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FEDERAL TRADE COMMISSION

I N D E X

IN THE MATTER OF IMPAX LABORATORIES, INC.

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A. Yes. Well, the -- typically we do define the relevant market and examine competitive conditions in the relevant market. I testified that on occasion you do have the natural experiment of observing, if you believe that generic entry would dissipate monopoly power, of observing the effects of generic entry and seeing whether in fact it dissipated monopoly power and expanded output.

Q. And can you remind us why output is important to look for?

A. Because from the economic standpoint, consumer harm comes about because of a reduction in output brought about by a monopolist.

The harm to consumers comes from the reduction in output, and so when we see monopoly power being dissipated, we see an expansion in output.

Q. And can you remind us, did you see an expansion of output in oxymorphone ER when Impax launched its product in January 2013?

A. No, I did not.

Q. And I believe you testified yesterday that in your decades of experience studying the pharmaceutical industry, you have seen instances where a generic entrant caused an expansion in output. Did I --

A. Certainly -- I beg your pardon.

Q. I'm sorry.

Did I get that right?

A. Certainly that generic entry has been followed by an expansion in output.

Q. And as I recall, yesterday you testified that if the brand company does not have monopoly power, then the analysis stops right there; correct?

A. That's correct.

Q. But if we assume that the brand company does have monopoly power, then can you please remind us how the analysis proceeds.

A. Well, then you proceed to the second prong of the analysis, whether you've assumed the monopoly power or found it to exist, which is to ask whether the settlement at issue was any less effective at dissipating completely or partially the monopoly power that you found or assumed than would have transpired but for the settlement.

So it's really a test of consumer benefits in two worlds, the world that we actually have with the settlement that took place and a but-for world where no settlement happened.

Q. And I believe you testified yesterday that the relevant but-for world is one in which the parties continue to litigate instead of settling the patent

case. Is that right?

A. That's correct.

And the reason for that is that we have no reason to believe that any alternative settlement would actually have been acceptable to the parties. To hypothesize a settlement and say they would have agreed to it would be the purest speculation, and so the only real alternative we have to the settlement that we have before us is that the parties continue to litigate.

Q. And can you remind us what that but-for world looks like in this case.

A. Well, we can be informed quite a bit about that but-for world by the events that unfolded actually in the world as we observed them and from what we understand about the economic incentives of the parties, in particular Endo.

And what we saw in the actual world was that Endo continued to acquire patents, both patents that had been applied for and patents that it acquired from others, and continued to assert them against ANDA filers.

Q. And yesterday you mentioned the Johnson Matthey patent.

Can you remind us when that patent issued.

A. That patent issued at the end of 2010. But Johnson Matthey had put Endo on notice of that pending patent in 2009.

Q. And Endo in the real world ultimately acquired that patent; correct?

A. It did. In March 2012.

JUDGE CHAPPELL: What other world would there have been?

MR. McINTYRE: Huh?

JUDGE CHAPPELL: You asked him about the real world. What other world would there have been?

MR. McINTYRE: That's a fair point, Your Honor.

JUDGE CHAPPELL: I've heard him say "actual world." I'm assuming that's the same thing; right?

THE WITNESS: Yes, Your Honor.

JUDGE CHAPPELL: Actual world, real world, this world?

THE WITNESS: The actual things that happened, the events that actually transpired, as opposed to what we need to really hypothesize as the alternative to the settlement.

BY MR. McINTYRE:

Q. And I believe you testified yesterday, Dr. Addanki, that in your report you assumed, in

reliance on Mr. Figg's opinions, that had Impax and Endo continued to litigate the original patent case to a final conclusion, that they would not have received a nonappealable, final judgment until November 2011 at the earliest. Did I get that right?

A. That's correct.

Q. And so can you walk us through, beginning with that point in the but-for world, the issuance of a Federal Circuit opinion in the patent litigation, how the but-for world would have played out from that point.

A. Well, again, I just want to remind all of us that in the actual settlement that we have before us, Impax and consumers got two things from that settlement, an entry on a date certain in January 2013 and a license under future Endo patents, so I think we need to keep those two mileposts in mind.

In the but-for world, had there not been a final, nonappealable resolution of the original patent case until November 2011, I would expect that Endo and Impax would have been embroiled in continuing patent litigation from the time of the settlement that we actually observed for many years after.

JUDGE CHAPPELL: Hold on a second.

When you say you would expect they would have been embroiled in continuing patent litigation, is that an assumption, a prediction, an opinion? What is that?

THE WITNESS: It is an opinion and a prediction, Your Honor. It is what I would expect as an economist looking at what Endo actually did, which was to sue ANDA filers on all the patents that it had and all the patents it was getting as of when it got them.

And so that's the basis for my expectation as an economist and my opinion that this is what would have happened, that the patent litigation would have not had any hiatus, it would have continued with new patents.

JUDGE CHAPPELL: So that is an opinion.

Is that based on some type of model or is that based on the facts as you assume them to be?

THE WITNESS: It's based on the facts that I see that Endo -- what Endo actually did, what I can infer about Endo's strategy from those facts, and what I would assume as an economist would be Endo's rational -- what I could infer as an economist would be Endo's rational strategy to pursue had it not settled with Impax.

JUDGE CHAPPELL: All right.

BY MR. McINTYRE:

Q. And so, Dr. Addanki, if, as you say, Endo and Impax would have been tied up in litigation for years in the but-for world, what does that tell us about

with an entry from Impax. And any such entry by Impax would have been a launch at risk.

Q. And what do you mean, that any such entry by Impax in the but-for world would have been a launch at risk?

A. What I mean is, as long as Impax and Endo continued to be embroiled in patent litigation, had Impax launched before resolution of that litigation, the launch would expose Impax to potential damages in the form of lost profits in a patent case.

Q. And remind us, I believe you testified yesterday that you have previously testified as an expert witness on patent damages? Correct?

A. On several occasions, yes. And I have written articles about it and lectured about it.

Q. And can you explain to us from an economic perspective what "lost profit damages" refers to.

A. The -- the concept there, Your Honor, is simply that the damages owed by Impax were it found to be infringing a patent, Endo's patents in this case, would be the profit that Endo would have made on each sale that Impax made in place of Endo.

And given that brand manufacturers, as we discussed yesterday, sell for higher prices than the generic manufacturers, that means that on every unit

and every pill that Impax sold in place of Endo, the patentee, the lost profit that Endo could claim on that pill would be greater than the profit that Impax would actually earn selling that pill, so the exposure to damages would exceed any profits from the launch.

Q. Dr. Addanki, did you assess Impax' economic incentives and disincentives for launching at risk?

A. Yes, I did.

Q. And what did you conclude?

A. Well, I concluded that it was perfectly reasonable for Impax to view a launch at risk as a losing proposition, and that's for two reasons.

One is exactly what I just said, which is the potential profit earned by Impax from the launch would fall short of the lost profit exposure should it have been found liable for infringement and liable for damages.

That's exacerbated here by the fact that Actavis also had a settlement agreement in place, a preexisting settlement agreement in place, with Endo which would trigger Actavis' entry upon the expiration of the 180-day exclusivity that Impax could claim.

Once Actavis entered, you would have further deterioration in Impax' profitability with further damages occurring to harm Endo, and so that just

worsens the picture from the standpoint of the cost-benefit analysis of the launch.

risk in the but-for world, how would consumers have fared?

A. Well, again, if Impax would not have launched at risk but for the settlement, we know that Impax was entitled to and actually did launch on January 1, 2013 and that it has remained on the market since that time.

But for the settlement, had there been continued litigation, as I fully expect there would have been because of all I've explained so far, and had Impax not been willing to launch at risk, then Impax would not have launched at any date before January 1, 2013, if at all, to date, just based on the events that have actually occurred in the real world with the ongoing litigation.

Q. And does your opinion depend in any way on how the patent suits between Endo and Impax would ultimately have been resolved?

A. No. This is simply a question of whether consumers would have been better off had Impax not settled with Endo and taking account of the continuing litigation that Endo engaged in and under the assumption that Impax would not have launched at risk.

It doesn't matter for purposes of my opinion there whether ultimately Endo would have prevailed in

these patent lawsuits or Impax would have prevailed, because all of those events would unfold after the dates we're talking about.

And just to remind us of the facts of what happened, in 2016 all generics were enjoined from selling oxymorphone ER, and today Impax is the only seller of that product.

Q. And so having applied your analysis in this case, what do you conclude about whether the Impax-Endo settlement agreement was anticompetitive?

A. Well, based on the facts I've analyzed, to begin with, the correct test is a two-part test, a screen for monopoly power, and if we assume or find monopoly power, we proceed to the second part. If we don't, we can stop the analysis there. The agreement would not be anticompetitive.

If we assume monopoly power, contrary to my

screen, what -- can you remind us what your conclusions are about the relevant market in this case.

A. The relevant market is no smaller than the market for long-acting opioids, extended-release long-acting opioids, in the United States. And Endo had no monopoly power in that market. Opana ER had no monopoly power in that market.

Q. Now, before we wrap up, Dr. Addanki, yesterday we spent some time discussing Dr. Noll's opinion that Impax received a large and unjustified payment as of June 2010 under the Endo credit and no-AG provisions of the settlement. Do you recall that?

A. I do.

Q. And I believe you testified that you reviewed both of -- both the original report and the rebuttal report that Dr. Noll had submitted in this case?

A. I did.

Q. Did Dr. Noll conduct any expected value calculations of the Endo credit and no-AG provisions either separately or in tandem?

A. Dr. Noll did not conduct an expected value calculation because he acknowledged that there were no probabilities available to populate such an expected value calculation.

MR. McINTYRE: Your Honor, may I briefly confer with counsel?

JUDGE CHAPPELL: Go ahead.

MR. McINTYRE: We have no further questions at this time.

JUDGE CHAPPELL: Any cross?

MR. LOUGHLIN: Yes, Your Honor.

JUDGE CHAPPELL: Go ahead.

MR. LOUGHLIN: Your Honor, may I approach with

"Actavis."

MR. HASSI: I've always said "Actavis." I heard him say "Actavis," and I know it's a client of his, so...

JUDGE CHAPPELL: Thank you.

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CROSS-EXAMINATION

BY MR. LOUGHLIN:

Q. Good morning, Dr. Addanki.

A. Good morning, Mr. Loughlin.

Q. Now, in your report, you discuss what you call a pure term-split settlement; correct?

A. I do.

Q. And by "a pure term-split settlement" you mean a settlement on an entry date without any payment terms; correct?

A. I mean a settlement on an entry date with no other terms whatsoever.

Q. Okay. I mean, there would be some other terms presumably; right? There would be normal contract terms, but you mean no terms related to any sort of payments.

A. I mean no terms related to anything other than whatever you attorneys would need to put in to make an agreement an agreement, but really no terms of any

economic import other than an entry date.

Q. Okay. Now, the settlement in this case is not a pure term-split settlement; correct?

A. That's correct.

Q. It has a no-AG agreement in it?

A. It has various provisions in it, including a no-AG agreement.

Q. It has an Endo credit provision in it?

A. That's correct.

Q. Now, Dr. Addanki, going into a settlement negotiation, all else equal, a branded company prefers later generic entry to earlier generic entry; correct?

A. That's correct.

Q. And all else equal, a generic would prefer earlier entry to later entry; correct?

A. Yes.

Q. Now, I want you to assume, Dr. Addanki, that a brand and a generic company are in settlement negotiations, and they cannot agree on an entry date in a pure term-split settlement. Okay?

A. Okay.

Q. And that's because the generic wants an earlier entry date and the brand wants a later entry date.

Do you have that?

A. Okay.

Q. The brand then offers a cash payment to the generic. Okay? And the parties reach a settlement. Okay?

A. Okay.

Q. In that hypothetical, you would assume that the entry date has moved back towards the brand's later entry date; correct?

A. So if there is nothing known other than they couldn't reach an agreement on an entry date and -- in your hypothetical, and the only thing that changes is that the brand says, I'll pay you some money, you're asking can we infer that the entry date -- and what do you mean by "the entry date"? They agreed on an entry date in your hypothetical.

Q. In my hypothetical, yes, after the payment of cash, the parties now have reached a settlement, including an entry date.

And my question is, we know from those facts that the entry date has moved back in time towards the brand's later entry date; correct?

A. When you say "moved back in time," I'm not sure what you mean by "moved back in time" because there was no entry date before.

Q. Okay. Then the entry date has -- the agreed-upon entry date is now going to be at the

brand's later entry date rather than the generic's earlier entry date; correct?

A. Well, by hypothesis, it's a date that the brand agreed to, right, so it is presumably within what the brand finds agreeable as an entry date. But I'm not sure you can call it later than or earlier than anything, because there is no other entry date on the table.

Q. Okay. Let's do it this way then.

A. Okay.

Q. We're going to do it the same way we did it in the deposition. Okay?

So we're going to assume that the generic wants a generic entry date no later than January 1, whatever year you want to pick. Okay?

A. Okay.

Q. The brand wants generic entry no earlier than June 1 --

A. Okay.

Q. -- whatever year -- the same year.

Do you have that?

A. Okay.

Q. The brand now -- and they can't settle, okay, under those terms.

A. Right.

Q. The brand now makes a cash payment to the generic. Okay?

A. Okay.

Q. And they reach a settlement.

A. Okay.

Q. The entry date is going to be June 1 or just about June 1; correct?

A. It's your hypothetical. I don't know. If you tell me it's June 1, okay, it's June 1.

Q. I'm not asking -- I'm not stating that as a hypothetical.

I'm stating that you can infer and you know as an economist that when I tell you they settled, the entry date that you're going to expect is going to be June 1; correct?

A. Well, it has to be agreeable to the brand, that's correct.

Q.

fact that they didn't agree. They didn't agree.

Parties do all sorts of things in negotiation. They've got postures.

So I don't think you can infer what someone's true reservation date was from a negotiation posture in a settlement negotiation. But in a hypothetical you can assume anything you like.

Q. Okay. And this is a hypothetical.

A. Right.

Q. Okay? Can you follow a hypothetical, sir?

A. Sure.

JUDGE CHAPPELL: I'm trying to follow your hypothetical also.

MR. LOUGHLIN: Great.

JUDGE CHAPPELL: And the way you presented it, you gave the witness two possible dates.

MR. LOUGHLIN: That's right.

JUDGE CHAPPELL: You told him to assume a cash payment.

MR. LOUGHLIN: Right.

JUDGE CHAPPELL: So if I'm following your hypothetical correctly, you're giving the witness only two possible choices, one date or the other date.

MR. LOUGHLIN: That's not -- I'll be clearer.

JUDGE CHAPPELL: All right.

BY MR. LOUGHLIN:

Q. Here's my hypothetical.

A. Okay.

Q. Going into the negotiation, the generic wants to come in no later than January 1.

A. So you're asking me to assume that we know that.

Q. We know it.

A. We know it. Okay.

Q. Okay?

The brand does not want generic entry to occur before June 1. We know it.

A. And again, that's something we can know what's the actual -- and that's called a reservation date, Your Honor. We know the actual reservation date for both parties.

Q. Under those --

(Counsel and witness speaking at the same time and cautioned by court reporter.)

BY MR. LOUGHLIN:

Q. Under that situation, there will not be a pure term-split settlement; correct?

A. That's correct.

Q. But under my hypothetical, now, the brand makes a cash payment to the generic. Okay?

A. Okay.
Q. And they reach a settlement. Okay?
A. Okay.
Q. You know, as an economist, that the entry date they will have agreed upon will be the brand's entry date of June 1; correct?
A. So if we know what the generic wants and we know what the brand wants, and you tell me that a payment made a settlement possible, then yes, I would say that both parties had to have agreed to it, and because you told me to assume that the brand would settle for nothing earlier than June 1, I would have to agree that it would be June 1.
Q. And the same is true if I change my hypothetical to, instead of a cash payment, now there's a no-AG provision; correct?
A. Oh, I don't know about that. I think that depends a lot on how a no-AG provision is valued.
JUDGE CHAPPELL: I'm not sure I understood your question. He answered it, but were you saying -- was your question, is the same true if there is no-AG agreement? That's not what I heard. Is that what you were asking? The same is true if there is no-AG agreement?
MR. LOUGHLIN: Rather than a cash payment,

there's a no-AG provision. I'll state the hypothetical differently.

JUDGE CHAPPELL: Is that what you understood?

