

3 A. Yes.

4 Q. In addition to preparing plans, you and the
5 people who worked for you sometimes also prepared
6 forecasts.

7 A. Correct.

8 Q. And when you prepared forecasts, you would try
9 to use the best information available to the company at
10 the time.

11 A. Correct.

12 Q. And your mandate from the CEO and the Impax
13 board was to be accurate in your planning.

14 A. Of course.

15 Q. In your plans at Impax, something called an
16 upside scenario is -- in your plans -- sorry. If I
17 move the microphone closer, it's going to start sliding
18 down the lectern.

19 JUDGE CHAPPELL: You can raise that entire --

20 MR. MEIER: Yes.

21 JUDGE CHAPPELL: -- lectern or whatever it's
22 called. There's a button somewhere that will raise the
23 whole thing.

24 MR. MEIER: Yes. The problem, Your Honor, is
25 it starts to slope, and if I move the microphone, I

1 have book here it starts to slope in on. Sorry about
2 that. Let me start that over.

3 BY MR. MEIER:

4 Q. In your plans at Impax, something called the
5 upside scenario is a set of assumptions that are the
6 most beneficial to Impax; correct?

7 A. I wouldn't characterize it as most beneficial.
8 It was better -- it was a more favorable forecast than
9 a base case.

10 Q. So a base-case scenario wouldn't include many
11 of the if-everything-goes-right assumptions for the
12 company?

13 A. Correct.

14 Q. So if I have it correctly, a base-case
15 scenario was more conservative than an upside
16 scenario.

17 A. Yes.

18 Q. Mr. Koch, let's shift gears now and talk
19 about Impax' efforts to develop generic Opana.

20 Opana ER is a brand product manufactured by
21 Endo Pharmaceuticals or at the time that you were at
22 Impax; correct?

23 A. Yes.

24 Q. And Opana ER is an opioid.

25 A. It is.

1 Q. Opana ER is used to treat pain.

2 A. It is.

3 Q. Opana ER's generic name is oxymorphone
4 hydrochloride extended release.

5 A. Correct.

6 Q. One shorthand for generic Opana ER used inside
7 of Impax when you were at the company was oxymorphone.

8 A. Correct.

9 Q. Another shorthand you'd use for generic Opana
10 inside Impax was just the initials O, X and M;
11 correct?

12 A. Correct.

13 Q. Impax' generic business unit was responsible
14 for developing oxymorphone.

15 A. A generic for it, yes.

16 Q. And that was the business unit headed by
17 Chris Mengler at the time you were at Impax.

18 A. Correct.

19 Q. While at Impax you were aware of a patent
20 lawsuit by Endo Pharmaceuticals against Impax involving
21 generic Opana ER.

22 A. I was.

23 Q. And Endo's lawsuit concerning generic Opana
24 started sometime after you joined Impax.

25 A. It did.

1 Q. You testified at your deposition that Impax,
2 quote, had a formulation of generic Opana that the
3 company felt didn't infringe Endo's patents; is that
4 correct?

5 A. I either felt it didn't infringe or weana thxrtof generi i

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1 A. He was, yes.

2 Q. And the global pharmaceuticals division, that's
3 just the same name -- I'm sorry -- that was Impax' name
4 for the generic business unit.

5 A. That's right. We called the business unit of
6 the generics division global pharmaceuticals from -- in
7 different contexts over time. Yes.

8 Q. And like you, Mr. Mengler was a member of
9 Impax' executive committee at the time that he was
10 there.

11 A. Yes.

12 Q. And Mr. Mengler had been leading the
13 negotiations with Endo for Impax before you took over.

14 A. He did. He was.

15 Q. But you took over to get the project across the
16 finish line; correct?

17 A. Larry asked me to get a specific set of
18 objectives in the final negotiations. Yes.

19 Q. Before you personally became involved in
20 actually negotiating with Endo, you were kept regularly
21 apprised of the status of the negotiations as a member
22 of Impax' executive committee.

23 A. Yes. The committee was regularly updated.

24 Q. And during the time Mr. Mengler was leading the
25 settlement negotiations with Endo, you would give input

1 to him on the settlement terms.

2 A. As would other members of the executive
3 committee. Yes.

4 Q. As would other members of the executive
5 committee; correct?

6 A. Yes.

7 Q. And Meg Snowden, an in-house counsel at Impax,
8 was involved in the negotiations with Endo, too.

9 A. She was.

10 Q. And Ms. Snowden worked with you to complete the
11 negotiations.

12 A. She did.

13 Q. Larry Hsu, Impax' CEO at the time, was also
14 involved in the settlement negotiations but not
15 directly in the conversations with Endo; correct?

16 A. Well, his role as CEO, he was ultimately
17 responsible, yes, but he did not have direct contact
18 with Endo.

19 Q. So Larry Hsu, Impax' CEO at the time, was also
20 involved in the settlement negotiations but not
21 directly.

22 A. Correct.

23 Q. You were negotiating with Alan Levin, Endo's
24 chief financial officer.

25 A. I was.

1 Q. And you saw the final settlement agreement.

2 A. I did.

3 Q. You signed the final settlement agreement.

4 A. That's correct.

5 Q. And you signed the final settlement agreement
6 on behalf of Impax.

7 A. I did.

8 Q. Do you remember when Impax' settlement
9 agreement with Endo was signed?

10 A. June -- I don't remember the day. June 2010.

11 Q. In your 19 years working in the life sciences
12 industry, have you ever heard the term "first-to-file
13 exclusivity"?

14 A. Yes.

15 Q. "First-to-file exclusivity" is a term you've
16 personally used?

17 A. In a general sense, businessman sense, yes.

18 Q. What does "first-to-file exclusivity" mean in
19 your businessman sense?

20 A. It's a concept granted to a first filer under
21 the FDA's ANDA regulations for new products, new
22 generic products.

23 Q. And Impax was the first company to file an
24 ANDA with the so-called paragraph certifications for
25 the 5, 10, 20, 30 and 40 milligram dosages of Opana ER;

1 correct?

2 A. Correct.

3 Q. I'm sorry. Let me try to --

4 A. Oh, I'm sorry.

5 Q. I'm going to try to finish my question.

6 A. I'm sorry.

7 Q. I'm sorry. My voice probably tailed off there

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1 A. Correct.

2 Q. And at the time, those dosages comprised over
3 95 percent of Endo's Opana ER sales?

4 A. I don't remember the number, but it was a vast
5 preponderance, so I wouldn't dispute it.

6 Q. And so Impax was eligible for the first-filer
7 exclusion route it.

8 A. Correct.

9 Q.

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1 factors enter into determining whether it was most.

2 Q. So first-to-file exclusivity is very valuable
3 to a generic company because it helps the generic
4 company make more money.