THE WITNESS: That's what I understood his question to mean, sir.

JUDGE CHAPPELL: All right.

BY MR. LOUGHLIN:

Q. I'll restate it just so the record is clear.

A. Okay.

Q. We're going to assume that the parties are in a settlement negotiation, the generic wants to come in no later than January 1. Okay?

A. I'm listening. Yes.

Q. The brand does not want the generic to come in any earlier than June 1; correct?

A. Okay.

Q. Okay?

They can't reach a pure term-split settlement; right?

A. Well, they can't -- based on the assumptions you've asked me to make, they can't, that's correct.

Q. Now, I'm telling you that the brand offers a no-AG provision and they settle. Okay?

Do you have that in mind?

A. Okay.

Q. You would expect --

JUDGE CHAPPELL: Hold on, hold on.

Just so I'm following this, there's no cash being offered now; correct?

settle, right, and that's what you're telling me, well, then if they settled, it had to be a date agreeable to both parties. And if it was a date agreeable to both parties, I have to assume that it was somewhere for some reason at a point where both would agree to. But not knowing what the value of the no-AG agreement is, if at all, I'm stuck sort of having to make assumptions about what might have happened in your hypothetical.

Q.

MR. LOUGHLIN: Your Honor --

JUDGE CHAPPELL: You're giving him two dates --

MR. LOUGHLIN: In my hypothetical, that's what I'm saying.

JUDGE CHAPPELL: All right. Thank you.

I'm not the witness, but I'm going to be reading the record trying to make sense of the hypothetical and the answer.

MR. LOUGHLIN: No. I appreciate that, Your Honor. I want it to make sense and I appreciate your questions.

BY MR. LOUGHLIN:

Q. Now, Dr. Addanki, I want to go back to my hypothetical. Okay?

Again, we're assuming that the generic in the settlement negotiation does not want to and will not accept an entry date later than January 1. Okay?

A. Okay.

Q. And the brand will not accept generic entry earlier than June 1; correct?

A. Okay.

Q. And so under that scenario, there will not be a pure term-split settlement; correct?

A. If we know that the latest the entry -- latest entry date the generic would accept is January 1 and the earliest entry date the brand would accept is June 1 and we actually know that, then I would not

expect to see a settlement.

Q. Okay. And then the brand provides some other form of value, net value, going to the generic. It doesn't matter what it is, whether it's a no-AG, whether it's cash or something else. There's net value from the brand to the generic, and they settle. Okay?

A. Okay.

Q. As an economist, you know the settlement entry date that they're going to agree on is the brand's June 1 date; correct?

A. No. No, you don't. Because you don't know what value the other terms may have conferred on the brand.

Q. Yes, but I'm -- in my hypothetical, the net value is going from the brand to the generic. Okay? Do you have that? And that allows there to be a settlement. Okay?

A. Well, there could be value going from the brand to the generic, but that doesn't mean there isn't value that could be accruing to the brand, not as a payment from the generic, but from whatever other terms they've entered into.

Q. In my hypothetical, the net of the value is going only to the generic. Okay?

Do you understand that?

A. Well, the point about net is you're netting -- you can only net things where they're opposite flows between the same points. That's a net, right. But if the brand is realizing value that is not coming out of the generic, then I don't think you can make any conclusions about where the date is going to end up.

Q. Okay. That's not part of my hypothetical, that the brand is getting value outside of the generic. That's not in my hypothetical. Okay?

In my hypothetical, there are two entry dates. The brand has a June 1 entry date. The generic has a January 1 entry date. Right?

A. You're talking about their reservation dates.

Q. Their reservation dates.

A. Okay.

Q. And now, I'm telling you they can't -- and they can't settle; right?

A. Right.

Q. And now I'm telling you that they do settle with an agreement where there is value, in whatever form, flowing from the brand to the generic. Okay?

I'm not talking about whether the brand is getting some value from outside the settlement. Within the context of the settlement, the value is

flowing in the direction from the brand to the generic. Okay?

A. Look, if you're asking me to assume that whatever payment terms that you're not specifying or whatever contract terms that you're not specifying do not create any value for the brand, not coming from the generic, I can assume that, but if you don't specify that, then it's perfectly possible, because it's certainly within my experience that when companies settle, often they try to find things that they can agree on which generate mutual value in order to break the logjam and settle. And this is just from my experience of three decades of patent cases.

But if you ask me to assume that that is not possible in your hypothetical, that it's essentially the same as a payment, you're asking me to assume that they wrote a check, they had contract terms, but they wrote a check, right, then okay, then we're back to your first hypothetical.

Q. And in that world, you would expect the entry date would be the brand's June 1 entry date; correct?

A. Again, under the circumstance of your hypothetical, if we know that January 1 is the drop-dead date for the generic and June 1 is the drop-dead date for the brand, we would not expect them

to settle. And then if you then tell me that the brand wrote a check to the generic, because that's what you're asking me to assume, and that they settled and ask me what the date is, yes, I would expect it would be June 1.

Q. Now, Dr. Addanki, if the branded product has monopoly power --

A. Yes.

Q. -- as you use that phrase in your report --

A. Yes.

Q. -- it can afford to pay some of its expected

Q. Here's the question.

A. Okay.

Q. The brand can afford to pay some of its expected profit to the generic to push back the entry date, correct, and still would be better off than earlier generic entry?

JUDGE CHAPPELL: The question is "can afford to." That's what he "ca proai afford

"That's just true." So if the pending question and he says that's true, why are you going to the deposition? He just answered your question, "That's just true."

MR. LOUGHLIN: Because I don't think he did answer my question. He gave a long preamble that said something different from what he said in the deposition.

JUDGE CHAPPELL: Well, regardless of that, I see "That's just true," so how is that not agreement?

MR. LOUGHLIN: Maybe it is, Your Honor, but I heard him answering his own question as opposed to my question. And I'm not sure I still got an answer to my question, that the brand --

JUDGE CHAPPELL: The last answer was: "It's true."

Go ahead.

MR. LOUGHLIN: Right.

BY MR. LOUGHLIN:

Q. My question was, Dr. Addanki, not simply that there's a difference between monopoly and duopoly profits but that the brand can afford to pay some of its expected profit to the generic to push back the entry date and still be better off; correct?

A. And as I had said, it is certainly true that when the brand has monopoly power, its monopoly

profits will be greater than the combined profits in duopoly, and so yes, it can pay some profit to the generic. But I've mentioned that it's also true without monopoly power because the brand will always earn a greater profit per unit than the generic.

Q. Now, Dr. Addanki, in your report, you discuss scenarios where parties may not be able to reach what you term a pure term-split settlement; correct?

A. I'm sorry. I discuss what?

Q. You discuss various scenarios --

A. Various scenarios, yes.

Q. -- where the parties to a settlement negotiation may not be able to reach a pure term-split settlement. Do you recall that?

A. Yes. I discuss -- I make the point that a pure term-split settlement may not be feasible, and I point out various economic reasons why without intending in any sense to exhaust all of the reasons why.

Q. And one of the reasons that you describe or one of the scenarios you describe is that a brand and a generic may not be able to reach a pure term-split settlement when the brand plans to introduce a new product that's going to replace its current product on the market; correct?

A. Yes.
Q. And that type of scenario can affect each party's preferred entry dates; right?
A. Yes.
Q. And that's because the brand's profits depend on whether generic entry occurs before or after the new product launch; right?
A. That's correct.
Q. In other words, if a patentee introduces a new product before the generic can enter, the prescriptions would get shifted from the original product to the new product; correct?
A. Well, if the patentee expects that prescriptions will get shifted from the original product to the new product, and indeed the new product is intended as a replacement for the original product, and the patentee believes that it can move those prescriptions for whatever reason, the product quality or what have you, then yes, that is exactly right.
Q. And if the brand is successful in shifting prescriptions from the current product to the new replacement product, that leaves fewer prescriptions of the original product that can be substituted by the generic; correct?
A. Are you talking now about what is anticipated

or what is -- what occurs?

Q. What is anticipated.

A. In other words, if in the anticipation of the brand it is able to move those prescriptions -- well, the point is not so much what the generic is doing. The point is what is the brand doing. In other words, the brand is making sales that do not face generic competition. That's correct.

Q. And from the generic's perspective, there are going to -- it expects that there are going to be fewer prescriptions available for its product, its AB-rated generic product, because the brand will have shifted the market to the new product; correct?

A. But now we're talking about the generic's expectations, so if the generic expects that the brand will be able to move prescriptions before the generic enters, then there will be fewer prescriptions for the generic to be able to be substituted for.

Q. And that expectation on behalf of both the brand and the generic creates further diversion between the entry dates that the generic would be willing to agree to and the dates that the brand would be willing to agree to; correct?

A. What do you mean by "further"?

Q. There would be -- well, I'll get rid of the

word "further." Okay? And I'm discussing the scenario you discuss in your report.

And the point of your scenario in the report is that those differences in expectations about what's going to happen with a new product creates a divergence in the acceptable entry dates for the brand and the generic; correct?

A. I've explained in my report that it can. That's correct.

Q. And what you mean by that is the brand again wants later generic entry; correct?

A. Well, we've established I think at the outset that a brand wants later generic entry and the generic wants earlier generic entry. That's generally true.

Q. Right.

And in the scenario that you lay out in your report regarding the new -- the potential new reformulated product, again, the brand wants even later generic entry so that it has time to get its product on the market before generic entry; correct?

A. The point I made in the report was fairly straightforward, and we can go to the pages in the report, if that's helpful.

The point I made in the report was simply that among the factors that can make it impossible, as an

economic matter, for a brand and a generic to agree on a pure term-split settlement is the prospect that the brand might introduce a new product that would supplant or replace the product for which the generic manufacturer has an ANDA. And I explained that. And it's just one of the ways in which the brand and generic may find themselves unable to reach an agreement, even if all the other stars aligned, was the point I was making there.

Q. And by all the other stars aligning, you include the fact that the parties may have exactly the same views of the merits of the patent litigation; correct?

A. Yes. That contrary to my experience and common sense, that parties actually would have identical views over what's going to happen in a patent lawsuit, yes.

Q. But we're just talking about what's in your report; correct?

A. That's right.

Q. Now, in that scenario where the parties agree on the patent merits but still cannot agree on a pure term-split settlement because of this expectation of a new product being launched, you would expect that a payment from the brand to the generic could cause a

settlement, and if it does, the entry date will move to the brand's later expected entry date; right?

A. As I explained in my report and I explained at length in my deposition, the problem for both the brand and the generic -- and this infuses all of my discussion of how to analyze these settlements and what's feasible -- the problem facing both of them is there is so much intrinsic uncertainty about the future, and if you settle, you're agreeing to a course of action which is going to expose you to uncertainty.

And I had mentioned that the prospect of a product reformulation was one such source of uncertainty, particularly acute for the generic because it knows or should know from the economic perspective that it doesn't know anywhere near as much as the brand knows about what those plans are.

And I had explained in my deposition -- and I think the report is entirely consistent with that -- that it's the mitigation of uncertainty that is really much more important than anything else, and so both sides may be looking for contractual provisions that would help mitigate uncertainty attendant upon product reformulation, upon other things, but that's the core of what can bridge the gap when a settlement cannot be reached otherwise. And this is one of those

situations.

Q. I'm sorry. What is the core that can bridge the gap when a settlement cannot be reached otherwise?

A. The mitigation of uncertainty.

Q. And how do they mitigate uncertainty?

A. Well, whatever contractual provisions they get into that mitigate uncertainty can certainly help bridge a gap. And I certainly view the Endo credit provision here as a provision that, from the economic standpoint, is helping mitigate uncertainty.

Q. My question, Dr. Addanki, was, if the parties in the scenario of a reformulation, potential reformulation, cannot reach a pure term-split settlement, okay, because they have different reservation dates, and then the brand pays cash to the generic, you would expect -- and then they settle, okay, you would expect, just like we talked about before, that the agreed-upon entry date is going to move to the brand's reservation date; correct?

A. As a general matter, your very first hypothetical really encompasses all of these in the sense that if you say by assumption we know that the generic's entry date, the drop-dead date for the generic, is January 1 in your example, and the brand's drop-dead date is June 1, and the brand writes the

generic a check and they settle, the question you asked then about that hypothetical as to whether that entry date would be June 1 and I answered yes, it really is the same answer to the question you're just asking.

If there's a divergence of entry dates and we assume that to be true and then you would tell me to assume that there was a payment and a settlement and ask me what the date is, the answer will be the same.

But if you take it out of the realm of the payment, then I say, well, it depends on what the terms are because the key to reaching settlement is mitigating uncertainty.

Q. Do I understand that the answer to my question is yes?

A. The answer to your question is it's no different from your first hypothetical, if that's what your hypothetical is.

Q. Dr. Addanki, if the answer to my question is yes, you're free to say "yes." Okay?

A. I guess what I'm trying to explain to you and to the court is that it doesn't much matter what causes a divergence that results in an inability to reach a term-split settlement. If you ask me to assume that we know what the reservation dates are and further

ask me to assume that a payment engendered a settlement, then the outcome is pretty clear.

Q. Okay. And what I'm telling you, Dr. Addanki, is that if I ask a yes-or-no question, you can say "yes" or you can say "no." You don't have to give a long explanation. You can just answer my question. Okay?

A. I understand that. But when the hypotheticals are complicated, I think it's worth explaining them.

Q. Now, in developing your economic framework in this matter, you did not consider the current legal standard; correct?

A. I'm an economist. I'm really not a lawyer of any kind.

Q. Is that --

A. I did not consider legal standards, no.

Q. And your economic framework is --

A. I'm sorry. Excuse me. I should amend that answer a little bit.

I'm generally aware of an analysis under the rule of reason, and that is the extent of the guidance, of the legal guidance to my analysis, so I think that's the more complete answer.

Q. Okay. So is the answer then, in developing your economic framework in this matter, you did

governing reverse payment settlements?

A. I've not been guided by legal jurisprudence regarding reverse payment settlements beyond what I said about conducting a rule of reason analysis.

Q. Now, your economic framework is to compare expected consumer benefits under the settlement at issue compared to expected consumer benefits under continued litigation; correct?

A. That's correct.

Q. And the expected value is a mathematical expected value; correct?

A. "Expected value" when we use the term in economics is a mathematical expectation, which is a probability-weighted average of the different outcomes that could occur. That's correct.

Q. It's a mathematical formula.

A. That's correct.

Q. And the expected value is a calculation, a mathematical calculation, based on that formula; correct?

A. It's a mathematical calculation, that's correct.

Q. And for purposes of calculating expected values, you need information regarding the probabilities of who's going to win the patent case;

correct?

A. As I explained in my testimony and as I explain in my report, in some instances you do and in some instances you need not actually utilize probabilities, which was the question that I was asked on direct about does my opinion here depend upon the probabilities of the patent litigation outcomes in any way, and my answer was no, it does not. As it happens in this case, we don't need to consider those.

Q. I'm not asking about your opinion in this case yet.

A. Oh.

Q. I'm still just asking about the way that you calculate expected values under this mathematical formula. Okay?

A. When you need to evaluate an outcome that's inherently probabilistic, then the best you can do, if it's an inherently probabilistic outcome, is to assign probabilities to the various possible outcomes and calculate an expected value. That's correct.

Q. Okay. And as an economist, you would rely on the expert opinions of others to get the probabilities of who would win the patent case if you were going to do an expected value calculation; correct?

A. Certainly I would have no opinion as an

economist about the probabilities involved in the outcomes of a patent case, so I would be relying on some other sources of information for that. It could be other experts. I don't know that that exhausts the other possibilities, but I certainly wouldn't have any independent opinion about the probabilities of the outcomes of a patent lawsuit.

Q. And you read Mr. Figg's opinion in this -- or his report in this case; correct?

A. I did.

Q. And you saw Mr. Figg opine that it's not possible to reduce the odds of winning a patent litigation to a number that can be plugged into a formula; correct?

A. I'm aware that he said that.

Q. And you didn't actually do an expected value calculation in this case; correct?

A. I didn't need to.

Q. So that's a yes, you didn't do one?

A. I didn't do one. I didn't need to do one.

Q. And so you didn't do a calculation of expected consumer benefits under the settlement; right?

A. Again, there was no need to evaluate any probabilities because I could reach a definite conclusion in my analysis without having the result of

probabilities.

JUDGE CHAPPELL: If that's a no, you need to say "no."

THE WITNESS: And no, I did not, sir.

BY MR. LOUGHLIN:

Q. And you didn't determine an actual expected entry date under litigation; correct?

A. I determined that it would be later than January 1, 2013 but not by how much. That's correct.

Q. And you didn't look at consumer benefits from continued litigation as of the time of the settlement; correct?

A. I looked at -- I did not. I looked at it as of today.

Q. Right.

You looked at consumer benefits under continued litigation as of the time of your report, which was in September of this year; correct?

A. That's correct.

Q. And as of September, your opinion was that the expected entry date under continued litigation was sometime later than January 1, 2013; correct?

A. That's correct.

Q. And so you did your analysis of expected consumer benefits under continued litigation knowing

what actually happened in subsequent patent cases; correct?

A. Yes.

Q. Now, if you were hired in June of 2010 to assess the expected value of continued litigation, you might come up with one number in June of 2010 that would be -- might be different from the expected value you got in September of 2017; right?

JUDGE CHAPPELL: Just so we're clear, are you asking -- because of that magical date, June 2010, are you wanting him to assume at the time of settlement, after the settlement or before the settlement? Or does that have nothing to do with your question?

MR. LOUGHLIN: At the time of settlement. And thank you for that clarification.

BY MR. LOUGHLIN:

Q. So I'll restate the question. Okay?

If you were hired, at the time of the settlement between Impax and Endo, to assess the expected value of continued litigation, you might come up with a different value than you did in September of 2017 knowing the outcome of what happened in the subsequent patent cases; correct?

A. It's -- the answer is yes, but it's not just having to do with what happened in subsequent patent

cases. It's yes, having to do with all of the things that we know happened as events unfolded from 2010 to now.

We take account of all of the information we have at our disposal to come up with the best answer that we can, so I would have come up -- I would have used all of the information at my disposal in June of 2010 had I done the analysis at the time of the settlement, and it may have been a different answer. I don't know because I haven't done it.

Q. And if sometime later than today there were reversals in the court of appeals on some of the patent decisions that were rendered related to Endo's patents, that could cause you to have a third calculation of expected values under continued litigation, correct, as of that time; right?

A. Well, again, as I haven't calculated any expected values, I would not be calculating expected values were I to do this analysis later than now, because, as I've testified, my opinion does not depend on expected values in this case. It doesn't need to.

And so my opinion would be the same even if I were to do this analysis next year or the year after next in a context in which, as you posited, Endo patents had been found invalid or decisions had been

reversed.

Q. But if Endo patents sometime after today were later found to be invalid or unenforceable for some reason, reversing some of the district court rulings that are pending right now, that would -- could cause you to have a different view of consumer benefits under the settlement; correct?

A. Because all I analyzed was the difference between consumer benefit under the settlement and what would happen but for the settlement, nothing that happens henceforth from now forward is going to change my conclusion that entry but for the settlement would have been later than January 1, 2013, so I think the answer is no.

Okay?

Q. Well, let me ask it this way.

A. Okay.

Q. Okay?

If subsequent to today there were reversals by the court of appeals on cert 8e0EMC /Spa7ettSep the you a differentwer is noTjErT‡cul 12 0on exp /difenfu

A.

So no, I haven't got a first one, I haven't got a second one, I haven't got a third one.

Q. Okay. Well, can you take a look at the deposition again at page 49 lines 20 -- and it carries over to page 50 line 3.

A. Page 40 you said? 49.

Q. Page 49.

And I'm looking at line 20, and it continues down to page 50.

Are you there, Dr. Addanki?

A. I am.

Q. And do you see I asked you, "And if subsequent to today, there were reversals by the court of appeals

page 49 set it up as a series of hypotheticals, were I to be hired to calculate the expected value of litigation in June 2010, were I to be hired to calculate the expected value of litigation in June 2017, and so on.

Were I to be hired to calculate expected values, I would do it. I haven't done it in this case.

Q. Sure.

And if you were hired to do it subsequent to today and there were reversals in the court of appeals, you may come up with yet a third calculation of expected values of continued litigation; correct?

A. The expected value of continued litigation that you calculate at any point in time, you would use all of the information at your disposal when you do the calculation. That's correct.

Q. Now, at the time of the settlement, Impax didn't have the information you have today regarding what has happened in subsequent patent cases; correct?

A. Impax did not.

Q. And at the time of the settlement, Endo didn't have the information you have today regarding what has happened in subsequent patent cases; correct?

A. It did not.

Q. And Endo didn't know if it was going to win at the district court level in June of 2010; right?

A. It did not.

Q. And so that in June of 2010, Endo faced a risk that Impax would be able to enter the market before January 1, 2013; correct?

A. Yes.

Q. Now, Dr. Addanki, in your opinion, the only way to measure whether a settlement is anticompetitive is to see if the settlement entry date is later than the expected entry date under continued litigation; correct?

A. In the situation where your -- you have no other information to go on, that can be correct. That's right.

Q. Well, avoiding the risk of competition is not an anticompetitive effect, in your opinion; correct?

A. So when there's no monopoly power, settlements are in general going to be -- settlements of this nature, settling patent litigation, are not going to be anticompetitive.

If you find that there is monopoly power, then you're still going to have to ask the question, are consumers better off with the settlement or without.

The question isn't what motivated the parties.

The question is what were the effects of the settlement.

So a settlement that was intended -- I'm answering your question -- that was intended to mitigate or obviate or avoid risk may or may not end up being anticompetitive. You have to look.

Q. Okay. Well, then I'm going to ask my question again slightly differently.

A. Okay.

Q. Okay?

Assuming there is monopoly power, avoiding the risk of competition is not an anticompetitive effect, in your opinion; correct, Dr. Addanki?

A. So, again, I'm not quite sure how to analyze your -- interpret your question because a pure term-split settlement avoids the risk of competition.

I'm not sure what you mean by "avoid the risk of competition" beyond the fact that if you have a date certain, you've ruled out entry dates before that date certain. And that's true of any term-split settlement with any terms.

Q. All right. Then let me ask it this way then.

If there is monopoly power, in your opinion, a payment that allows the brand to avoid the risk of competition does not create an anticompetitive effect;

correct?

A. Again, for me as an economist, I can't read people's minds. I don't know what motivates either a brand company or a generic company because I can't -- I'm not a mind reader. That's not my expertise.

I can evaluate effects. And it's a question of the effects. And it's a question of the effects relative to the but-for world without the settlement.

And so given what I've already told you about any settlement has the effect of mitigating risk, avoiding risk, if you ask me then, well, does the fact that there was a payment make it anticompetitive, the answer is no. That by itself doesn't make it anticompetitive. You have to analyze the effects of it to see if it's anticompetitive.

Q. And by "effects" you are not including the fact that the brand has avoided the risk of competition before a certain date in the future; correct?

A. Any settlement is going to mitigate some risk. That's the reason companies do it.

So it's avoiding risk, yes. All settlements avoid risk.

Q. So the answer to my question is yes, that's correct; right?

A. It is correct that by itself the avoidance of

risk does not constitute an antitrust problem, in my view, as an economist.

Q. Okay. And your opinion is that the entry of a lower-priced generic competitor does not by itself reveal anything useful about whether consumers are dissipa ow.um[Okay.)certainly is that the en.035 Td(lowetry o are

A. 1-5?
Q. Correct.
A. I have it.
Q. It's -- on the bottom it should say "RX 547.0019."
Do you see that?
A. I do.
Q. Okay. And do you see in paragraph 31?
A. Yes.
Q. In the very top, you're talking about the restriction in output that causes a loss of consumer welfare.
Do you see that?
A. Yes.
Q. And then the next clause says (as read) the entry of a low-priced competitor does not, by itself, reveal anything useful about whether consumers are better off as a result of the entry, or whether the incumbent firm had exercised market power or, indeed, even possessed any market power to be exercised.
Do you see that?
A. I don't know if you deliberately misquoted that. I used the words "monopoly power." Both times you said "market power."
Q. Oh, did I? Oh, I apologize for that. I did

not deliberately misquote you.

A. Okay.

Q. That's what your sentence says; right?

A. Would you read it again because I think the record is not --

Q. Sure.

I'm reading the clause that says "the entry of a low-priced (sic) competitor does not by itself reveal anything useful about whether consumers are better off as a result of the entry."

Do you see that part?

A. Yes.

Q. That's the part I'm asking you to focus on.

A. Yes. Yes. Do you see that part?

generic entry does as far as consumer benefit is concerned. It depends on the circumstances.

Q. Now, Dr. Addanki, if AB-rated generic entry occurs and sales are shifted from the brand to a lower-priced generic, your opinion is that you can't tell if consumers are better off; correct?

A. As I've explained in the report, the brand and the generic are different. The brand engages in various activities that can have real value for physicians and patients. Those values -- those activities cease when there's an AB-rated generic or get greatly curtailed when there's an AB-rated generic.

Consumer benefit may go up or down depending upon the value of those activities and the price that you see in the marketplace. And as I've said before, output is the best test of whether on net consumers are better off or not, because if those activities have real value, you will not see the lower price actually producing more output.

So that's the complete answer. You can't tell just by -- from -- just from the fact that there's a generic coming in at a lower price, you cannot tell if consumers are better off or worse off on that.

Q. So that's a yes to my question; right?

Q. Now, Dr. Addanki, in your report you discuss the value of the no-AG and the Endo credit provisions under the settlement; correct?

A. That's correct.

Q. And you spend three paragraphs discussing that; correct?

A. I don't know. If you can point me to it, we can look.

Q. Yes. It's paragraphs 125, 126 and 127 of your report. It begins on page 62 of your report. That's RX 547.

A. Yes.

Q. 547.0066.

A. Right.

Q. Okay. So my question is just, you spend three paragraphs, right, 125, 126 and 127, discussing the value of the no-AG and Endo credit provisions; correct?

A. Yes.Yes.

A. I do.
Q. Now, your report doesn't offer any specific criticisms of Dr. Noll's calculations of the ex ante value of the no-AG and Endo credit provisions to Impax at the time of the settlement; correct?
A. Well, no. I think -- I think in 126 what I say is that there are absolutely reasonable scenarios in which you get calculations that are different because you have simultaneously valueless provisions, and that's what I explain in 126 and 127, and that's a criticism of his calculation.
Q. Let me maybe make my question clearer. Okay?
A. Okay.
Q. I understand that you criticize part of his opinion, but you didn't offer any criticisms of the way that Dr. Noll calculated the ex ante value --
A. You mean his formulas?
Q. Correct.
A. I did not.
Q. And what you say at the end of paragraph 125 is that Dr. Noll provides an incomplete assessment of the ex ante value of these provisions to Impax at the time of the settlement; right?
A. Right.
Q. And then you explain in paragraph 126 why you

believe Professor Noll's analysis is incomplete; right?

A. That's correct.

Q. And what you say is, in the first sentence of 126, "Contrary to Dr. Noll's assertion that 'if one provision is valueless, the other has substantial value,' it is possible that the 'No AG' and Endo Credit provisions would have provided zero value to Impax"; right?

A. Yes. I wrote that.

Q. Now, in your report, you don't assess the likelihood that both the no-AG provision and the Endo credit provision would have provided zero value to Impax; correct?

A. I do not assign a probability to it. That's correct.

Q. You don't assess the likelihood in any other way; correct?

A. Well, no. I do explain that knowing the provision, the way it's written, that it would make sense for Endo to have planned its migration of patients from original to reformulated in a way that minimized patient loss and minimized whatever obligations might be payable under the Endo credit provision.

And so that -- that's a statement about what I

You don't say "likely," you say "possible"; correct?

A. Right. But if you read -- I mean, well, certainly what I intend to say and what I've said in this whole section is that the -- it would make economic sense for Endo to have done that, and indeed, it seems like that's what Endo had in mind, based on the discussion in footnote 207. But I've certainly not assigned probabilities. That's correct.

Q. And I just want you to listen to my question. Okay?

A. Okay.

Q. My question is, the word you used was "possible"; correct?

A. Yes.

Q. Now, did you see any documents or testimony about what Impax' chief negotiator thought about the likelihood of Impax getting no value from the no-AG or Endo credit provisions?

A. I saw some documents suggesting that Impax thought that the provisions provided some safety net. There may have been other documents that I don't recall.

Q. Now, in your report, you didn't calculate a mathematical expected value of the sort you discussed

with respect to the continued value of litigation; correct?

A. I did not.

You're asking if I calculated expected value of continued litigation?

Q. No. I'm asking if you calculated a mathematical expected value of the payment.

A. I did not.

Q. And you didn't assess the mathematical expected value of the payment either as of the time of the settlement in June of 2010 or in September 2017; correct?

A. With -- in September 2017, we know the payment with a probability of one. It was $102 million.

So I'm not sure I understand your question.

Q. Well, with respect to continued litigation, you assess expected values as of September 2017. Do you recall that?

A. I think I've testified repeatedly that I have not calculated expected values. I didn't need to calculate expected values.

I've calculated that the consumer benefit would be better under the settlement because entry would have occurred later but for the settlement. I've not calculated an expected value.

Q. Okay. But you did a calculation regarding continued litigation as of September 2017; correct?

A. I made an assessment that consumers are better off with the settlement as of September 2017.

Q. Right.

And you didn't do any sort of calculation or assessment of the expected value as of September 2017; correct?

A. The expected value of what?

Q. Of the payment.

A. Of the payment.

Q. Yes.

A. We know the payment with certainty. The expected value is the same as the payment. It's $102 million.

Q. So if you looked at the mathematical expected value of the payment as of September 2017, you would take into account the fact that Endo actually paid $102 million under that provision; correct?

A. There's no mathematical expected value. It is the number. There's no uncertainty about the number. $102 million was paid, for reasons that I explained at length yesterday.

Q. Now, in principle, it is possible to determine the expected value of the no-AG provision and Endo

credit; right?

A. To whom?

Q. To Impax.

A. So the expected value to Impax would depend upon what was in Impax' or the negotiators for Impax' minds. And if you knew what they were thinking about probabilities looking forward, assuming they thought about it in those terms, you could in principle calculate an expected value.

Q. Right.

And to do that, in principle, you would have to assign probabilities to all the potential outcomes under the no-AG and Endo credit; right?

A. No. You would have to know what probabilities they assigned to outcomes.

Q. You'd have to know that for each of the possible outcomes; correct?

A. You would have to know however they were thinking about it. Whether it was a question of outcomes or they were thinking about it as a probability distribution of some kind I don't know. It's what was in Impax negotiators' or Impax management's minds at the time.

Q. And you don't have that information.

A. I do not.

Q. No. It's page 114 at --
A. 114. Pardon me. Okay.
Q. Are you with me?
A. Yes.
Q. Okay. And up at the top on line 1 I'm asking you is it possible to determine expected values of the no-AG and Endo credit.
Do you see that?
A. Yes.
Q. And you answer, and then in line 15 I say, "You didn't do it here; correct?"
And your answer was: "No, I didn't do it at all here.
"QUESTION: Okay.
"ANSWER: I don't think it's actually in any practical sense doable."
A. Right.
Q. That was your answer; right?
A. It was the answer to the question is it possible to determine the expected value, not the expected value to Impax or the expected value to Endo, but the actual expected value. And I took your question there as I take it now, if you ask me the same question, to mean an objective expected value, and I say yeah, you cannot do that.

Q. And so rather than a mathematical expected value, you're sort of talking about anticipated value as of the time of the settlement; right?

A. I don't know what you're asking about. What do you mean, I'm talking about?

Q. Well, rather than -- well, all right. Let me start that over.

Let me ask you to look at paragraph 126 of your report.

A. Oh, of my report. Okay.

Q. That's RX 547.0069. It's page 65 of your report.

A. I have it.

Q. Are you there, Dr. Addanki?

The top of page 65?

A. Yes.

Q. Do you have it?

A. Yes.

Q. And it says, "Therefore, there were a wide range of potential values for the 'No AG' and Endo Credit provisions (including zero) and thus uncertainty about the expected value of any payment represented by the 'No AG' and Endo Credit provisions at the time of the settlement."

Do you see that?