5 A. Yes, it does.

6 Q. You are familiar with the term
7 "authorized generic"; correct?

8 A. I am.

9 Q. And "the authorized generic" is a term of art
10 used in your industry to describe an arrangement that a
11 brand company enters into with a generic manufacturer
12 to market a generic product of their own brand;
13 correct?

14 A. Yes.

15 Q. And in your experience, it's common for a brand
16 to launch an authorized generic.

17 A. It's hard to characterize it as common. It's
18 not un- -- it's not infrequent or rare. It happens
19 from time to time. But it's hard to know what one
20 means by "common." It happens frequently. It happens
21 often.

22 Q. As an element of negotiating a settlement
23 agreement with a brand, a no-authorized-generic
24 agreement would be a provision that Impax would
25 typically seek in a settlement; correct?

1 A. A lot of variables go into that answer because
2 it would depend on the plans by the brand to the extent
3 they were known. It would depend on the brand's prior
4 experience and history.

5 So it's not a categorical answer, but a general
6 answer is yes.

7 Q. So as an element of negotiating the settlement
8 agreement with a brand, a no authorized generic would
9 be a provision Impax would seek.

10 A. Yes.

11 Q. And Impax would seek a no-AG agreement because
12 the more control over the market a generic has, the
13 more predictable the outcomes will be, so the absence
14 of an authorized generic would mean more control.

15 A. The absence of an authorized generic would
16 mean --

17 Q. More control for the generic company.

18 A. That's correct. Yes.

19 Q. And control can often lead to higher profits;
20 correct?

21 A. Yes, it can.

22 Q. The settlement agreement that you signed on
23 behalf of Impax with Endo included a
24 no-authorized-generic provision; correct?

25 A. It did.

1 Q. And a no-authorized-generic term was part of
2 the settlement you signed.

3 A. Yes.

4 Q. And Endo agreed not to launch an authorized
5 generic of Opana ER in competition with Impax' generic
6 Opana; correct?

7 A. That's what "no AG" means. Yes.

8 Q. In addition to the no-authorized-generic term,
9 another subject of the settlement negotiation with Endo
10 was the date when Impax could enter the market with
11 generic Opana ER; correct?

12 A. Yes.

13 Q. And the date was one of the most important
14 elements of the settlement agreement.

15 A. Yes.

16 Q. Impax was seeking as soon a launch date as
17 possible as close to the expiration of your 30-month
18 stay as you could get.

19 A. Correct.

20 Q. The launch date under the settlement agreement
21 that you eventually entered into was January 1, 2013.

22 A. Correct.

23 Q. And Impax agreed to a specific launch date in
24 return for eliminating the uncertainty of the patent
25 litigation with Endo.

1 A. I'm sorry. Could you repeat that.

2 Q. Yes, I will.

3 Impax agreed to a specific launch date in
4 return for eliminating uncertainty of the patent
5 litigation with Endo.

6 A. Yes. Correct.

7 Q. Impax got final FDA approval to market generic
8 Opana shortly after entering the settlement agreement
9 with Endo.

10 A. That's what I remember. Yes.

11 Q. So you didn't actually get final FDA approval
12 until after you entered the settlement agreement.

13 A. Correct.

14 Q. So final FDA approval was sometime after
15 June 8, 2010?

16 A. Correct. Shortly after but after.

17 Q. Did it ever occur to you that when Impax agreed
18 not to launch generic Opana until January 2013 it was
19 giving Endo time to switch the market to a reformulated
20 version of Opana?

21 A. Yes.

22 Q. It did occur to you?

23 A. Yes.

24 Q. So you understood that when you entered the
25 agreement?

1 A. Well, it was understood when we entered into
2 the negotiations we had developed what we called a
3 carrot and a stick as a way to get more control than
4 just the lost control over that period of time.

5 Q. Do you remember discussing a negotiation term
6 that was referred to as an acceleration trigger with
7 Impax?

8 A. There was an acceleration trigger term
9 discussed with Endo. Yes.

10 Q. But the meaning of this acceleration trigger,
11 that changed over time during the negotiations;
12 correct?

13 A. Not really.

14 Q. Oh, it did not?

15 A. No. We never got an accelerated trigger.

16 Q. Right.

17 So -- but when it was first discussed, you
18 were talking about the opportunity for an earlier
19 launch date than the generic entry date Endo proposed.

20 A. Right.

21 Q. And Impax' interest in negotiating an
22 acceleration trigger with Endo was because one of the
23 other tools available to a brand is to develop
24 alternative products and switch the market.

25 A. Correct.

1 Q. You were concerned about Endo switching the
2 market on you before you had a chance to launch your
3 generic Opana; correct?

4 A. We were.

5 Q. And when a branded company does that, the brand
6 tries to switch patients away from the brand product
7 that Impax has the generic to in favor of a line
8 extension or other products that would not be covered
9 by Impax' ANDA.

10 A. Correct.

11 Q. But at some point the negotiations with Endo
12 moved away from an accelerated launch date in favor of
13 something that you understood as the make-whole
14 provision; correct?

15 A. Yes.

16 Q. You remember a term in the settlement agreement
17 that eventually was called the Endo credit?

18 A. I'm familiar with that term, but it was not a
19 term used while I was at Impax.

20 Q. So you remember calling the Endo credit term a
21 make-whole provision when you were at Impax.

22 A. Correct.

23 Q. And the make-whole was part of the carrot and
24 stick that I think you mentioned a moment ago that
25 Impax gave to Endo as an incentive to continue to

1 invest in the products to which Impax had the generic.

2 A. That's correct.

3 Q. And in return for Endo giving Impax an
4 agreement to accept the carrot and stick, Impax stopped
5 pursuing an earlier launch date.

6 A. It stopped pursuing that trigger, yes.

7 Q. In return for Endo giving Impax an agreement to
8 accept the carrot and the stick, Impax stopped pursuing
9 an earlier launch date; correct?

10 A. I wouldn't characterize it that way. We met
11 complete resistance to the concept of an earlier launch
12 date. We replaced that concept with another form of
13 insurance we called the carrot and the stick, which was
14 a royalty and downside protection.

15 Q. You said you wouldn't characterize it that way,
16 but if I showed you your deposition transcript
17 testimony where you actually said that, would that
18 refresh your recollection that you actually did
19 characterize it that way?

20 A. Yes.

21 Q. Okay. Could you please pull up the binder,
22 please. And if you look at the tabs, there's one
23 that's the very last one, at the bottom says "DEP."

24 Do you see that?

25 A. Yes.

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1 straighten it out a little bit by describing what was
2 going through my mind as we were evaluating this
3 settlement.

4 There was a period of time between the date of
5 our approval and the -- a date-certain launch of
6 January '13. We were worried about the control the
7 brand had over their product during that time, and we
8 were looking for a way to gain -- take back some of
9 that control away from the brand.

10 The tool that we ultimately pursued was the
11 what I called carrot and stick as an incentive in the
12 form of a carrot to incent them to continue to invest
13 in the product and a stick in the form of a penalty
14 should the market degrade over that period of time.

15 Q. And the penalty was what eventually was called
16 the Endo credit; correct?

17 A. That's correct.

18 Q. And you recall hearing that Impax was
19 eventually paid \$102 million by Endo under the terms of
20 the patent settlement agreement.

21 A. Correct.

22 Q. And that's the patent settlement agreement you
23 negotiated and signed for Impax on June 8, 2010.

24 A. Was there a question?

25 Q. Yes, there was.

1 The patents -- and that's the patent settlement
2 agreement --

3 A. Oh, sorry. Yes, it is.

4 Q. -- that you negotiated and signed for Impax on
5 June 8, 2010; correct?

6 A. Correct.

7 Q. In addition to negotiating the settlement
8 agreement with Endo, you negotiated an agreement that
9 became known as the development and co-promotion
10 agreement; correct?

11 A. I did.

12 Q. You also signed the development and
13 co-promotion agreement with Endo.

14 A. I did.

15 Q. You signed the co-promotion and development
16 agreement with Endo on behalf of Impax.

17 A. I did.

18 Q. Impax had not talked to Endo about the
19 development and co-promotion agreement before entering
20 into the patent settlement negotiations.

21 Let me try that again. I kind of mangled it.
22 I can see that you didn't hear me very well.

23 A. Okay.

24 Q. Impax had not talked to Endo about the
25 development and co-promotion agreement before actually

1 entering into the patent settlement negotiations;
2 correct?

3 A. That's correct, yes.

4 Q. The product that was to be the subject of the
5 development and co-promotion agreement eventually
6 became known as IPX-203.

7 A. It is. Yes.

8 Q. And Impax hoped that IPX-203 would become a
9 line extension of a product Impax called IPX-066.

10 A. It is. That's correct.

11 Q. If successful, IPX-203 would have been a brand
12 product.

13 A. It would have, yes.

14 Q. And as far as you know, Endo was the only
15 potential partner Impax was negotiating with concerning
16 IPX-203.

17 A. That's correct.

18 Q. At the time of the development and co-promotion
19 agreement, IPX-203 was at a very early stage of
20 clinical development.

21 A. Yes.

22 Q. In fact, IPX-203 was preclinical.

23 A.

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1 Q. Had it even been formulated at the time that
2 you had negotiated the agreement with Endo?

3 A. I don't know that the formulation had been
4 finalized. I think formulation work was underway.

5 Q. We've been talking about two agreements that
6 Impax entered with Endo in June of 2010, a settlement
7 and license agreement and a development and
8 co-promotion agreement.

9 You were involved in providing input on the
10 terms and conditions for both of those agreements;
11 correct?

12 A. I was, yes.

13 Q. And other members of Impax' executive committee
14 were also involved in giving their input on both
15 agreements.

16 A. They were.

17 Q. And both agreements were negotiated at the same
18 time.

19 A. They were.

20 Q. Both agreements were completed during the same
21 time.

22 A. They were.

23 Q. Sometimes you would talk to the Endo people
24 about the settlement terms and the development terms in
25 the same call.

1 A. I would.

2 Q. Most of the negotiations were actually done by
3 telephone; correct?

4 A. That's correct.

5 Q. And sometimes the terms for both of the
6 agreements were discussed at the same meetings that you
7 participated in within Impax.

8 A. I'm sorry.

9 Q. All right. So you would have meetings
10 internally within Impax.

11 A. Yes.

12 Q. Correct?

13 A. Yes.

14 Q. Like the G5 meetings?

15 A. Okay. Yes.

16 Q. And sometimes the terms for both of these
17 agreements were being discussed at the same
18 G5 meetings.

19 A. That's correct, yes.

20 Q. And you were discussing both at the same time?

21 A. Yes.

22 Q. And it was the same team negotiating both?

23 A. The same points of contact negotiating both.

24 Both -- both Endo and Impax had separate teams for each
25 of the projects because one was brand and one was

1 generic.

2 Q. Right.

3 But the teams that were actually doing the
4 negotiations --

5 A. Yes.

6 Q. -- on the call was the same people for Impax
7 doing both agreements; correct?

8 A. The contact, yes. The point of contact was the
9 same.

10 Q. And the same people for Endo; right?

11 A. That's correct.

12 Q. And you and Endo were both trying to get these
13 deals done.

14 A. We were, yes.

15 Q. I'd like to now talk to you about something
16 known in the pharmaceutical industry as launch at
17 risk.

18 You're familiar with the term "launch at risk";
19 correct?

20 A. I am.

21 Q. It's a term you've personally used?

22 A. Sure. Yes.

23 Q. It means launching a generic product in the
24 presence of patent litigation with a brand; correct?

25 A. Yes.

1 Q. And in your experience in the seven years at
2 Impax, Impax would evaluate at-risk launches from time
3 to time.

4 A. Infrequently, but yes.

5 Q. And whether Impax should launch generic Opana
6 at risk was under consideration by Impax in 2010.

7 A. It was, yes.

8 Q. But Impax ultimately settled its litigation
9 with Endo before Impax had final FDA approval to launch
10 generic Opana; correct?

11 A. It did.

12 Q. Successfully launching oxymorphone was a key
13 company goal for Impax in 2010; correct?

14 A. At certain points in time during 2010, the
15 February or January-February time frame, yes, it was.
16 That later changed in 2010 as developments unfolded
17 with the negotiations.

18 Q. All right. Well, successfully launching
19 oxymorphone was a key company goal for Impax in 2010;
20 correct?

21 A. January-February time frame.

22 JUDGE CHAPPELL: Hold on a second.

23 Impax referred to the generic drug as
24 Opana ER?

25 THE WITNESS: Yes.

1 A. Yes. But it's formulated with hydrochloride,
2 and there are some other ingredients. The shorthand is
3 "oxymorphone."

4 JUDGE CHAPPELL: So the prescription bottle
5 would say, if you've got the generic at CVS, it would
6 say "oxymorphone."

7 THE WITNESS: "HCl."

8 JUDGE CHAPPELL: "HCl." Okay. Thank you.

9 BY MR. MEIER:

10 Q. For hydrochloride?

11 A. I believe so, yes.

12 Q. Impax' CEO, Larry Hsu, would communicate the
13 company's key goals to management and staff annually;
14 correct?

15 A. Yes.

16 Q. And Dr. Hsu would do this in writing; correct?

17 A. Yes.

18 Q. And division heads like you would use the key
19 company goals to make sure you had the plans and
20 resources in place to accomplish those goals.