A. Right.
Q. And when you used "expected value" in that paragraph, you didn't mean mathematical expected value; correct?
A. No. I did.
Q. Oh, you did?
A. I did.
Q. Now, let me turn back to paragraph 126 --
A. Okay.
Q. -- Dr. Addanki, in your report.
And this is where you're offering your criticism of Professor Noll and why his analysis was incomplete. Do you recall that?
A. Yes.
Q. If you look down near the bottom of that paragraph 126 on page 63, do you see the sentence that begins "Therefore"?
A. Yes.
Q. And you say, "Therefore, it is possible that, had Endo launched reformulated Opana ER and discontinued original Opana ER shortly before January 2013, its Prescription Sales (of original Opana ER) in the last quarter of 2012 may not have dropped below 50 percent of their quarterly peak."
Do you see that?

A. I do.
Q. And then you continue, "In this scenario, there would have been no Endo Credit paid to Impax."
Do you see that?
A. I do.
Q. Did you look -- and -- let me start that over.
You said today I believe that you would expect that Endo would have managed its launch to accomplish the result that it didn't have to pay any Endo credit; correct?
A. It would certainly have been in Endo's economic interest to do so and within Endo's ability to do so, because it was Endo that controlled -- would have controlled the pace of the launch but for the Novartis plant shutdown.
Q. And I believe your testimony was that you would expect that to be Endo's plan. Correct?It would certainlauldsMCID2

Endo actually ended up having to do. I don't remember the full range of documents that I saw.

Q. Do you recall looking at documents in 2010?

A. Endo documents in 2010?

Q. Let me be clearer. Endo documents dated from 2010 that you were looking at during your analysis.

A. I don't remember.

Q. Okay. Can we put up CX 3038, Corinne.

I believe it's in your binder, Dr. Addanki. If

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docume't view.)48

Q. Do you have that, Dr. Addanki?

A. I have that.

Q. And (I Do you see that this subject at this says Q.)TJ-4.8 -2.035 Td"EN32888, Ce8,

Q.

Q. And it says, "Product Launch - Schedule indicates March 2011, but could range from December 10 to June 11."

Do you see that?

A. I do.

Q. And you didn't consider this document in coming up with your opinions; correct?

A. Well, a document that predates both the settlement which put Impax off the market till January 2013 and that contained the Endo credit provision is not going to inform my analysis of what Endo would have done, knowing what was in the settlement, very much. I may have seen this, but no, it doesn't, doesn't tell me a whole lot.

Q. My question was that you didn't consider it. Correct?

A. I may have considered it. I don't recall.

Q. Well, let's look at your report then.

A. Okay.

Q. If you look in your report -- your report is RX 547 in your binder.

A. Yes.

Q. Do you see that?

It's on page RX 547.0095 carrying over to 0096.

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Q. Corinne, can you put up CX 1108.

Dr. Addanki, we're going to put up CX 1108. It

A.

Q. Let me ask you to turn to CX 3038, Dr. Addanki.
A. Okay.
Q. And that should be in your binder as well.
Oh, I'm sorry. I've already shown you this one. I meant CX 2738. I apologize for that.
A. I have it.
Q. And do you see this document says "ELC 2012 Budget Review" for Endo Pharmaceuticals in the first page?
A. Yes.
Q. And it's dated October 12, 2011?
A. Yes.
Q. And that's after the settlement; correct?
A. That's correct.
Q. Could you turn to CX 2738-008.
A. I have it.
Q. And do you see up at the top it says "Opana ER TRF Supply and Conversion Scenarios"?
A. Yes.
Q. And do you understand that "TRF" refers to the reformulated version of Opana ER?
A. I do.
Q. And do you see on the left-hand side there's various scenarios?

A. Yes.
Q. The base scenario, wholesaler stocking begins with Bio- -- Biconcave, do you see that?
Do you see that column?
A. Yes.
Q. Okay. Under the base scenario, the wholesaler stocking would begin in August of 2012; correct?
A. That's correct.
Q. This is as of October 2011; right?
A. Right.
Q. The upside scenario wholesaler stocking would begin July 5, 2012; correct?
A. Right.
Q. The downside scenario has various wholesaler stocking dates between April 1, 2012 and September 10, 2012; is that right?
A. Right.
Q. And then down at the bottom you see there's something called an emerging view.
Do you see that?
A. Right.
Q. And that lists the wholesaler stocking as beginning in February of 2012; right?
A. Right.
Q. And you didn't consider this document in

forming your opinions, did you, Dr. Addanki?

A. I don't believe I cited this document. No.

Q. Do you want to check?

A. Sure.

Q. You can look back at RX 547.0095.

(Document review.)

A. No, this is not cited.

Q. Now, Dr. Addanki, turning back to your report, paragraph 126 at RX 547.0067?

A. Right.

Q. Are you there?

A. I am.

Q. Okay. We were discussing this sentence that begins "Therefore" --

A. Yes.

Q. -- near the bottom of page 63 --

A. Yes.

Q. -- where you're saying it's possible that had Endo launched reformulated Opana ER and discontinued original Opana ER shortly before January 2013, its prescription sales of original Opana ER in the last quarter of 2012 may not have dropped below 50 percent of their quarterly peak.

Do you recall that sentence?

A. I do.

situations where a company reformulated its product and switched from the original to the reformulated?

A. How many times? I don't keep track, but certainly more than half a dozen, probably more than ten.

Q. Have you written on that topic?

A. I'm sure that my writings have touched on the topic. I can't remember specifically any article exclusively devoted to that topic.

Q. So you haven't written on this topic, and your expertise is limited to looking at this scenario six to ten times; is that right?

A. No. The point is that having been familiar with about, say, ten or more times of studying it, in each of those cases reference is typically made to what can be expected in a transition of that kind, so I'm generally familiar with that part of brand company strategies.

Q. Did those scenarios have something like an Endo credit in them?

A. I don't remember.

Q. Did you -- were you measuring how quickly sales of the original product declined after the reformulated launched?

A.

about the transition in prescriptions being dispensed from an original product to a reformulated product.

Q. And you were measuring whether they declined by 50 percent or more --

A. No.

Q. -- a certain time period?

A. Pardon me. Sorry. Go ahead.

Q. No. I -- you were measuring whether they declined by 50 percent or more within a certain time period; is that right?

A. No, I was not.

Q. If Endo launched its reformulated Opana ER and discontinued original Opana ER just before January 1, 2013 and sales of original Opana ER dropped below 50 percent of their quarterly peak, Endo would have to pay the Endo credit; correct?

A. It would have to pay a credit, the amount of which would depend on by how much they fell below that peak.

Q. Now, I think you mentioned earlier that it takes some time for the reformulation -- let me start that over.

I think a minute ago you testified that it takes some time for the brand to switch prescriptions from the original product to the reformulated product;

correct?

A. Yes.

Q. It takes months for that to happen; correct?

A. Typically, yes.

Q. So it's possible that if Endo launched reformulated Opana ER and discontinued original Opana ER just before January 1, 2013, Endo would not be successful in switching patients to the reformulated Opana ER before entry of generic versions of Opana ER on January 1, 2013; correct?

A. Well, again, we need to be clear what we mean by "just before." I wasn't suggesting that it would be December 31.

But these are the moving parts that Endo had under its control, was when it was going to introduce reformulated and when it was going to discontinue original. And my point is simply that knowing what obligations it had under these terms and knowing that transition takes time, I would have expected Endo to have managed that transition.

I haven't studied exactly how many months it would have taken or what specifically would have been Endo's optimal plan. That wasn't part of my work.

Q. But what Endo doesn't have within its control is how quickly doctors are going to start prescribing

the new product for the old product; correct?

A. That would be the part that Endo would be field-testing were it to do it -- were it to do the transition according to its own timetable as opposed to being hurried to it by Novartis plant crisis. It would be doing that testing and getting its ducks in a row to make sure that that transition happened in a predictable way.

Q. It would be doing that testing by talking to doctors?

A. Yes. Exactly.

Q. But ultimately whether the doctors actually prescribe the new product is not within Endo's control; correct?

A. Well, I mean, to some extent, it is because discontinuing the original product essentially makes that happen. But the transition is something that I would expect Endo would manage based on the best research it could do on physicians' opinions and physicians' behavior.

Q. But when Endo stops selling Opana ER, there's still Opana ER -- original Opana ER is still in the pipeline; correct?

A. Right.

Q. Wholesalers have it, retailers have it;

correct?

A. Yes.

Q. And doctors can still prescribe it; correct?

A. Yes.

JUDGE CHAPPELL: We're going to take a short break. I'll be asking you for a time estimate when we

Q. And you would expect Endo to conduct the launch of reformulated Opana ER to maximize its overall profits as a company; correct?

A. Generally speaking, yes.

Q. And you would expect Endo to conduct the launch of reformulated Opana ER to maximize its overall profits as a company even if that meant they had to pay the Endo credit; correct?

A. It would be the overall profit, and if they could make more profit elsewhere by incurring the Endo credit, they would, yes.

Q. And you haven't studied whether Endo would maximize its overall profits by launching earlier -- launching its reformulated Opana ER earlier and paying the Endo credit versus launching just before or shortly before January 2013 and avoiding the Endo credit, as you discuss in your report; correct?

A. I don't think those are -- I don't think those are the -- it's not a choice between those two possibilities. The point would be that I would expect Endo to launch and manage its transition in such a way as to maximize its profits. And if you hypothesize that that optimal launch might include some payment under the Endo credit, it may. Yes.

Q. But you haven't studied that.

saw, but that wouldn't surprise me.

Q. Now, Dr. Addanki, I believe you testified earlier that parties posture in negotiations; is that right?

A. They do.

Q. And because parties posture, you can't tell the true reservation dates of either party in a settlement negotiation; is that right?

A. No. You can't tell the true reservation dates of either party in a negotiation for reasons that have much more to do -- that have to do with much more than just posturing. It's not possible to divine what's in someone's head.

Q. So I think you and I are agreeing that you cannot tell the true reservation dates that two settlement parties actually held; is that right?

A. You cannot.

Q. Okay. So you don't know what Endo's true reservation date was in its settlement negotiations with Impax; correct?

A. I do not know what was in Endo's mind, so I do not know what the true reservation date was for Endo or anyone negotiating on behalf of Endo.

Q. Okay. So you don't know the earliest date of generic entry that Endo was willing to allow in its

settlement negotiations with Impax; correct?

A. I have no knowledge of what was going on in the minds of anyone at Endo with regard to that question.

Q. And you don't know Impax' true reservation date in its settlement negotiations with Endo; correct?

A. Again, I don't know what was going on in anyone at Impax' minds with regard to that.

Q. You don't know whether the parties might have been able to reach settlement with entry dates that Endo and Impax were willing to accept absent any payments; correct?

A. I don't know of any alternative agreement that I can be sure Endo and Impax would have entered into. That's correct.

Q. But you don't know if there weren't any either; correct?

A. That's correct.

Q. Now, I want to change subjects a bit, Dr. Addanki, and talk about market definition --

A. Okay.

Q. -- and market power. Okay?

Now, Dr. Addanki, you agree that the general question for defining a relevant product market is to

determine whether buyers switch products in response to a change in relative prices to make the change -- the price change unprofitable?

A.

is no, you don't agree that products can be in the same -- let me start that over -- so maybe the answer is -- let me start that over.

Am I correct that your opinion is that products cannot take sales from each other and not be in the same relevant market?

Is that too many negatives?

A. That's too many negatives.

JUDGE CHAPPELL: Too many negatives.

BY MR. LOUGHLIN:

Q. I'll start over. Perhaps -- let me ask you this question.

Do you agree that products can take sales from each other and not be in the same relevant product market?

A. I suppose it's hypothetically possible that there's products taking sales from one another in response to relative price changes and yet the products don't serve as any kind of competitive constraints. I wouldn't rule it out, but I don't think of it as a common occurrence.

Q. Okay. Now, you agree, I believe, Dr. Addanki, that when you are determining the candidate set for your relevant product market, you start with the narrowest competitive set and then you expand, correct,

if necessary; correct?

A. I'm not sure what you mean by the narrowest set. You consider the products that are the meaningful competitive constraints on the product or products at issue.

Q. Okay. Well, let me -- I'll re-ask it.

A. Okay.

Q. Do you agree, when you're looking at your candidate relevant market or when you're trying to look at the competitive set, that you start with the narrowest set and then expand? Do you agree with that principle?

A. Certainly you would be looking for products that were more powerful competitive constraints, and you would look to those before you started looking to less powerful competitive constraints. And if that's what you mean by "narrow," then yes. It depends on the strength of their competitive constraining effect.

Q. You're looking with the set that -- you start with the set that represents the closest competitive interactions for the products at issue; correct?

A. You're starting with the set that provides the most powerful competitive constraints. That's what you're doing.

So -- and then you go outward from there.

Q. You go outward from there if necessary.
A. Right.
Q. And here, you started with oral -- excuse me. Let me start that over -- you started with long-acting opioids as your candidate set; correct?
A. No. I started with Opana ER and then looked to what was closely constraining Opana ER and found that it was the set of long-acting opioids that was constraining Opana ER.
Q. When you say you started with Opana ER, what do you mean?
A. I mean the nucleus for the analysis is Opana ER.
Q. The branded Opana ER?
A. Well, the product whose monopoly power I'm evaluating.
Q. And then you took Opana ER and then you included in your set other long-acting opioid products; correct?
A. Those were the other products that were constraining Opana ER. That's correct.
Q. So you started with Opana ER and other long-acting opioids, and that's where you ended up with your product market definition; correct?
A. No. I started with Opana ER, and I ended up

with a set of long-acting opioids.

Q. What did you do to evaluate Opana ER as a relevant product market? And where is that in the report?

A. So the question of whether Opana ER is a product market unto itself was quickly disposed of the moment you start looking at what these products are, how they're used, what they do and how they compete, so there was never really any meaningful question of Opana ER being a relevant market by itself.

Q. Okay. So let me just ask, what candidate set did you start with here?

A. I started with Opana ER.

Q. Okay. Can I ask you to turn to your deposition.

A. Okay.

Q. Specifically paragraph 138 --

A. 138.

Q. -- page 138.

A. Okay.

Q. Do you see at line 2 I'm asking you a question about the candidate relevant market?

Do you see that?

A. Yes.

Q. And then at line 11, I ask you, "What set did

you start with here?"

And you answered, "So, I would say the starting point here was oral long-acting opioids, but frankly, there was a fair amount of information about the transdermal, as well. So, it wasn't clear whether, in fact, oral was a particularly appropriate sort of closest set even though, to a layperson, it might have seemed that way."

That was your testimony in the deposition, wasn't it, Dr. Addanki?

A. Yes, it was.

Q. And you chose your candidate set of long-acting opioid drugs by looking at Endo's business documents; right?

A. Not only. I've described all of the things that I looked at. But certainly Endo's business documents played a significant role.

Q. And Endo's business documents discuss other products that you did not include in your competitive set; correct?

A. They may have.

Q. Now, in general, when looking at relative changes in price for purposes of defining a market, economists look at small price changes; right?

A. So there is a particular thought experiment

that's contained in the Horizontal Merger Guidelines put out by the FTC and the DOJ which invites the analyst to think about what would happen in the event of a small, significant, nontransitory increase in price and proceeds down that road. And there are certainly circumstances in which that is possible to implement in practice. There's plenty of other situations where it's just not possible to implement in practice.

And so you take whatever evidence you can find that informs your question about economic substitutability, so the answer to your question, the complete answer to your question, is no. You take whatever you can find. If you can actually conduct an experiment with a small, significant, nontransitory price increase, you do. But sometimes you can't. Often you can't.

Q. Okay. And here, you were not able to determine whether the price changes that affected changes in formulary status that you discuss in your report, whether those were small price changes; correct?

A. I did not go about doing that analysis. But certainly a 30 percent to 38 percent change in rebate would probably translate into a net price that fell

about in the range of a SSNIP; correct?

A. Well, I don't know where it went to 30 from. If it had gone to 30 from 25, that would have been a SSNIP, too. I just haven't done that analysis. But certainly these changes don't seem out of the realm of a SSNIP.

Q. But you don't know that because you haven't done the analysis; correct?

A. Well, I haven't done a SSNIP analysis, that's correct. But the difference between a 30 and 38 percent rebate I can tell you is a SSNIP.

Q. Okay. I'm going to ask you again. Okay?

You don't know whether getting to that 30 percent amounted to a price change in a window or a range of a SSNIP; correct?

A. So not the 30 to 38 but wherever it was to 30?

Is that what you're asking?