21 A. Yes.

22 Q. And the key company goals were also used as a
23 tool for setting compensation for Impax' employees.

24 A. Yes.

25 Q. The key compensation -- the key company goals

1 were used as a tool in setting the compensation of
2 executives at Impax like you.

3 A. Correct.

4 Q. In fact, the key company goals were used as a
5 tool in setting your compensation while at Impax.

6 A. That's correct.

7 Q. So, Mr. Koch, would you please look into your
8 binder at Exhibit Number CX 2562. That's the very
9 first tab.

10 And while you're doing that, I'll just state
11 for the record that this exhibit is included in JX 2
12 and has been admitted in evidence, and it is not
13 subject to Your Honor's in camera ruling.

14 JUDGE CHAPPELL: Thank you.

15 MR. MEIER: And I would ask Ms. Martin to pull
16 this up.

17 BY MR. MEIER:

18 Q. The first page is an e-mail from Dr. Hsu;
19 correct?

20 A. Yes.

21 Q. And you're one of the people who Dr. Hsu sent
22 the e-mail to. It's the third line down.

23 Do you see that?

24 A. I do.

25 Q. And you're Art Koch; correct?

1 A. I am.

2 Q. And the date of this e-mail was January -- I'm
3 sorry -- February 28, 2010; correct?

4 A. Yes.

5 Q. And the subject is key -- company key goals
6 2010.

7 A. Correct.

8 Q. And the e-mail says, "Attached please find the
9 finalized 2010 company key goals based on discussion in
10 the off-site meeting."

11 Do you see that?

12 A. I do.

13 Q. Did you participate in the off-site meeting?

14 A. Yes.

15 Q. And the next sentence says, "Please use this
16 document in setting your MBOs"; correct?

17 A. Correct.

18 Q. And "MBOs" means management by objective?

19 A. It does.

20 Q. Now, let's turn to the second page of CX 2562,
21 looking sort of at the very top first.

22 JUDGE CHAPPELL: Before you do that, where is
23 Impax located?

24 THE WITNESS: Head office is in Hayward,
25 California. There was a second office on the

1 East Coast in Doylestown, Pennsylvania.

2 JUDGE CHAPPELL: Thank you.

3 BY MR. MEIER:

4 Q. Looking at the second page of 2562, at the very
5 top, these are the 2010 company key goals for Impax;
6 correct?

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

8 Q. And now if we look to the middle of the page,
9 under the heading Generics Business, do you see the

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1 And Impax took steps in 2010 to prepare to
2 launch generic oxymorphone in 2010.

3 A. It did, yes.

4 Q. Impax management asked the manufacturing
5 people to begin to manufacture launch quantities in
6 2010.

7 A. Correct.

8 Q. And this required the purchase of raw
9 materials.

10 A. Among other things, yes.

11 Q. And it required the manufacture of pills.

12 A. Right.

13 Q. And some of the manufactured generic Opana by
14 the time of the settlement was already manufactured in
15 something called bright stock; correct?

16 A. Correct.

17 Q. And bright stock is product that's
18 manufactured, placed in bottles, but hasn't actually
19 been labeled yet.

20 A. That's correct.

21 Q. And some of the manufactured generic Opana by
22 the time of the settlement was manufactured as finished
23 goods; correct?

24 A. Yes.

25 Q. And "finished goods" means it's manufactured,

1 A. I would.

2 Q. And when you were comfortable, you would
3 circulate the minutes to the board of directors.

4 A. Correct.

5 Q. And there would be a motion to approve the
6 minutes at the next board meeting.

7 A. There would.

8 Q. And this motion would be voted on by the
9 board.

10 A. And recorded in the minutes.

11 Q. I'm sorry?

12 A. And recorded in the minutes.

13 Q. Okay. And when you say publishing the minutes
14 a moment ago, you mean the minutes would go into the
15 minute book.

16 A. That's correct.

17 Q. And the minute book is a record of Impax.

18 A. It is.

19 Q. And as secretary of the board, you would
20 actually sign the board-approved minutes?

21 A. I would.

22 Q. And you wouldn't sign the minutes unless you
23 believed they were accurate?

24 A. Correct.

25 Q. The purpose of the board minutes is to create a

1 record of the -- the purpose of the board minutes is to
2 create a record to show the deliberations the board
3 considers in the administration of the company.

4 A. Correct.

5 Q. The board minutes serve as a permanent
6 corporate record of the company.

7 A. That's correct.

8 Q. Do you recall testifying at your deposition
9 that no one at Impax would go to the board of directors
10 and make a recommendation about an at-risk launch
11 without the approval of the executive committee first?

12 A. Yes.

13 Q. Mr. Koch, I'd like to show you what's been
14 marked as CX 2663. It's in your binder.

15 And before pulling that up on the screen, I'd
16 just like to state that 2663 is included in JX 2, it
17 has been admitted in evidence, and that Impax has
18 requested partial in camera treatment for this exhibit,
19 but not for the part I plan to use. And consequently,
20 we've created a blacked-out version that blacks out the
21 in camera part.

22 With Your Honor's permission, I'd rather not
23 have the courtroom sealed. I've blacked out -- and I
24 represent to Your Honor that we've blacked out the
25 part that they've asked for in camera treatment of

1 because it's not the part I'm going to be asking
2 about.

3 JUDGE CHAPPELL: No. That's good. Thanks.
4 Go ahead.

5 MR. MEIER: Ms. Martin, would you please
6 project the redacted version of CX 2663 which blacks
7 out the in camera portion of this exhibit. Thank you.

8 BY MR. MEIER:

9 Q. Mr. Koch, you've seen CX 2663 before; correct?

10 A. I have, yes.

11 Q. And CX 2663 is the minutes of the Impax board
12 of directors meeting for May 25 and 26, 2010?

13 A. It is.

14 Q. And that's a few weeks before you actually
15 signed the settlement of the negotiations with Endo;
16 correct?

17 A. It is, yes.

18 Q. And if we look at the very last page, page 4 of
19 the minutes, that's your signature on page 4 of the
20 minutes; correct?

21 If we could just pull that up real quickly.

22 A. Yes, it is.

23 Q. And that's your signing in your capacity as
24 secretary of the board.

25 A. Correct.

1 Q. Going back to page 1, if we look at the second
2 paragraph, this is a paragraph that begins with
3 "Mr. Mengler reviewed."

4 Do you see that?

5 A. I do.

6 Q. And if I understand this correctly, Mr. Mengler
7 was making a presentation to the Impax board of
8 directors at this time.

9 A. That's -- yes.

10 Q. That's what you're reporting on in this
11 paragraph; correct?

12 A. Correct.

13 Q. And still looking at the second paragraph,
14 there's a sentence toward the bottom before the
15 blacked-out part where it starts with "He expressed the
16 view."

17 Do you see that?

18 A. I do.

19 Q. And it says, "He" -- meaning Mr. Mengler;
20 correct?

21 A. It is.

22 Q. -- "expressed the view that oxymorphone was a
23 good candidate for an at-risk launch"; correct?

24 A. Yes, it does.

25 Q. And if anyone had expressed disagreement with

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1 Q. And that was part of your official duties as
2 CFO.

3 A. Correct.

4 Q. And you were speaking on behalf of the company
5 when you did that.

6 A. I was.

7 Q. And it was part of your job responsibilities to
8 do that.

9 A. It was.

10 Q. And you'd make a prepared statement; correct?

11 A. I would.

12 Q. And then you'd also answer questions from
13 analysts; correct?

14 A. Yes.

15 Q. And Impax' earnings calls are public.

16 A. They are.

17 Q. So actually anybody could listen in.

18 A. That's correct.

19 Q. And the earnings calls are recorded.

20 A. They are.

21 Q. And there are various services out there that
22 prepare written transcripts of earnings calls;
23 correct?

24 A. That's correct.

25 Q. And one such transcription service is called

1 CQ Roll Call, Incorporated; correct?

2 A. Correct.

3 Q. And that happens to be the transcription
4 service that Impax used when you were there.

5 A. That's correct.

6 Q. Mr. Koch, I'd like to show you what's been
7 marked as CX 2703. It's also in your binder. It's the
8 third tab.

9 But before I call it up, let me state that,
10 Your Honor, CX 2703 is included in JX 2 and has been
11 admitted in evidence. The exhibit is a public document
12 and is not subject to your in camera ruling.

13 Ms. Martin, would you please put CX 2703 up on
14 the screen. Thank you.

15 Mr. Koch, looking at the cover of CX 2703, what
16 is it?

17 A. It's the cover published by the service
18 describing the Q3 2011 Impax Laboratories Earnings
19 Conference Call - Final, Fair Disclosure Wire,
20 November 1, 2011 Tuesday.

21 Q. So the date of the conference call would have
22 been November 1, 2011?

23 A. That's correct.

24 Q. Let's turn to page 3.

25 And I'm going to direct your attention to the

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1 Q. And by "recent settlements" you mean recent
2 patent settlements?

3 A. It's implied. Yes.

4 Q. And you were telling the investment community
5 at that time that Impax is going to save three million
6 in litigation expenses because of settlements.

7 A. Yes, that's correct.

8 Q. And one of those recent settlements was the
9 Endo settlement.

10 A. It was.

11 Q. But that was not the only settlement because
12 you used the plural "settlements"; correct?

13 A. Correct.

14 Q. So the Endo settlement was one of a number of
15 settlements for which Impax was able to lower its
16 estimate of litigation expenses by \$3 million;
17 correct?

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

19 Q. That's what you say.

20 A. That's what it says.

21 Q. No. That's what you said at the conference
22 call; correct?

23 A. Correct.

24 Q. Turning now to page 13 of the earnings
25 conference call transcript -- and actually, before I

1 Q. And you say, "Well, the switchout is a very
2 well-known strategy"; correct?

3 A. Yes.

4 Q.

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1 had a reasonable outcome almost no matter what Endo
2 did.

3 A. That's correct. We viewed it as insurance.

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

6 JUDGE CHAPPELL: Any cross?

7 MR. HASSI: Yes, Your Honor.

8 JUDGE CHAPPELL: Go ahead.

9 MR. HASSI: Your Honor, may I approach the
10 witness to give him a binder?

11 JUDGE CHAPPELL: Yes.

12 I've got a question for Mr. Meier.

13 Did you mean to ask whether if Endo did a
14 switch to Opana tamper-resistant? Didn't you mean
15 crush-resistant?

16 MR. MEIER: Well, at the time, it was called
17 tamper-resistant, Your Honor, if you look --

18 JUDGE CHAPPELL: So that's what you meant to
19 ask?

20 MR. MEIER: I meant to ask tamper-resistant.
21 That was the question that the analyst had asked. It
22 eventually became -- the name changed from
23 tamper-resistant to crush-resistant.

24 JUDGE CHAPPELL: All right.

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1 A. I do.

2 Q. What is "inventory" a reference to in the
3 financial statements of Impax?

4 A. "Inventory" refers to the carrying value of
5 product held for future sale, and it's usually carried
6 at cost or the -- an estimate of that cost as described
7 in its accounting policies.

8 Q. If you turn to the next page, page 101, using
9 the CX number -- and Robert, if we could blow up the
10 top of the page -- there's a section that starts on the
11 third line. It says, "When the Company concludes FDA
12 approval is expected within approximately six months,
13 the Company will generally begin to schedule
14 manufacturing process validation studies as required by
15 the FDA to demonstrate the production process can be
16 scaled up to manufacture commercial batches."

17 Can you start by telling us, what is process
18 validation?

19 A. It's a concept in manufacturing to show the
20 steps, the manufacturing steps necessary to manufacture
21 the pill, the product, and process validation is the --
22 a way to demonstrate to the agency that you can --
23 you've made small batches, now you can make large
24 batches similar to commercial volumes.

25 Q. In the statement I just read, was that

1 consistent with Impax' practices in 2010 when you were
2 the CFO?

3 A. Yes.

4 Q. With respect to -- strike that.

5 Why does a company have to do process
6 validation?

7 A. The FDA requires it.

8 Q. And would Impax schedule process validation for
9 a product even if it was the subject of active
10 litigation?

11 A. Yes.

12 Q. It goes on to say, "Consistent with industry
13 practice, the Company may build quantities of
14 pre-launch inventories of certain products pending
15 required final FDA approval and/or resolution of patent
16 infringement litigation, when, in the company's
17 assessment, such action is appropriate to increase the
18 commercial opportunity, FDA approval is expected in the
19 near term, and/or the litigation will be resolved in
20 the Company's favor."

21 Was that an accurate statement of Impax'
22 practices in 2010?

23 A. Yes.

24 Q. And why would a company build pre-launch
25 inventories of certain products?

1 A. Because the readiness, the preparedness for
2 launch, sometimes involved long lead items, and it's
3 much less expensive, in terms of the company's
4 financial goals, to prepare a small cost item to be
5 prepared for the launch into a large market.

6 Q. Can you explain what you mean when you say a
7 small cost item launched?

8 A. Cost of the pills is very low relative to the
9 market value of the products usually, so it's a small
10 cost.

11 Q. Did Impax build from time to time pre-launch
12 inventories of products that were still the subject of
13 litigation?