Q. Yeah, that's my --

A. I don't know because I don't know what it was before.

Q. Now, yesterday do you recall that you discussed Exhibits 9I and J in your report?

A. Yes, I do.

Q. Let's take a look at Exhibit 9I.

A. I have it.

Q. And this is your chart showing changes in formulary status for Opana ER relative to other branded long-acting opioid products; right?

A. Right.

Q. And this one is for commercial plans.

A. That's correct.

Q. Now, you don't know what caused the changes in formulary status that you represent in Exhibit 9I; correct?

A. I do not. In other words, I don't know for each formulary that changed all the factors that prompted the change. I do not.

Q. Right.

And you don't know if there were -- let me start that over.

Assuming that the formulary status changes were the result of price changes, you don't know what those differences in prices were; correct?

A. I do not.

Q. You don't know what the differences in any rebates were; correct?

A. Well, I know some of them, but I don't know all of them.

Q. For purposes of this chart you know what the rebates were?

A. Well, on commercial plans, I don't recall actually if I've seen rebate terms specifically for commercial plans, so I don't remember.

Q. And you don't know what differences in copays there were that are referenced in this chart; correct, if any?

A. No. I have the data on the formulary treatment, so I believe I do have that information.

Q. Well, can you tell us then what the changes were in the --

A. Not from that bar chart, no.

Q. Oh, okay.

You don't know what the effects on quantities of Opana ER sold were as a result of any of these formulary changes; correct?

A. Again, when you say any of them, I'm not sure what I've reviewed in the documents. I certainly wouldn't know what the changes were for all of them because I don't have the data.

Q. Do you know what the quantities -- the difference -- what the effects on quantities of Opana ER sold were as a result of any of the formulary changes that you reflect in Exhibit 9I?

A. That's what I don't recall. I recall seeing some information on the changes in volumes associated

with formulary changes, but beyond that general recollection, I don't remember anything specific.

Q. And the same is true -- I could ask all those same questions about Exhibit 9J about Medicare plans and I'd get the same answers; correct?

A. With the Medicare plans I actually have specific information about plans that I've cited in my report. As to whether there were volume changes associated with that that I've seen, I don't recall.

Q. Now, Dr. Addanki, in connection with doing your market definition analysis, you didn't consider the conduct being alleged in this case; correct?

A. My question was, was there monopoly power possessed by and being exercised by Opana ER at the time of the settlement, so -- and that was a question that I could address independently of anything else.

Q. So the answer to my question is yes, I'm correct?

A. That's correct.

Q. And you don't think the alleged conduct is relevant to relevant product market definition; correct?

A. Well, it's -- it's -- it sets the predicate for why you're doing this in the first place. But beyond that, the question of whether a particular

product enjoyed monopoly power or not stands on its own. We can address that question and answer it.

Q. In fact, when you are assessing monopoly power, it doesn't matter what the market is; right?

A. Well, ultimately you're assessing monopoly power in the context of a market, so I don't know that I'd agree with that.

Q. Okay. Well, let's turn to your deposition.

A. Okay.

Q. Page 146.

And looking down at the bottom, line 21.

Do you have it, Dr. Addanki?

A. Yes.

Q. My question was: "So, when you're assessing monopoly power, it doesn't matter what the market is?"

And you said, "No. If you want to assess whether Opana ER had monopoly power in 2010 at the time of the agreement, you can do that exercise and market definition as one step in that."

Do you see that?

A. Yes.

Q. That was your testimony?

A. My testimony was that I was disagreeing, that if you want to assess whether Opana ER had monopoly power at the time of the agreement, you can do that

exercise combined with a market definition exercise as one thing.

Q. Now, yesterday, when you were discussing market definition, one of the pieces of evidence you relied upon was CX 1106.

Do you recall that?

A. I haven't memorized exhibit numbers. I'm sorry.

Q. Okay. Well, let's put CX 1106 up on the screen.

I think you'll find it in your black binder that you got from respondent's counsel. I don't have it in my binder, Dr. Addanki. You're welcome to look at it on the screen or in the binder if you prefer.

A. Do you know what tab it is in the black binder?

Q. I'd have to look that up.

It's tab 4.

A. 4. Thank you.

I have it.

Q. And CX 1106 is an e-mail from Demir Bingol of Endo along with a PowerPoint presentation.

Do you see that?

A. Right.

Q. And it's from July 2009.

Do you see that?

A. Yes.

Q. Could I ask you to turn to page CX 1106-005.

A. 005. I have it.

Q. Do you see that there's a column labeled Event?

A. Right.

Q. And the third row under that column says, "Generic Opana ER may not be available until early to mid-2011."

Do you see that?

A. Yes.

Q. And then if you go over to the next column in that same row, the column headed Key Learning/Implication, do you see that?

A. Yes.

Q. The key learning/implication of generic Opana ER may not be available until early to mid-2011 says -- the first bullet says, "Each month that generics are delayed beyond June 2010 is worth about $20 million in net sales per month."

Do you see that?

A. I do.

Q. Now, you didn't discuss that portion of CX 1106 in your market definition section of your

A. I have it.
Q. And this is a page from your materials considered list?
A. Yes.
Q. You can turn to the first page if you want to -- prior page if you want to verify that?
A. I have it.
Q. Under Expert Reports, you don't list Dr. Savage's report, do you?
A. I did not, no.
Q. Dr. Addanki, now, you believe that there are two ways that the settlement benefited consumers in this case; right?
A. I'm not sure I would express it that way. Unless you're referring to some specific sentence, I think it benefited customers -- consumers by having entry occur before it might have but for the settlement, entry by Impax.
Q. Right.
I think you expressed, at least in your deposition, that one way that you believe the settlement benefited consumers was that it allowed entry earlier than you believe would have occurred under continued litigation; correct?
A. That's correct.

Q. And the other is that Impax got a license to patents that came later in time that covered Opana ER; is that right?

A. No. I think my opinion is that -- and I think this is what I've expressed -- that was part of the reason that Impax was able to enter notwithstanding the subsequent patent litigation filed by Endo.

I think I've expressed the opinion in my deposition that it's possible that the resolutions that have occurred to date of patent litigation following on the original patent litigation here that resulted in Actavis, the other generic, being enjoined, leaving Impax the only supplier of original Opana ER, actually oxymorphone ER, that may be viewed as a benefit as well, and that's over and above the entry date issue I talked about.

Q. But there aren't any others that you've expressed in your report; correct?

A. I believe not. That's right.

Q. Okay. Now, Dr. Addanki, if you're right that patent litigation, had it continued between Endo and Impax, would not have concluded until sometime after January 1, 2013, there was no reason for Endo to settle at all; right?

A. Somewhat like the lottery ticket I bought that

didn't win, I should never have bought it, Endo did not know at the time of the settlement what Endo knew -- knows now. Impax didn't know at the time of the settlement what Impax knows now.

Q. Okay. And similarly, you don't know what would have happened in the patent litigation between Impax and Endo if they didn't settle; correct?

A. Do you mean who would have won?

Q. Yes.

A. I don't know.

Q. You don't know, for example, if Endo's patents would have been found invalid; correct?

A. We're talking about the patents at issue in the original lawsuit.

Q. Yes.

A. Which subsequently expired.

Q. Correct.

A. I don't know.

Q. And for example, if the Endo patents at issue in the Impax-Endo patent litigation were found .

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Q22

be different what would have happened in a but-for world with no settlement; correct?

A. What happened -- the events that took place in the real world give us the best possible information that we have at our disposal about what would have happened in a but-for world, which was different only in some respects from that real world.

So yes, there's things we don't know about the but-for world, but our best guide to it is still the real world.

Q. Sure.

But things could have been different in the but-for world had they not settled; correct?

A. That's -- that's sort of a tautological question. I suppose it's possible.

Q. Now, Dr. Addanki, you discussed this morning your opinions on launching at risk. Do you recall that?

A. I do.

Q. In your report, you did not assess how often generics that launch at risk are found liable for patent infringement later, did you?

A. I did not.

Q. And you did not assess in your report how often generics that launch at risk that are found liable

actually end up having to pay infringement damages, did you?

A. I did not.

Q. And you didn't assess the likelihood that Impax would have launched at risk in this case; correct?

A. I did not come up with a probability, no.

Q. You understood that Impax' position in this lawsuit was that it would not launch at risk; correct?

A. That's my understanding, yes.

Q. And you took that assumption and you assumed the truth of it; correct?

A. Well, I examined whether it made economic sense for a company in Impax' position to have that view, and it did, but yes, I assumed that it would not.

Q. And you didn't consider the interrogatory response that Impax provided in this case listing the launches-at-risk decisions that it has made; correct?

A. I'm certainly aware of those launches and have understood the circumstances of those launches, so they were not germane to the particular situation here because those launches took place in different circumstances.

Q. Where did you get the understanding about

Impax' launches or its launch decisions at risk that you just referred to, Dr. Addanki?

A. From -- I don't recall the specifics, but from review of Impax' activities in the past.

Q. Okay. Let's take a look at your report again.

A. Okay.

Q. Let's go back to RX 547.

A. Okay.

Q. .0093.

A. Okay.

Q. Again, this is your documents considered list?

A. Yes.

Q. Do you see anywhere on this list anything indicating that you looked at the interrogatory response that Impax provided in this case listing the launch-at-risk decisions that it's made?

A. If it would be called out as an interrogatory response and not take some other form, that's easy enough to check. But I wasn't suggesting that I was

interrogatory response or not.

Q. That's my question.

Did you look at it in forming your opinions in this case?

A. I just don't recall.

Q. And you don't see it in your materials considered list; right?

A. Again, if it would be titled an interrogatory response, I would assume it will be in court documents, and I don't see it.

Q. Well, I don't know how it would be titled. This is your report, sir.

Can you look at it and tell me whether it's in there or not?

A. Not beyond what I just testified to, which is, if it is listed under that title, it would be in court documents, and I don't see it there.

Q. Okay. And you don't recall looking at the letters of intent that Impax was getting from customers to purchase generic Opana ER from Impax upon launch in June of 2010; correct?

A. Again, I don't recall if I've seen those or not.

Q. Now, can I ask you to turn to page 69 of your report.

A. Okay.
Q. That is -- begins at RX 547.0036.
A. I have it.
Q. Oh, I'm sorry. No. I have that wrong. I apologize.
Page 69, paragraph 137, RX 547.0073. I apologize, Dr. Addanki.
A. I have it.
Q. Do you see you say, in paragraph 137, "I understand that Impax personnel have stated that Impax would not have launched its generic versions of original Opana ER before final adjudication of the patent litigation"? A.

A.Yes 1 Tf(.)Tj EMC /Spa26 <MCID 11 >BDC /TT0 1 Tf3 0 Td(I have it.)Tj27MC /Span <MCI

would have launched at risk; correct?

A. Well, I'm not in the position to make any

A. Yes.
Q. And you say she's the former president of the generic division at Impax and she testified that Impax was incredibly conservative and at-risk launches associated with any potential liability would have gone to the board of directors for approval; correct?
A. Yes.
Q. That's not a statement that Impax would not have launched, is it?
A. It's not.
Q. And then you cite or you refer to Margaret Snowden.
Do you see that?
A. Yes.
Q. Vice president of intellectual property litigation and licensing at Impax. And you say she testified that, to her knowledge, Impax' management team had not recommended to the board of directors to launch its generic versions of original Opana ER at risk.
Do you see that?
A. Right.
Q. That's not a statement that Impax would not have launched at risk either, is it?
A. No.

Q. And then you refer to Theodore Smolenski.

Do you see that?

A. I do.

Q. The former senior director of portfolio management and strategy at Impax. And you say he recalled that, at the time of the settlement, Impax had not made any decision to launch that product -- the product on a certain date.

Do you see that?

A. I do.

Q. That's not a statement that Impax would not have launched at risk, is it?

A. That's correct.

Q. And then you say Todd Engle, vice president of sales and marketing at generics -- at Impax' generic division, testified that he did not think Impax would have launched at risk upon the FDA approval because Impax is pretty risk-averse.

Do you see that?

A. I do.

Q. That's not a statement that Impax would not have launched at risk either, is it?

A. It's not.

MR. LOUGHLIN: I have no further questions, Your Honor.

JUDGE CHAPPELL: Will there be any redirect?

MR. McINTYRE: Yes, Your Honor. Probably about 20 minutes or so.

JUDGE CHAPPELL: Let's go.

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REDIRECT EXAMINATION

BY MR. McINTYRE:

Q. Dr. Addanki, at the beginning of Mr. Loughlin's cross-examination, do you recall that he posed a number of hypotheticals to you in which he asked you to assume that we knew the brand company's and the generic company's reservation dates?

A. Yes.

Q. And as I believe you testified later, we don't know what Impax' reservation date here was, do we?

A. We do not.

Q. And do we know Endo's?

A. No, we do not.

Q. Dr. Addanki, did you review the reports and testimony that have been offered by Dr. Bazerman, the FTC's negotiation expert?

A. Yes.

Q. And do you recall whether he identified Impax' reservation date?

A. I don't think he knew what Impax' reservation

dates per se were.

Q. And do you recall whether he identified what Endo's reservation date was?

A. Again, I don't believe he could identify a specific date.

Q. Dr. Addanki, you testified a moment ago that you did not calculate an expected value of consumer benefits under the but-for world of continued litigation here because you didn't have to.

Can you explain why that was not necessary in this case?

A. I didn't have to, Your Honor, because of exactly as I testified when response to the question in my direct testimony about whether my opinion depended at all upon the probabilities of the outcomes of

opinion dependent on recent patent court rulings from 2016 or 2017?

A. It is not.

Q. Now, counsel for the FTC reviewed with you an exhibit that was marked as CX 3038. If you want to look at it, it's in your white binder.

A. I have it.

Q. And the date of this e-mail was April 2, 2010; correct?

A. That's correct.

Q. That was before the settlement was entered?

A. Yes.

Q. Do you recall at this point in time whether Endo had yet submitted its NDA for reformulated Opana ER?

A. It had not.

Q.

A. I2ntered?

received NDA approval for reformulated Opana ER?

A. I believe it was late in 2011.

Q. And before Endo received NDA approval, was there any -- did it have the ability to launch reformulated Opana ER?

A. No, it did not.

Q. And counsel for the FTC also reviewed with you

still be being dispensed?

A. Yes.

Q. We talked a bit about a SSNIP analysis.

To your knowledge, did Dr. Noll calculate any cross-elasticities between Opana ER and any other long-acting opioids?

A. He did not. Not to my knowledge.

Q. And did Dr. Noll perform a mathematical SSNIP test?

A. To my knowledge, he did not.

Q. And I believe you may have covered this during your cross-examination, but you mentioned that the change in rebate year over year from 30 percent to 38 percent that was offered to an insurance company, it -- did I get this right, that you testified that that change in rebate would be a SSNIP?

A. It would.

Q. And so what does that tell you?

A. By itself, it doesn't tell you anything. It does tell you that there was a change in rebate terms which was a small enough price increase that it was something that was entered into, it was proposed and accepted, which tells me that even small price changes were competitively potentially significant.

Q. And when we discussed the UPMC study yesterday,

does that formula change described in that study -- would that represent a change in the relative price between various long-acting opioids?

MR. LOUGHLIN: Objection. Beyond the scope of cross, Your Honor. I didn't discuss the UPMC study.

MR. McINTYRE: You discussed extensively on cross SSNIP analysis, changes in relative price. The UPMC study that we did discuss yesterday is directly probative of changes in relative -- consumer responses to changes in relative price.

JUDGE CHAPPELL: I heard plenty on cross about SSNIP, but I didn't hear Mr. Loughlin relate it to this insurance study.

MR. McINTYRE: That's true, Your Honor. Mr. Loughlin did ask, as I recall, a number of questions to Dr. Addanki about responses to changes in the relative price, and I just want to confirm with the witness whether he has seen evidence of changes -- consumer responses to changes in relative price in this case.

JUDGE CHAPPELL: You can ask him that question. That's more foundational.

MR. McINTYRE: Okay.

JUDGE CHAPPELL: The current question, the objection is sustained.

saving, but there was substantial volume change in response to a formulary change. And the formulary changes we're talking about more generally are in response to price changes, so UPMC tells us that indeed price changes lead to formulary changes -- pardon me -- lead to volume changes. Excuse me.