14 A. Yes.

15 Q. This statement says that doing so is consistent
16 with industry practice.

17 As someone who's got twenty-plus years in the
18 life sciences industry, do you think that building
19 launch quantities before approval is consistent with
20 industry practice?

21 A. Yeah. I believe it's routine, yes.

22 Q. If Impax builds pre-launch inventories for
23 products that are still the subject of litigation, does
24 that indicate that Impax expects the litigation will be
25 resolved in its favor?

1 A. It -- it may. It does not always, but it may.

2 Q. Okay. The statement goes on to say, "The
3 capitalization of unapproved pre-launch inventory
4 involves risks, including, among other items, FDA
5 approval of product may not occur; approvals may
6 require additional or different testing and/or
7 specifications than used for unapproved inventory, and,
8 in cases where the unapproved inventory is for a

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1 Q. And when you reserve against a product, what
2 happens to the product?

3 A. It's destroyed.

4 Q. Is that just a cost of doing business?

5 A. It is. Routinely.

6 Again, it's a small cost and it is a -- the
7 best way to describe it is a cost of doing business in
8 the generic industry.

9 Q. Do you know whether Impax made process
10 validation batches of oxymorphone?

11 A. Yes.

12 Q. And do you know what happened to those process
13 validation batches?

14 A. I believe they were ultimately destroyed.

15 Q. When Mr. Meier was asking you questions about
16 product that was made and bright-stocked, was that a
17 reference to process validation batches?

18 A. It included process validation batches and
19 some manufacturing that was done over and above that.
20 Yes.

21 Q. Was it unusual for you to have to write off
22 process validation batches such as you did with Opana?

23 A. No.

24 Q. How frequently did Impax have to write off
25 unused product or material?

1 Q. Do you recall what the status of that
2 litigation was?

3 A. I don't recall. Sorry.

4 Q. Do you recall whether there had been a
5 favorable district court decision for the generics on
6 that product?

7 A. Yes. Yes, there was -- there had been.

8 Q. And under what circumstances did Impax launch
9 OxyContin at risk in 2005?

10 A. We made a very controlled launch of the
11 product, capping the risk of the at-risk launch at
12 25 million in sales.

13 Q. How would Impax cap the launch at 25 million in
14 sales?

15 A. We would only sell -- we would sell \$25 million
16 worth of product and then withdraw from the market.

17 Q. And why would Impax cap its risk in this case
18 at \$25 million?

19 A. Well, because even in the case where we have a
20 favorable ruling from the lower court, there's still
21 risk of the patent litigation, and Impax, being a small
22 company, could not risk -- could not bet the company on
23 any one product and therefore had to cap its risk,
24 you know, given -- tailored to the specific market
25 characteristics.

1 Q. Do you know whether when you launched OxyContin
2 at risk whether any other generics were on the market
3 at that time?

4 A. I b eup a/Tjr 1 BD BDsp 4MCID 0BDC 1.8 -2.115 Td(Q.)TjEMC

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1 directors because every at-risk launch is a board-level
2 decision.

3 Q. If the executive committee was not in favor of
4 recommending a launch at risk, what would happen?

5 A. Work would stop and we would discontinue the
6 effort.

7 Q. And if the executive committee were to
8 recommend a launch at risk, did I hear you correctly it
9 would go to the board?

10 A. We would. That was always a board-level
11 decision.

12 Q. And how would the executive committee share its
13 recommendation to launch at risk with the board? What
14 format --

15 A. It would be a very formal presentation of the
16 background, the basis for the conclusion by the
17 executive committee to move forward, and then a draft
18 of a resolution seeking their vote and -- on the
19 matter.

20 Q. Who would participate in that presentation to
21 the board in the 2010 time frame?

22 A. It would be legal, the generics president,
23 myself, manufacturing. It would be a team.

24 Q. You mentioned a limit on the OxyContin risk.

25 Would as part of its recommendation to the

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1 the process of a launch at risk, so we shouldn't be
2 barred from addressing these subjects now.

3 MR. MEIER: Your Honor, I will agree that I
4 didn't press that issue during the deposition with
5 Mr. Koch, but that's because we had been foreclosed
6 time and time again in the depositions of other
7 witnesses about this issue.

8 If Your Honor will recall, when I put up that
9 CX 2663 where Mr. Mengler spoke to the board and I told
10 you that there was pieces of it that had been blocked
11 out by -- because of in camera, there was also a piece
12 where Meg Snowden, the general counsel or person in the
13 general counsel's office that you're going to hear from
14 later, that that was redacted for privilege.

15 After Mr. Mengler made the statement about this
16 would be a great opportunity to launch at risk, they
17 redacted Meg Snowden's comments to the board about that
18 very thing. I think it's inappropriate.

19 Maybe we haven't quite crossed that line yet,
20 but I think we're getting very, very close to that
21 line, Your Honor.

22 It's inappropriate to have this businessperson
23 now come up here and try to explain how the company
24 went about thinking about at-risk launch when everybody
25 in this room knows that lawyers were involved in those

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1 and I'm not asking questions that were objected to.

2 JUDGE CHAPPELL: But again I'll say what I said
3 earlier regarding a trial brief that came flying in
4 recently, that facts are facts, and every fact doesn't
5 get to be tested by someone's expert on analysis, on
6 fundamentals and other things. Facts are facts.
7 Witnesses can testify to facts, unless a question was
8 objected to and the question wasn't answered.

9 MR. HASSI: Thank you, Your Honor.

10 And I just wanted to add --

11 JUDGE CHAPPELL: And if you can show me,
12 Complaint Counsel, a question that was asked, what did
13 you do when the light turned green, objection,
14 privilege, that same question won't be allowed. That
15 answer won't be allowed.

16 MR. MEIER: I understand that, Your Honor. But
17 I'm also suggesting to the court that when it was
18 objected to with other witnesses, it's not appropriate
19 now to bring it in through this witness just -- I
20 didn't ask him -- I stayed away --

21 JUDGE CHAPPELL: And again, are you telling me
22 it's the same question?

23 MR. MEIER: No. We'll have to look for the
24 exact same questions, but as I said, Your Honor, the
25 document that I put up earlier shows that they did

1 exactly that. They redacted out the legal advice that
2 Ms. Snowden gave immediately after Chris Mengler said
3 this is a great opportunity for an at-risk launch. The
4 very next sentence, they blacked it out and they
5 redacted it for privilege.

6 And I don't think it's appropriate now to have
7 Mr. Koch come in here and sponsor testimony about how
8 they went about thinking about the risk of an at-risk
9 launch when we were prevented from exploring that in
10 discovery.