Q. Thank you.

Now, if you could please turn to your report. This is RX 547. And we're going to be looking specifically at RX 547.0094.

A. Yes.

Q. And this again is from the documents considered list that is attached to your report; correct?

A. Yes.

Q. And looking under the heading that says "Testimony," do you see that?

A. Yes.

Q. And it says here that you reviewed the testimony of Carole Sue Ben-Maimon and the accompanying exhibits?

A. Yes.

Q. And that you also reviewed the deposition of Margaret Snowden and the accompanying exhibits?

A. Yes.

MR. McINTYRE: Your Honor, may I briefly confer

MR. McINTYRE: No, Your Honor.
JUDGE CHAPPELL: Thank you. You may stand down.
THE WITNESS: Thank you, sir.
JUDGE CHAPPELL: How much time to you need for this fact witness?
MR. HASSI: For the fact witness? I would guess about an hour on direct. I've never met him before, so I don't know how verbose he will be, but I would say probably about an hour.
JUDGE CHAPPELL: You have one fact witness, and then you're through for the day with your witnesses?
MR. HASSI: Yes, Your Honor.
JUDGE CHAPPELL: What's your level of confidence on Tuesday next week that you will finish?
MR. HASSI: Very high, Your Honor.
JUDGE CHAPPELL: How many witnesses?
MR. HASSI: Two fact witnesses, Your Honor, and both should be relatively -- relatively brief, subject to again the cross-examination.
JUDGE CHAPPELL: All right. We'll take our lunch break now.
MR. HASSI: Thank you, Your Honor.
JUDGE CHAPPELL: And we will reconvene at

2:15.

We're in recess.

(Whereupon, at 1:18 p.m., a lunch recess was taken.)

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

(2:16 p.m.)

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

Call your next witness.

MR. HASSI: Your Honor, respondents call Dr. Robert Cobuzzi to the stand.

JUDGE CHAPPELL: The next witness for today needs to be available on short notice.

MR. LOUGHLIN: Yes, Your Honor. He's here.

JUDGE CHAPPELL: All right. Thank you.

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Whereupon --

ROBERT JOSEPH COBUZZI, JR.

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

DIRECT EXAMINATION

BY MR. HASSI:

Q. Dr. Cobuzzi, could you state your full name for the record, please.

A. My name is Robert Joseph Cobuzzi, Jr.

Q. And who is your current employer, sir?

A. Endo Ventures Limited. It's part of Endo International.

Q. And just generally, what is Endo Ventures?

A. Endo Ventures is the Irish subsidiary of Endo International. We're specifically responsible for management of the global supply chain for Endo.

Q. And what is your position with Endo Ventures?

A. I'm the president of Endo Ventures.

Q. And in that position, who do you report to?

A. I report to the chief operating officer of the company.

Q. When did you begin working at Endo?

A. May 2, 2005.

Q. And what was your title when you began working at Endo?

A. I was director of I believe it was scientific licensing at that point.

Q. And how long did you hold that position?

A. Several years. I don't remember the specifics.

Q. Do you recall what your position was in 2010?

A. 2010. I would have been the senior vice president of corporate development at that point.

Q. And can you briefly tell us what your responsibilities were as senior vice president of corporate development?

A. Sure. I would have been responsible for managing the team that evaluated deal opportunities, be they individual product licenses or company

acquisitions that we were looking at.

Q. And how long were you in that position as senior vice president of corporate development?

A. Approximately six years. I don't remember the start and end dates.

Q. When did you go to Endo Ventures?

A. I started formally there in March of 2015.

Q. Did you hold any positions at Endo between being SVP of corporate development and your current role as president of Endo Ventures?

A. Yes. I was the senior vice president of R&D strategy and operations, so I was basically the head of U.S. R&D for Endo.

Q. I'd like to back up a second and ask you to describe for us your educational background, please.

A. So I have a bachelor's degree in biochemistry and art history from Colby College in Maine.

I hold a Ph.D. in biochemistry and biophysics. It was changed to molecular and cellular biochemistry at the time that I graduated from the program.

I completed a postdoctoral fellowship in experimental therapeutics at Roswell Park Cancer Institute in Buffalo, New York.

Q. And you mentioned a Ph.D.

What was the topic of your Ph.D. dissertation?

A. It was in the area of Parkinson's disease, looking at putative toxins that could have been causative agents within the disease, at least as far as it was understood at that time.

Q. And on a high level -- you mentioned postdoctoral work -- could you describe what that work entailed.

A. Sure. We were looking at specifically trying to identify agents that would break DNA as therapeutic agents for oncology. I was in a laboratory in the Department of Experimental Therapeutics, as I said, and we were trying to identify drugs that could be useful chemotherapeutics.

Q. And after your postdoctoral studies, what did you do next?

A. I went to work for what was Merck, Astra Merck, as a clinical program scientist at that time.

Q. When you were at Endo -- well, strike that.

So it sounds like from your Ph.D. dissertation you have a background in Parkinson's disease; is that right?

A. That would have been the area, yes, in which I did my research.

Q. Did any of your colleagues likewise have a background in Parkinson's disease treatments?

enter into any pharmaceutical collaborations with other pharmaceutical companies?

A. Yes.

Q. On a high level, could you describe what kind of collaborations you entered into.

A. Goodness. Sorry. Could you be a bit more clear. Are you looking for acquisitions or what types of deals?

Q. Well, we're going to be talking about a co-promotion and development agreement in this case that I suspect you're familiar with.

Were there other deals like that that you entered into when you were at Endo?

A. There were some. There was a large variety of different deals. I wouldn't say there's any one-size-fits-all solution. We did many deals.

Q. And in your role as senior vice president of corporate development, what role would you have played in developing those deals?

A. So as indicated, I was responsible for managing the team that would have conducted the evaluation both on the scientific side, the commercial side, the financial side for the models, and for then working with the CEO and the board of directors to go through the approval process.

Q. When you were in that role, did in-licensing collaborations play any specific role at Endo?

A. Yes.

Q. And could you describe what role they played for Endo.

A. Endo historically has not had a research function. There is no molecule discovery per se, so anything that we brought into the company had to be acquired from the outside, so that would have been the purpose of the in-licensing.

Q. And do you do that -- well, strike that.

When you talk about in-licensing, can you describe what you mean by "in-licensing"?

A. So in-licensing specifically, in particular what we were trying to doing with it, would be to bring in a molecule or a technology that another company or individual or an institution would have had that hopefully was going to solve a problem that we were looking to solve, be it a gap in the portfolio or a particular type of product we were looking for.

Q. When you in-licensed a product or a molecule, was there any one stage of development that at which the in-licensing happened?

A. Could you be a bit more specific.

Q. Sure. I apologize.

We've heard in this trial that pharmaceutical products go through a development stage and different trials with the FDA, for example.

Is there any one stage where those deals take place or do they cut across the spectrum?

A. The latter. I would say for Endo in particular they were across the spectrum.

Q. Were there any -- can you give us some examples of products that Endo has in-licensed?

A. Sure.

I think one of the more notable ones was a product called Belbuca that ultimately we brought in, we developed, we licensed it from a company, got it approved, commercialized it, so that would be one.

We've also done early-stage development deals as well where we've identified companies themselves that had molecules that were of interest to us because of the therapeutic area, but we had, as I said, no discovery pipeline ourselves in place, and so these were very early, very speculative agreements that we'd enter into.

Q. Let me ask you about a couple of products in particular.

How did -- Endo in 2010 was selling Lidoderm; is that right?

A. Yes.

Q. How did Endo acquire the rights to sell Lido- -- or how did Endo develop Lidoderm?

A. So Endo actually licensed Lidoderm from a Japanese company called Teikoku, and this was in conjunction with the Hind family. Dr. Hind would have been the developer of this product, so my recollection is that in the late '90s is the time that Endo licensed this in. It was before I joined the company.

Q. This case centers around Opana ER.

Was Opana ER an in-licensing candidate?

A. So it's a bit more complicated answer.

So Endo had a previous -- had previously been responsi7e time that n more cota .

particular therapeutic areas or types of products that Endo was focused on seeking pharmaceutical partners for?

A. I think, first of all, I have to caveat it by saying that it's never been that focused. There's been areas in general.

But in 2005, the areas of significant interest would have been pain, in particular, neurology, areas of movement disorders, Parkinson's disease being one of those, gastroenterology, and other areas where there are either compatible markets for the pharmaceutical sales force to sell products that would be complementary or where there was therapeutic overlap with the other products that we were developing.

Q. And you just described something as "compatible markets for the pharmaceutical sales force to sell products."

Can you explain what you mean by that?

A. Sure.

I'm prefaced by saying I'm not the commercial person, but as my commercial colleagues would have told me, there's call points that they go out to, certain physician populations that they go out to, and if they could have similar products in the bag that

might be of interest to those physicians, that would be, quote, a compatible call point.

Q. When you were in your role as senior vice president of corporate development, would those areas, pain, neurology, be relevant to the work you were doing in seeking out pharmaceutical collaboration partners?

A. Yes.

Q. By 2010, had the therapeutic areas that we were just talking about, pain, neurology -- had the company's focus shifted away from those areas?

A. Yes. There was a new CEO by that time, and his primary interest would have been the areas of urology, endocrinology and oncology. It's a bit more complicated than that, but that would have been the principal focus.

Q. Does that mean that Endo and its sales force had abandoned things like pain and its adjacencies, neurology?

A. No.

Q. Did you still have a -- to your knowledge, a sales force out there selling pain products?

A. Yes.

Q. Are you familiar with the product Frova?

A. I am.

Q. And can you just tell us briefly what Frova was.

A. Frova is a molecule named -- frovatriptan is the actual chemical. And it's a treatment for migraine.

Q. And did Endo bring Frova to market?

A. Yes.

Q.

not just a single population of physicians who see migraineurs.

Q. You mentioned primary care physicians.

Do they prescribe Frova, to your knowledge?

A. To my knowledge.

Q. And do you recall whether -- well, strike that.

What's the relationship between central nervous system diseases and neurology?

A. Neurology is a subset of central nervous system diseases.

Q. During the time that you were looking at collaborations, did Endo look at doing collaborations in the central nervous system area generally?

A. It's unfortunately a bit more complicated than that, but I would say not generally, no.

Q. What area -- what therapeutic area did Parkinson's disease treatments fall into?

A. Broadly speaking, movement disorders.

Q. And is movement disorders related to either neurology or CNS7 BDC 1.8 -2.035 Td(mp BDC 1.8 -2.035 Td(A.)TjEMC

Q. Did you, when you were in corporate development, look into any opportunities -- I'm setting aside for a minute the one with Impax -- but other opportunities related to Parkinson's disease?

A. Yes. We looked at multiple.

Q. Do you recall any in particular that you looked at?

A. Yes.

Q. Can you describe ones you looked at?

A. Sure.

We looked at -- there was a series of compounds -- and I'll apologize up front. I don't remember all the names of these. It's been a while.

But we looked at -- from an Italian company called Newron, we looked at a couple of products they had.

We diligenced a Finnish company that actually had a product with a totally novel mechanism of action.

And there were a couple of others that we looked at as well. I just don't remember all the details and names.

Q. Now, did there come a point in time where Endo negotiated a collaboration agreement with Impax related to a Parkinson's disease treatment?

A. Yes.
Q. And were you involved in that?
A. I was.
Q. What was your role in the negotiations or development of the co-promotion agreement with Impax?
A. So I was the head of corporate development, and so it was my team that did the evaluation, and we had responsibility at least in part -- no one ever fully has singular responsibility -- but for negotiating the deal with Impax.
Q. And you mentioned a team.
What was your role on that team?
A. I was the leader of the team and effectively the lead scientist.
Q. And what was the subject product of the collaboration between Impax and Endo?
A. The deal was done for IPX-203.
Q. Did Endo suggest there be any other products, that any other products be the subject of a collaboration between Endo and Impax?
A. I'm sorry. Could you state that again.
Q. Did Endo suggest that Impax and Endo collaborate on any other products in addition to or instead of IPX-203?
A. Yeah. I'm just -- sorry. I'm just responding

to the way the question was phrased, but IPX-066 was another product that was discussed.

Q. Can you describe for us what IPX-066 was?

A. It was a well-known combination of drugs, carbidopa and levodopa, that had been formulated to extend the release profile or change the kinetic parameters of the drug.Can youcribe for us what IPX-068 was? A.

Q. I want to ask you some questions about IPX-203, and I want to do them on sort of a high level. When we get to the specifics about the drug and the development, we're going to do an in camera session so that that information can be kept confidential.

But on a general level, can you describe why Endo was interested in IPX-203?

A. Yeah. Similar to what was mentioned a moment ago, it would have been the perceived compatibility with the sales call points we had with the pain sales force.

The two underlying molecules, albeit there was some modification, you know, get too deep into the technicalities, but carbidopa and levodopa were known molecules. The data from IPX-066 that we had seen indicated that the extended-release formulation conferred a benefit to the product, and so the totality of it was there was enough reason to believe that there was potentially a product there.

Q. Did you receive information from Impax about the IPX-203 product concept?

A. Yes.

Q. Do you recall what format you received that information in?

A. My recollection is it came in the form of a PowerPoint slide deck.

MR. HASSI: Okay. Your Honor, if I could request -- that particular PowerPoint is in camera. I'd like to request an in camera session at this time to discuss some of the specifics of the product.

JUDGE CHAPPELL: At this time we'll go into in camera session, and I'll need to ask those that are not subject to the protective order to vacate the courtroom.

(Whereupon, the proceedings were held in in camera session.)

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(The following proceedings were held in in camera session.)

(End of in camera session.)

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(The following proceedings continued in public session.)

JUDGE CHAPPELL: Lawman, let them in.

THE BAILIFF: Will do.

MR. HASSI: Shall I wait, Your Honor?

JUDGE CHAPPELL: Wait on the crowds to file in.

MR. HASSI: Okay.

(Pause in the proceedings.)

JUDGE CHAPPELL: Go ahead.

BY MR. HASSI:

Q. Sir, in addition to the PowerPoint that we just looked at, did you receive other -- did Endo receive other information from Impax about IPX-203?

A. I don't remember specifically.

Q. Do you recall whether you -- whether Endo received information about IPX-066?

A. Yes. I believe there was a slide deck that we received for that as well.

Q. And was the information relating to IPX-066 relevant to assessing IPX-203?

A. I believe so.

Q. And can you explain why?

A. Well, IPX-066 and IPX-203 were both to use the same formulation, that is, the -- the delivery

A. "OEW" stands for opportunity evaluation worksheet. It was basically a written explanation of the opportunity that included an assessment of the science, the potential commercial opportunity and any financial analyses that were done around it.

Q. It goes on to talk about -- it says, again a reference to you, "will be looking for the valuation work re financial forecasts."

What was the relationship of valuation work and financial forecasts to the OEW?

A. So part of the analysis of any opportunity we look at is to understand its value to Endo and specifically the financial value based upon all the various inputs, the scientific, medical and commercial inputs, and so this valuation was, if you will, a mathematical or a financial assessment of that.

financial analyses that were doking igSssmentgaeex lS/udof t/2l9Edo

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A.

business.

Q. And how would Ms. McHugh as the head of the commercial business help you evaluate the IPX-203 opportunity?

A. She would have been ultimately responsible for the commercial assessment of the product, any product that we looked at.

Q. And what do you understand the reference to "the work that has been done on IPX-066 would be an appropriate proxy from a commercial perspective for the economics on IPX-203"?

A. So anytime we do a commercial assessment we look for a comparable model to use -- in this case it gets referred to as a proxy -- so that we can make some estimation as to what we think the performance might look like in the marketplace from a sales revenue standpoint.

Q. Do you recall how long Endo spent reviewing information regarding IPX-203?

A. Not specifically.

Q. Does the time frame that you spent working on IPX-203 stand out in your mind in any way as being unusually long, unusually short, anything like that?

A. It was short.

Q. Was it -- was it unusually short?

A. Sorry, but "unusually" is a qualitative statement.

Q. And I apologize.

Is there a usual in terms of, when you're doing a business development deal, how long one of those deals takes from start to finish?

A. No. There's -- there's no usual.

Q. In any event, did you feel like Endo had sufficient time to assess the information it needed before entering into the development and co-promotion agreement with Impax?