11 JUDGE CHAPPELL: The facts regarding when the
12 company has done at-risk launches, when they haven't
13 done at-risk launches, those are facts, and if those
14 facts were disclosed, those are coming in.

15 MR. MEIER: A hundred percent, Your Honor, a
16 hundred percent. That's different than this
17 discussion that's been going into what the board and
18 what the executive committee was presenting to the
19 board about their assessment of the risk. That's quite
20 a different question than how many times have you
21 launched at risk, what kinds of factors do you
22 generally consider when you launch at risk.

23 This is very specific advice that was being
24 given to the board that we've been prevented from
25 seeing.

1 JUDGE CH3 558 7209.6uELL: Did B tell me that these are 10
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3 Mr. Meil2 askRigthem. And I'll rC from his 10
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5 B're telling me this is information that's alrC y been rCve
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7 redaction on 2663, obviously that's just speculation in term
8 The paragraph goes on to speak abBTsomething 10
9 completely different, and so we don't know -- we don't know
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11 the view that oxymorphone was a good candidate for an at-ris
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1 answers to their questions and report back to the board
2 those answers and use the special committee as a tool
3 during the evaluation by the board.

4 Once everybody was satisfied, we would go to
5 the board for a full vote on the draft resolution to go
6 for an at-risk launch.

7 Q. And if the board authorized an at-risk launch,
8 what form would that authorization take?

9 A. It would be recorded in the minute book.

10 Q. Would there be a resolution?

11 A. Yes. There would be a resolution and a vote,
12 and both would be recorded in the minute book.

13 Q. If the board authorized the company to launch
14 at risk, would the company necessarily launch at risk?

15 A. You know, market conditions change on a daily
16 basis, and it's hard to say that by the time we were
17 able to launch at risk even with board approval
18 conditions still warranted it, so nothing about an
19 at-risk launch is set in stone. It's very fluid
20 because of the dynamics of the market and the
21 litigation.

22 Q. We've been talking about an at-risk launch.

23 What does the risk in an at-risk launch refer
24 to generally?

25 A. It's a very serious risk under the patent

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1 review of the recent results and a forward-looking
2 outlook for the next period of time.

3 I would make a presentation on the financial
4 performance against the company's budget and any
5 updates to that budget we were seeking as a result of
6 changes in condition.

7 Q. If at a board meeting management made a
8 recommendation to the board to authorize an at-risk
9 launch, is that the kind of thing that you would as the
10 secretary record in the minutes?

11 A. Very carefully. Yes.

12 Q. What about if there were a discussion about a
13 launch at risk at the board level? Would you include
14 that in the minutes as the secretary?

15 A. Yes.

16 Q. If there were a board vote on a launch at risk,
17 what would you as the secretary do?

18 A. That would be carried in the minutes.

19 Q. If a resolution were voted on by the board,
20 would that resolution appear in the minutes?

21 A. Yes.

22 Q. And if the board authorized a launch at risk,
23 how would that be reflected in the minutes?

24 A. The resolution authorizing management would be
25 recorded in the minutes and the vote on that resolution

1 also recorded.

2 Q. You were asked some questions -- do you recall
3 that Mr. Mengler made a presentation at the
4 May 2010 board meeting?

5 A. I do.

6 Q. Okay. If we can bring up CX 2662. And I'll
7 note for the record this document is in evidence and is
8 not in camera.

9 And looking at the cover e-mail of 2662, do you
10 recognize this?

11 A. Yes.

12 Q. Okay. Who was Mr. Mengler at the time?

13 A. President of the generics division.

14 Q. And he's sending this e-mail to a
15 Laura Bisbing.

16 Can you tell us who Ms. Bisbing was?

17 A. Laura was my secretary. She was responsible
18 for sending board materials out in advance of the
19 meeting.

20 Q. Let's take a look at the attachment that
21 Mr. Mengler sent.

22 Do you recognize this document?

23 A. Yes.

24 Q. And what is it?

25 A. Impax' board of directors meeting presentation

1 by Chris Mengler, president of global pharmaceuticals
2 or generics division.

3 Q. If you would flip to page -4, please, Robert.

4 What was Mr. Mengler's presentation to the
5 board about? What was the purpose of his
6 presentation?

7 A. As I said, each of the division heads would
8 give a history, a presentation on the recent past and
9 an outlook ahead. This is his presentation on sales
10 and marketing for the division.

11 Q. Let's turn to page -13 if we could.

12 What is this? What is this page about?

13 A. I'm sorry?

14 Q. What is -- what did Mr. Mengler indicate to the
15 board about oxymorphone at this meeting?

16 A. He's updating them on the status of the
17 product.

18 Q. Okay. There's a note toward the bottom. It
19 says under Remaining Issues "Validation Complete."

20 What does that mean?

21 A. Well, there are two different bullet points.
22 "Remaining Issues," I don't know what he meant. But
23 "Validation Complete" means we've completed the process
24 validation.

25 Q. And the next bullet says "Several additional

1 batches needed for full launch quantities."

2 What does that mean?

3 MR. MEIER: Your Honor, I'm going to object.

4 If they want to ask Mr. Mengler what
5 Mr. Mengler meant in his presentation to the board,
6 that seems appropriate to me, but to come in and bring
7 Mr. Koch in to talk about what Mr. Mengler was saying
8 and what Mr. Mengler was presenting, I think that's
9 inappropriate. And Mr. Mengler will be here I believe
10 tomorrow.

11 MR. HASSI: Your Honor, Mr. Koch was asked and
12 I want to connect this to the board minutes and a
13 reference in the board minutes about Mr. Mengler's
14 presentation. This is the presentation that Mr. Koch
15 wrote about in those minutes, and we think we're
16 entitled to ask him a few questions related to this.

17 JUDGE CHAPPELL: Well, the objection is
18 sustained as far as your asking this witness what
19 another witness intended or meant. If you're asking
20 what he heard or what he understood, I'll allow that.

21 MR. HASSI: Thank you, Your Honor.

22 BY MR. HASSI:

23 Q. What did you understand Mr. Mengler to be
24 conveying to the board about additional batches needed
25 for full launch quantities?

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1 JUDGE CHAPPELL: That objection is sustained.
2 That answer will not be considered.

3 MR. HASSI: Understood, Your Honor.

4 MR. MEIER: Your Honor, if I could also be -- I
5 appreciate your ruling, but --

6 JUDGE CHAPPELL: Well, he was violating what I
7 said earlier in that he was testifying to his
8 interpretation of what another man meant. That's why
9 I'm sustaining it.

10 MR. MEIER: Thank you very much.

11 BY MR. HASSI:

12 Q. Let's go to 2663, which are the board minutes.
13 And if we could blow up the second paragraph.
14 Mr. Koch, do I understand you were the author
15 of these minutes?