A. Given the availability of the IPX-066 data, yes.

Q. And did you feel like you had sufficient information to enter into that agreement with Impax?

A. Sorry. "Sufficient" is fairly subjective, but I think we had enough to come to the conclusion and do the deal given the deal construct that we came up with in the end.

Q. And you just mentioned the deal construct.

What do you mean by "the deal construct"?

A. So the deal construct in this instance was one that effectively left the responsibility for developing the product with Impax, and it was done on the basis of an upfront payment, and so by the time there was an

additional payment that Endo would have to make, essentially the risk associated with proving the concept would have been retired at that time, so we would have been relatively comfortable with the way that we were able to mitigate our risk just given the deal construction.

Q. Did you come to a conclusion about whether or not Endo should enter into the development and co-promotion agreement with Impax?

A. Sorry. What do you mean by "you"?

Q. You and your -- did you and your team that was

e-mail, Robert.

And blow up the e-mail on the bottom of the page.

And sir, looking at Exhibit CX 2748, is this an e-mail you sent to others at Endo?

A. Yes.

Q. Okay. And what's the subject of your e-mail?

A. So the people on this page would have been the members of the executive team on the To row, and the subject is to explain that we were providing a copy of the OEW, the opportunity evaluation worksheet, that we talked about a moment ago and asking if there were any feedback from any of these people with regard to the opportunity and the -- essentially the evaluation of the opportunity itself.

Q. And it refers in here to a Project Imperial.

Was that a code name that Endo used for the development and co-promotion agreement opportunity with Impax?

A. Yes.

Q. Was it normal to use code names when you were working on a development deal?

A. Yes.

Q. And in your e-mail, on the last sentence of the first paragraph, you write, "I believe this OEW

provides adequate and fair representation of what I would define as a good deal for Endo."

What were you telling the executive team at Endo by -- in that sentence?

A. I was providing my opinion on what I thought was the outcome of the evaluation.

Q. And what was your -- what was your team's collective opinion on the outcome of the evaluation of entering into a development and co-promotion agreement with Impax?

A. That it would be a good deal for Endo.

Q. Can you describe briefly what the -- what the OEW is?

A. I think similar to what we talked about before, the OEW is the opportunity evaluation worksheet. It is a summation of all of the analyses that have been conducted by the various functions that have the opportunity to look at whatever it is that's being looked at. Sorry that sounds vague, but in this case it would have been IPX-203 and the information from 066 would have been compiled together, and those analyses and conclusions are included in the OEW itself.

Q. Was the OEW itself a standard form for evaluating opportunities?

A. At that time, yes.
Q. Did Endo prepare an OEW for 066 as well as 203?
A. I don't remember specifically.
Q. Let's -- let's look at tab 4 in your binder. This is CX 1007.
And it's in evidence. And there are portions in camera. We're only going to be looking at the cover e-mail, which is not in camera.
And if you could, Robert, blow up the -- thank you.
Sir, is this an e-mail that you sent to a group of individuals at Endo?
A. Yes.
Q. And can you identify who the people are in the To line and the CC line? Who are you sending this to?
A. So these would be the people that were actually going to perform the due diligence.
Ernest Kopecky was the clinical representative of the team.
Paula Clark would have been the regulatory representative.
Frank Diana was the person with expertise in formulation, how the drug is put together.
And Stephen Bai would have been the person who

was responsible for doing what we would call pharmacokinetic analysis, looking to determine how readily the product is taken into the blood.

Q. How about the individuals on the CC line? Could you identify them as well.

A. So Ivan Gergel would have been the head of R&D at that time.

Kevin Pong -- we spoke of him -- he was the lead evaluator. He reported to me.

And Charles Gombar was the head of project management for Endo.

Q. At the end of the first paragraph of your e-mail, the last sentence, you write, "As this is an area we know well as a company both in terms of past evaluations and by virtue of the fact that we previously held the rights to IR Sinemet, this should not be a difficult evaluation."

Can you explain what you were telling your team in that sentence?

A. I was telling the team that from my perspective, I didn't think this was going to be difficult to evaluate.

Q. And why wasn't it going to be difficult to evaluate?

A. We knew the space, we knew the underlying

molecules, the carbidopa and levodopa, and we looked at a number of Parkinson's opportunities in the past, so we knew the general landscape or the area in which we were looking at this as a commercial opportunity.

Q. Now, you mentioned earlier that ultimately you would go to the board of Endo with this -- with the OEW and the information about the deal?

A. Yes.

Q. Okay. If you'd look at tab 5 of your binder, it's CX 1209.

And this document is in evidence, also partially in camera. We're only going to work with the public sections of it.

And if we could start by blowing up the e-mail.

8th of June, and there's also included with this an OEW, the opportunity evaluation worksheet, the summary of the opportunity of what we looked at.

Q. Okay. I want to look at some specific sections of the OEW.

Let's go first to page -3.

And the information that's -- the information that's redacted is the in camera information, so this is the public version.

But if you could take a look at item 3 on this page, there's a reference to Endo as a company is quite familiar with Parkinson's disease -- excuse me -- with the Parkinson's disease area.

Can you tell us what you meant by including that in the OEW?

A. It was just to provide context for the reviewers of this document as to how we would go about looking at this and the fact that we'd experience in the past of looking at products within the Parkinson's disease space.

Q. If you would turn to page -7. And I'm using the -- there are page numbers at the very bottom. I think in this case they're one off the page numbers of the document.

And I apologize. It actually -- actually

starting on page -6, there's a section 7, Scientific Opportunity Summary. The questions I want to ask you are on page -7.

A. Okay.

Q. And do you see at the top of page 7 -- if, Robert, if you could pull up directly beneath the redaction -- it says, "Although IPX-203 has not yet been formulated, Impax has developed and performed clinical studies on a similar CD-LD formulation which they have named IPX-066."

What were you telling your board there?

A. So these words weren't written by me directly; they were written by the team. But my reading of this is that it was indicating that even though IPX-203 -- and the word "formulated" isn't quite correct. Sorry -- but even though it's slightly different, it's similar to this other product, IPX-066, which contains carbidopa-levodopa, CD-LD as it says here, in a formulation which had been developed and for which some clinical studies had been performed at that time.

Q. Just below that there's a section that says "Path to Approval."

What does that section analyze? At a high level.

A. The section itself is supposed to describe the

steps that would be required on a standard or nonstandard development pathway to take it all the way through the approval process to get the marketing authorization.

Q. And did you believe at this point in time in presenting this information to your board that there was a path to approval for IPX-203?

A. Yes.

Q. And what role does the path to approval play in Endo's overall assessment of a drug candidate?

A. Sorry. It's a broad question.

Q. It is.

What I'm trying to specifically get at is, is there regulatory risk in the path to approval?

A. Absolutely.

Q. Is that any -- is it any difc /Sa s-- is it an-roval. is iB

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foundation.

We haven't established that this witness was involved in the regulatory risk or assessing regulatory risk.

MR. HASSI: And Your Honor, this witness has already testified that he led a team and he identified the regulatory person on that team.

JUDGE CHAPPELL: Do you understand the question?

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: Overruled.

THE WITNESS: So every drug that is developed has inherent risk in the development program. Even drugs that ultimately get commercialized still have risks.

This had a risk profile that we understood, which I think is the best that we could ask for a drug in development.

BY MR. HASSI: drug

in developepment.

page -11, please, Robert.

Do you see here there's a reference to "Market research provided by Impax is similar to work done several years ago by Endo in evaluating other PD-related opportunities"?

Had Endo evaluated other Parkinson's disease opportunities by this point in time in 2010?

A. Yes.

Q. And did that assist you in your evaluation of IPX-203 as a candidate?

A. Yes.

Q. It goes on to say, "This work indicates that most physicians who treat PD patients" -- and I -- PD, do you understand that to be Parkinson's disease?

A. I do.

Q. -- "are generally satisfied by existing treatment options with two exceptions: 1) existing treatments do not modify the course of the disease, they only" -- is it "palliate symptoms"?

A. Yes.

Q. -- "and 2) existing drugs begin to lose effectiveness within 10 to 15 years after initiation of therapy due to the development of feedback inhibition and other biochemical mechanisms that can be classified loosely as 'resistance.' Other unmet needs

include a need for better control of efficacy over time."

Was IPX -- was the hope that IPX-203 address any of those specific unmet needs?

A. The hope is that it would address what's listed as exception number 2.

Q. And can you briefly describe how it would address exception number 2?

A. The biology of the disease isn't extremely well-characterized. But given experience with carbidopa and levodopa in the past, the belief was that if you could improve absorption and extend the period of time within the body the drug could be absorbed that you might get more of the drug into the system and thereby be able to have a more effective treatment for the product. And the hope is, by doing that, you could lower the dose. And the more that you're able to lower the dose or at least maintain a person on a steady dose over time, the hope was that that would reduce this loss of effectiveness.

Q. If we could go to the next page, -12.

And if you could blow up the section Estimation of Market Opportunity and beneath that.

I'm sorry. Actually, if we could go up the paragraph above that first. Sorry, Robert.

It says here, in the second sentence, "IPX-066 has been developed by Impax to address physician's desire for a superior long-acting carbidopa-levodopa product, and IPX-203 represents a still greater improvement in pharmaceutical profile with a value proposition that includes faster onset of action, superior management of motor fluctuations and convenient oral dosing in a simplified regimen that could require no more than twice-daily administration, and in some cases even once-daily administration."

Can we start -- can you just explain what "faster onset of action" means?

A. So it's the time from when the drug is effectively placed in the mouth by the patient to the time when the effects are realized.

Q. Is that sometimes referred to as time to on?

A. Time to onset, yes.

Q. And superior management of motor fluctuations, what does that mean?

A. Parkinson's disease is a movement disorder, so the fluctuations would be the choreic or sort of spastic movements or the inability to move, akinesia, or unintended movements, dyskinesias, so it was an attempt to try and control some of that.

Q. And then the reference to oral dosing in a

simplified regimen, what was the advantage that IPX-203 could present in that area?

A. So some patients who take Parkinson's -- treatments for Parkinson's disease, as their disease progresses, they have to take the drugs more and more frequently. The hope was here and what was being posited by Impax is that the formulation would improve the duration of time the drug was active in the body, and so the hope was that they would have to take the drug less frequently.

Q. Is that an advantage if you have to take the drug less frequently?

A. Yes. These are patients who have a difficult time when the drug is not working even picking up the pill, so the less frequently you have to go through that activity, yes, it would be an advantage.

Q. If we could move down the page, Robert, to the Estimation of Market Opportunity.

And if you could just summarize for us in a few words, sir, what this -- what in this section of the OEW you and your team were telling the board of directors of Endo.

A. This piece that we're looking at here and with what -- I'm looking at both pages simultaneously -- but it's an attempt to express to the reader what we saw

quantitatively as the opportunity or commercial opportunity for the product, including giving some of the high-level assumptions that would have factored into establishing what we saw as that quantitative opportunity.

Q. I want to go back to page -3.

And you mentioned earlier or you described the deal structure as mitigating the risk to Endo.

And if you look at note 6 on page -3, it reads, "The deal structure acceptably mitigates Endo's exposure despite the early development stage."

Can you explain what you meant by that?

A. So the way it's described here is that the $10 million upfront to access the technology and support is one piece of it, but further payment is contingent upon completion of defined clinical milestones, which in this case was Phase II studies, so proof of concept would have been established before further payments were made.

Q. And how does that mitigate the risk to Endo?

A. So we know what the cost is up front. Drug development is extremely expensive.

And so we could quantify how much money we were paying and we weren't having to place any internal resources. Frankly, in this particular instance, we

were using cash as opposed to from an accounting standpoint using our P&L, our profit and loss statement, as a way of financing the development to establishing proof of concept, completion of Phase II.

Q. And in terms of that, the cash you were using, was $10 million a lot of money to buy into this opportunity?

A. For me it's a lot of money. For the company, I would say no.

Q. And can you explain why it's not, $10 million for this opportunity is not a lot of money to Endo, even if it might be a lot for you or me?

A. I think unfortunately it's a relative statement because it's both how much we pay, which is reflective of the development cost of the product, but there's also what gets negotiated with the other side because in the end it's still a deal, it's not simply paying for development of the product.

Q. So the $10 million is part of a larger arrangement between Impax and Endo; is that what you're saying?

A. I'm saying it's negotiated as a deal for IPX-203, and then as part of that deal, as for any other in-licensing deal that we would do, it's not an uncharacteristically large amount of money, no.

compares the base, optimistic and conservative cases or at least components of those cases. It weights them.

And then it goes through and it looks at the co-promote components, so we're not looking at the totality of all expected sales for the product but just those components that we would have realized as the co-promotion partner.

And then NPV is the net present value or the value for the cash spent today and relative to what we would spend in the future and receive in the future.

And then the IRR or the anticipated internal rate of return, we had a hurdle rate of 10 percent for the company, so this exceeded the internal hurdle rate for the company.

Q. Is that a good thing to exceed the internal hurdle rate?

A. Yes.

Q. Let's go back to the cover e-mail of this, your e-mail to the board of directors.

Is it fair to say that in this e-mail and with the attached OEW you were recommending that development and co-promotion agreement as an exciting opportunity for Endo to your board of directors?

A. Yes.

Q. And you go on to say -- and this is in the

second to last paragraph -- you say "it further builds out our product pipeline for the future with a drug candidate that fits with our commercial footprint."

What did you mean by that?

A. So this was at a time for Endo that there wasn't a lot in the pipeline itself, meaning there weren't products that were going to come to market in the future, and so this provided us something with future commercial potential, accepting all of the risk associated with developing any drug, and also that it was consistent with what we talked about were the compatible sales footprint with the pain sales force as it existed at the time.

Q. Would you have sent this e-mail to your board of directors if you didn't believe that the opportunity of entering into the development and co-promotion agreement with Impax was justified?

A. No.

Q. Do you know who Dr. John Geltosky is?

A. I know of him. I've had some passing contact in the past, but I don't know him, no.

Q. If I told you he was hired to evaluate the work that you and your team did on this development and co-promotion agreement, and let me summarize it by saying he gave you a failing grade, do you have any

reaction to that?

A. It's his opinion.

Q. Do you agree with him?

A. No.

Q. Did you feel like you had sufficient information to evaluate the opportunity with Impax at the time you evaluated it?

A. I'm a scientist. I don't feel as though there's ever sufficient information, but I think we had the information we needed or were going in all likelihood to get at that point.

Q. And he described you and your team as flying blind in conducting any aspect of your diligence on the DCA.

Do you agree with that?

A. I think that's his opinion.

Q. Since you entered into this development, since Endo entered into this development and co-promotion agreement, have you learned of any information that would have changed your mind about the conclusion that you made at the time?

A. I honestly haven't followed the development that closely, I moved on, and even in the capacity of corporate development we weren't responsible for alliance management or for monitoring the ongoing

development of products that we licensed.

A. Of the potential deals, yes.
Q. And then of the deals on which Endo enters into some confidentiality agreement, it conducts further due diligence on only a fraction of those products; correct?
A. Typically. Yes.
Q. And then from there, Endo executes deals on an even smaller fraction; correct?
A. Yes.
Q. In other words, Endo doesn't sign a deal on every opportunity that comes to Endo; correct?
A. That's correct.
Q. And part of your responsibility when you were senior vice president for corporate development was to evaluate potential deals; correct?
A. Myself and my team. Yes.
Q. And one of your responsibilities was to screen out those opportunities that came to Endo; correct?
A. Correct.
Q. And you were trying to determine which deals fit Endo's strategic objectives, in part; correct?
A. In part, correct.
Q. And you were trying to figure out which of those opportunities presented good deal opportunities for Endo; right?

A. Yes.
Q. And you didn't -- let me start that over.
Endo didn't have unlimited resources to enter into deals; correct?
A. No.
Q. And so part of your job was to make choices about which deals Endo should make; correct?
A. Myself and the team. Yes.
Q. And if you spent $10 million on a development deal, that had to come out of your budget; correct?
A. It came out of the company's cash.
Q. Do you recall testifying about sort of the general process of evaluating business development deals in your direct examination just now?
A. The general process, yes.
Q. Can I ask you to take a look at CX 1701. It should be in your binder. And it will also be on the screen, Dr. Geltosky (sic), if you prefer to look at it that way.
I called you Dr. Geltosky. I meant Dr. Cobuzzi. I apologize, Dr. Cobuzzi.
A. That's okay.
I'll read off the screen.
MR. LOUGHLIN: Your Honor, I'll just note for the record that CX 1701 has been admitted as part of

JX 2. It is not in camera.