16 A. Correct. Yes.

17 Q. And as the author of these minutes, what did
18 you intend when you wrote, "He expressed the view that
19 oxymorphone was a good candidate for an at-risk
20 launch"?

21 A. And the simplest way I can describe what I
22 meant is he thought it was a great market opportunity.
23 And that's what I intended to communicate in those
24 words.

25 Q. What do you mean by "a great market

1 opportunity"?

2 A. Oxymorphone was a very rapidly growing product,
3 and we had a tentative approval or we had an
4 application that was going to be successful, and it
5 presented a great opportunity.

6 Q. Looking at these minutes, was there a
7 recommendation from the executive committee to launch
8 oxymorphone at risk made at this board meeting?

9 A. There's no discussion of an at-risk launch by
10 any -- I regret that I used the words "at-risk launch."
11 It's confusing the readers. There was no discussion of
12 an at-risk launch.

13 MR. MEIER: Your Honor, again, this is parts
14 redacted. We don't know what it says. I'm not really
15 sure how Mr. Koch can confidently testify based on this
16 one paragraph when there's all these other redactions
17 on this page.

18 MR. HASSI: Well, we anticipated Mr. Meier's
19 objection. If Mr. Koch would like to see the
20 unredacted portions that Mr. Meier redacted and
21 appropriately because it's in camera, we've given him
22 an in camera version in his binder that he can look at,
23 and we don't have to project it up on the screen, and
24 he can read the parts that complaint counsel redacted
25 if he needs to assure himself --

1 JUDGE CHAPPELL: Was he at the meeting?

2 MR. HASSI: He was, Your Honor. He took the
3 minutes.

4 JUDGE CHAPPELL: The way I heard the answer, he
5 said that there was no discussion at the meeting. He
6 can certainly tell us that if he recalls it.

7 MR. MEIER: If he recalls that from the meeting
8 but not from these minutes and this is the --

9 JUDGE CHAPPELL: Well, I thought it was
10 redacted.

11 MR. MEIER: But this shows -- the first
12 redaction there where it says "and Ms. Snowden
13 discussed," they redacted that for privilege. That's
14 not redacted for the in camera purpose. That was
15 redacted for privilege.

16 That's exactly what I was talking about
17 earlier, is that as soon as Mr. Mengler finishes
18 making this statement -- and by the way, it's not a
19 new sentence, it's a continuation of Mr. Mengler's
20 expression -- you have the lawyer Ms. Snowden
21 discussing, and then that's been redacted.

22 That's not the in camera redaction. That was
23 redacted for privilege, and so we don't know what it
24 says under there. We've never seen what it says under
25 there. We were denied from seeing what's under there.

1 launch, would you have reflected -- of oxymorphone at
2 this meeting, would you have reflected that in the
3 minutes?

4 A. Absolutely.

5 An at-risk launch is something that, you know,
6 is a very serious undertaking by the company, and if
7 there was a discussion about it by the directors, I
8 would have noted that.

9 Q. If a resolution had been put before the board
10 with regard to an at-risk launch of oxymorphone at this
11 meeting, would it be reflected in the minutes?

12 A. Absolutely.

13 Q. Do you see one reflected in the minutes? And
14 if you need to look at the in camera version, it's in
15 your binder.

16 A. Yeah, I don't need -- there was no resolution.
17 I would have written the resolution, and there was no
18 resolution for oxymorphone.

19 Q. If the board was asked to vote about an
20 at-risk launch, would you have noted that in the
21 minutes?

22 A. Absolutely.

23 Q. Is there any -- was there any vote taken at
24 that meeting with regard to an at-risk launch of
25 oxymorphone?

1 A. There was not.

2 Q. In your time at Impax, was the board of
3 directors of Impax ever asked to vote on an at-risk
4 launch of oxymorphone?

5 A. No.

6 Q. Did management ever make a recommendation to
7 the board of directors for an at-risk launch for
8 oxymorphone?

9 A. We did not.

10 Q. In your testimony, Mr. Meier asked you whether
11 an at-risk launch was being considered by the
12 management. Do you recall that?

13 A. I do.

14 Q. Can you describe what sort of consideration
15 generally management was giving to an at-risk launch at
16 this point in time?

17 A. We were looking at possible scenarios and at
18 different points in time -- our calendar -- our fiscal
19 year is a calendar year, so in the beginning of the
20 year, we'll make a budget and we'll describe the
21 assumptions included in those budgets. And
22 frequently, almost on a monthly basis, circumstances
23 will change, requiring an update to those budgets.

24 So at different points in time and I remember
25 in early 2010 we were -- we budgeted, we forecasted, we

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1 So it's his analysis. He's communicating his
2 analysis of the market opportunity.

3 Q. Why would you share that information with the
4 board of directors if management is not prepared at
5 this time to recommend a launch at risk?

6 A. Because we were unsure of what direction we
7 were to ultimately take and we didn't want the case --
8 we didn't want to come back to the board seeking an
9 at-risk launch with them never having heard of it
10 before, so almost at the earliest time we can think of
11 we would scope out for them the market profile. And
12 this -- and that was what Chris was doing here.

13 Q. I want to jump now to the negotiation of the
14 settlement and the negotiation of the separate
15 development and co-promotion agreement.

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1 ten, ten to fifteen minutes.

2 JUDGE CHAPPELL: I don't see us finishing
3 before 6:00, so we're going to call it a day.

4 Is this a good breaking point?

5 MR. HASSI: It is a good breaking point, yes,
6 Your Honor.

7 MR. LOUGHLIN: Your Honor, can I ask a question?

8 Since the witness is on the stand, can I
9 assume that counsel is prohibited from discussing any
10 testimony with the witness until the case is over?

11 JUDGE CHAPPELL: You two work something out. I
12 don't want to hear things like this at the end of the
13 day. Talk among yourselves, come up with an
14 agreement, and if you can't settle it, let me know in
15 the morning.

16 Thank you, sir. You can take off. But be back
17 in the morning.

18 THE WITNESS: Thank you, Your Honor. I will.

19 JUDGE CHAPPELL: Anything further?

20 MR. HASSI: Nothing further from respondents,
21 Your Honor.

22 JUDGE CHAPPELL: Okay. Until tomorrow morning
23 at 9:45 we're in recess.

24 (Whereupon, the foregoing hearing was adjourned
25 at 5:32 a.m.)

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CERTIFICATE OF REPORTER

I, JOSETT F. WHALEN, do hereby certify that the foregoing proceedings were taken by me in stenotype and thereafter reduced to typewriting under my supervision; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

s/Josett F. Whalen

JOSETT F. WHALEN

Court Reporter