BY MR. LOUGHLIN:

Q. Now, Dr. Cobuzzi, this is an e-mail from you.

Do you see that?

A. Yes.

Q. And it's dated July 30, 2010.

Do you see that?

A. I do.

Q. So that's a few weeks after the entry of the development and co-promotion deal with Impax in early June of 2010; correct?

A. The date, yes.

Q. And this is a presentation -- well, let me start that over.

If you'd turn to the next page, this is a presentation by the corporate development group that you headed; correct?

A. I don't have -- it looks familiar, but I don't have enough context to specifically answer yes.

Q. All right. Well, let's turn back to the e-mail then.

A. Sorry. Is this an attachment to the e-mail? I don't know what tab we're looking at here.

Q. We're still looking at the same tab. It should say "CX 1701."

A. Okay.

Q. Okay. Do you see in the top e-mail that you sent on July 30, 2010, you say, "There have been a lot of questions regarding the Corporate Dev/BD process, so I have attached the slides I shared again with my department yesterday regarding organization, alignment, and roles and responsibilities."

Do you see that?

A. I do.

Q. And Corp Dev/BD, that's corporate development/business development?

A. That's correct.

Q. So the next page I believe is the set of slides that you attached; is that right?

A. Okay. Yes.

Q. And could I ask you to turn to CX 1701-011.

Are you there, Dr. Cobuzzi?

A. I am.

Q. And up at the top it says "Corporate Development Process."

Do you see that?

A. I do.

Q. And the first step in the corporate development process, there's a box that says "Asset Identification."

Do you see that?

A. I do.

Q. And the objectives there are to establish metrics and screening criteria based on BU/R&D-defined strategy.

Do you see that?

A. Yes.

Q. And "BU" stands for business unit?

A. That's correct.

Q. And asset identification then leads to initial screening.

Do you see that?

A. I do.

Q. And part of that is to identify, screen and prioritize assets, according to your key objectives.

Do you see that?

A. That was the objective.

Q. And if you get past the initial screening, there's a go/no go decision; correct?

A. In an ideal state, yes.

Q. And if you pass that go/no go decision, you get to the stage called evaluation; right?

A. That was the ideal state. Yes.

Q. And next to Evaluation -- and that phase, under the Key Objectives, it says, "Perform initial

evaluation - including high-level market opportunity assessment."

Do you see that?

A. Yes.

Q. And then it says, underneath it in the next bullet point, "Work with BU/R&D to gain internal alignment on strategic fit."

Do you see that?

A. I do.

Q. And after the initial evaluation, there's another go/no go decision; correct?

A. Yes.

Q. And presumably if you get past that stage, then you get to the stage that you entitled Due Diligence.

Do you see that?

A. Yes.

Q. And next to Due Diligence it describes the key objectives in the first bullet point as "Complete full opportunity evaluation - validate evaluation assumptions."

Do you see that?

A. I do.

Q. And underneath that, it says, "Develop commercial forecast and R&D plan, costs and timings

(including LCM)" and "Identify issues to be addressed by terms and contract."

Are those all objectives of the business development group in the due diligence phase?

A. They are in an ideal state.

Q. And then under due Diligence, there's another Go/No Go box.

Do you see that?

A. I do.

Q. And if you get past that go/no go decision, you get to negotiation and deal closure, according to this process that you presented to your team; correct?

A. Yes.

JUDGE CHAPPELL: Did this document apply in 2010?

MR. LOUGHLIN: Yes. This document is dated July of 2010.

BY MR. LOUGHLIN:

Q. And next to Negotiation and Deal Closure, the key objectives are: Define optimal tax, legal and operating structures.

Do you see that?

A. I do.

Q. Is that something that the corporate development group would do?

A. In conjunction with the tax, legal and operating teams. Yes.

Q. What do you mean by "operating teams"?

A. So where it says "operating structure" on there, we would have worked with the supply/manufacturing team, we would have worked with the clinical or other what we would term operating functions within the business to determine what the appropriate structure would be.

Q. Okay. And then underneath the first bullet point, the second one says, "Update valuation model." And then it says, "Negotiate structure, terms and conditions" and then finally "Obtain deal approval and communicate closure."

Do you see that?

Would the corporate development group typically be the one that's negotiating structure, terms and conditions?

A. In conjunction with the legal team negotiate, yes, but all the input to structure, terms and conditions was a broader team of people within the business.

Q. Dr. Cobuzzi, I believe under your examination with Mr. Hassi you mentioned that the corporate strategy for Endo was determined by the CEO. Is that

correct?

A. That's correct.

Q. And in 2010, I believe you said that the CEO's focus was urology, endocrinology and oncology. Is that right?

A. That was his primary focus. Yes.

Q. And I want to -- when you say "urology," you mean U-R-O-L-O-G-Y?

A. That's correct.

Q. Urology has to do with the urinary tract.

A. It does.

Q. Okay. Dr. Cobuzzi, you discussed with Mr. Hassi a few minutes ago some potential acquisitions or deals that Endo was looking at with respect to Parkinson's disease drugs. Do you recall that?

A. I do.

Q. And you mentioned an Italian company called Newron; is that right?

A. Yes.

Q. And I think you said there was a Finnish company; is that also right?

A. That's correct.

Q. Endo didn't do either deal with those two companies, did it?

A. No.

Q. Do you recall testifying in general about the strategic fit of IPX-203 to Endo with Mr. Hassi?

A. I remember being asked questions. Yes.

Q. Could I ask you to look in your binder at CX 1005.

And again, Your Honor, this document has been admitted as part of JX 2, and it is not in camera.

Are you there, Dr. Cobuzzi?

A. I am.

Q. Now, do you see there is -- up at the top of CX 1005-001 there's an e-mail from someone named

A. They are.
Q. And Endo had used LEK frequently in the past.
A. Yes. We have.
Q. And you attended this presentation by LEK; correct?
A. I don't remember if I attended.
Q. Could I refresh your recollection by showing you your transcript from 2014?
A. Sure.
Q. Take a look in your binder. You should see a tab that says "IH" near the back of the binder.
A. Okay.
Q. And specifically page 149.
A. Okay.
Q. And do you see line 6 says, "And what was your role in this presentation?"
And your answer was: "I was one of the people to whom the presentation was made."
Do you see that?
A. I do.
Q. Does that refresh your recollection that you attended this presentation?
A. It's another three years on. I just don't remember. Sorry.
Q. Okay. Now, Dr. Cobuzzi, Endo paid a couple

hundred thousand dollars for this presentation; correct?

A. I don't remember how much was paid.

Q. Could I refresh your recollection by having you look at some of your testimony from before?

A. Of course.

Q. On the same page, the bottom of 149, line 20, do you see that?

It says, "Do you know how much it cost to have LEK do this sort of research and presentation?

"ANSWER: Vaguely.

"QUESTION: How much vaguely? I'm just looking for a ballpark number."

And then over on the top of 150, it says, "A couple hundred thousand dollars."

Does that refresh your recollection?

A. It does of what's written here. I said it was vaguely at that time three years ago, yes.

Q. Okay. Could I ask you to turn to page CX 1005-064.

A. Sorry. 064?

Q. Yes.

A. Okay.

Q. Do you see at the top it says "Excluded Pre-Reg/Reg Products: Endo's products, Generics, OTC,

and co-promotes"?

A. I do.

Q. This was a list of products at the preregistration or registration stage that LEK was excluding as a product that it was recommending Endo might be interested in pursuing; right?

A. From what's on the page, it's what LEK recommended, yes.

Q. What it recommended in terms of products that Endo should not bother pursuing; correct?

A. Based upon what's here, I don't remember the context, sorry, no.

Q. That's what you understand by "excluded"?

A. That's what I understand it was saying, yes.

Q. And if you look down, the sixth row under Generic Name says "carbidopa plus levodopa, Impax."

Do you see that?

A. I do.

Q. And the company with U.S. rights is Impax Laboratories; correct?

A. That's what it says. Yes.

Q. And IPX-066 was a carbidopa plus levodopa product from Impax Laboratories; correct?

A. That's correct.

Q. And IPX-203 was also a carbidopa plus levodopa

product, with the exception of the esterified version of levodopa; correct?

A. With that exception. And a change in formulation.

Q. Now, in CX 105-0064 in that sixth row, do you see where it says in the final column "LEK Exclusion Rationale"?

Do you see that?

A. I do.

Q. And it says "Generic."

Do you see it?

A. I do.

Q. In 2010, there were generic versions of carbidopa plus levodopa on the market; correct?

A. Yes.

Q. Dr. Cobuzzi, could I ask you to turn in your binder to CX 1001.

And Your Honor, I'll note for the record that CX 1001 has been admitted as part of JX 2 and it is not in camera.

Dr. Cobuzzi, do you see on the first page of CX 1001 it says "Corporate Devel -2DfBvel -2Df".2 -2.ecCtT.ecCeTnen

A. I do.

A. I was on 1011. Sorry. Yes. Fine.
Q. Do you have it?
A. I do.
Q. So this is a presentation to Endo's board of directors; correct?
A. Yes.
Q. And that presentation was given on February 24, 2010; correct?
A. That's the date. Yes.
Q. And you were involved in making this presentation to the board of directors as part of the corporate development group; correct?
A. In all likelihood. I don't remember, but probably, yes.
Q. Could I ask you to turn to CX 1001-015 of this document.
A. Okay.
Q. And do you see the title is String-of-Pearls Strategy, Portfolio Build Opportunities?
A. Yes.
Q. And then pages CX 1001-016 through 25 list a number of potential products that Endo could acquire to increase its portfolio of products; correct?
A. Correct.
Q. And these products were all within Endo's

acceptance criteria; is that correct?

A. Based upon publicly available information at that time, yes.

Q. And none of the products listed from CX 1001 through -- 0016 through 25 is a Parkinson's disease drug; correct?

A. I'd have to look through the list.

Q. Well, take your time, do that.

(Document review.)

A. No. You're correct.

Q. So in February of 2010 there were no Parkinson's disease drugs that Endo was actively pursuing; correct?

A. Not that we were actively pursuing, correct.

Q. Dr. Cobuzzi, could I ask you to turn to CX 1002.

A. Okay.

MR. LOUGHLIN: And Your Honor, I'll note for the record that CX 1002 has been admitted as part of JX 2 and is not in camera.

BY MR. LOUGHLIN:

Q. Dr. Cobuzzi, the first page of CX 1002 says Corporate Development and Strategy Departmental Off-Site 7 March 2010."

Do you see that?

A. I do.
Q. This was prepared for an off-site meeting you had for your corporate development department; correct?
A. That's correct.
Q. In March of 2010.
A. Yes.
Q. Could I ask you to turn to CX 1002-0016.
A. Okay.
Q. Do you see up at the top it says "TAT Focus Areas"?
A. I do.
Q. And "TAT" means therapeutic area team?
A. That's correct.
Q. And so this lists the therapeutic areas that were the primary interest for looking for opportunities for Endo as of March 2010; correct?
A. That's correct. The primary areas.
Q. And Parkinson's disease is not listed on this page, is it?
A. Not as a primary area. No.
Q. Now, Dr. Cobuzzi, you testified earlier today that with respect to Impax, Endo was initially discussing a product called IPX-066; correct?
A. Yes.

Q. And that was a Phase III product; correct?
A. Approximately, yes.
Q. Now, you personally did not seek out the opportunity for IPX-066; right?
A. I didn't personally seek it out, no.
Q. And nobody in the corporate development group sought out IPX-066; correct?
A. No.
Q. By "no" you mean correct?
A. I do mean yes --
Q.
Q. Q.

correct?

A. I don't remember specifically, but it sounds about right.

Q. Now, with respect to IPX-066, Endo hired a company called Equinox to conduct a tpDes foectas.

Q. Now, do you see the top e-mail or the only e-mail on this page is from someone named Sam Rasty?

Do you see that?

A. I do.

Q. Now, Mr. Rasty -- or is it Dr. Rasty?

A. It's Dr. Rasty, yes.

Q. Dr. Rasty worked for you in the corporate development group; correct?

A. That's correct.

Q. And he says -- and he's e-mailing someone named David Godolphin, who appears to be at the Equinox Group; is that right?

A. Yes. Correct.

Q. And he says, in the second sentence, "We have an urgent forecasting need for a 505(b)(2) neurology in-licensing candidate currently in Phase III development and I'm writing to see if you have any capacity to provide guidance about the value potential of the asset based on your prior experience in the area and some rough market sizing."

Do you see that?

A. I do.

Q. And the in-licensing candidate currently in Phase III development was a reference to IPX-066; correct?

A. I'd have to find the context, but that sounds about correct.

Q. Well, IPX-203 was not a Phase III product; right?

A. No, it wasn't.

Q. In the next sentence, he says, "There is no time for market research on this as we need the forecast by Wednesday of next week (that's right, it's not a typo!!), so this would basically be a guidance about the range of the value potential as opposed to a fully vetted sales forecast."

Do you see that?

A. I do.

Q. And Mr. Rasty was relaying to Equinox the timeline that you were given by Mr. Levin; correct?

A. That appears to be the case.

Q. Now, you never got a fully vetted sales forecast for IPX-066; correct?

A. I don't remember if we got, but from this it looks like we didn't even ask for fully vetted sales forecasts.

Q. And Equinox didn't do any work for IPX-203; correct?

A. I don't remember specifically, but that sounds about correct. I think we relied upon the work that

Q. And if you go to the prior -- to the e-mail that's just above it on CX 1008-002, do you see Mr. Godolphin's response to you?

A. I do.

Q. And Mr. Godolphin says to you, "Our best point estimate of peak U.S. revenue at this time is $107 million."

Do you see that?

A. Yes.

Q. That means the highest annual sales amount is $107 million; right?

A. Yes.

Q. And that's Equinox' estimate of the peak sales of IPX-066 itself, not what Endo's revenues from the -- a co-promotion deal would be; correct?

A. I believe that's correct. Yes.

Q. And so Endo presumably would have earned some fraction of that $107 million, assuming that estimate was right; correct?

A. If it were co-promote.

Q. Right.

And then do you see Mr. Godolphin makes a few observations on -- looking back at CX --

A. I do.

Q. -- 1008-002?

Do you see?8

Do you see that?
A. Yes.
Q. At 7:39 p.m.?
A. Yes.
Q. And May 25, 2010 was a Tuesday. Do you recall that?
A. I don't recall what day of the week it was.
Q. Okay. Well, let's look -- let's look back at CX 1008, which we just looked at.
Do you have CX 1008 there?
A. I do.
Q. Do you see the second e-mail from you to Mark Bradley?
A. I do.
Q. It says it was sent on Thursday, May 27?
A. I see.
Q. So that means that May 25 would have been a Tuesday; correct?
A. That's fine. You asked me if I remembered the day, and I didn't remember the day it was. That's all.
Q. No. I understand. And now I'm asking if you -- do you agree with me that May 25 would have been a Tuesday.
A. I agree with you, yes.

Q. Okay. And in the -- do you see the sentence -- it's the third line that says, "We have very little time for this evaluation"?

A. I do.

Q.

correct?

A. I believe that they're all scientists and I believe that as scientists they always want as much time as they can get, so it's tongue in cheek, yes.

Q. Now, Dr. Cobuzzi, could I ask you to turn in your binder to CX 1208.

And Your Honor, I'll note for the record that CX 1208 has been admitted as part of JX 2 and it is not in camera.

So this is an e-mail from you, dated June 1, 2010.

Do you see that?

A. I do.

Q. And the subject is Imperial OEW.

Do you see that?

A. I do.

Q. And this -- and you're attaching the most recent version of the Imperial OEW that reflects all changes received as of last night; correct?

A. That's correct.

Q. And one of the first people you're sending this to is Dave Holveck.

Mr. Holveck was the CEO at the time; correct?

A. That's correct.

Q. And then the next person you're sending it to

is Alan Levin?
A. That's correct.
Q. Mr. Levin was the CFO at the time; correct?
A. Yes.
Q. And if you turn to the second page, CX 1208-002, this is the OEW for IPX-066; correct?
A. Yes.
Q. As of June 1, 2010, you believed that Endo and Impax were still discussing a deal on IPX-066; right?
A. That's correct.
Q. You wouldn't have circulated an OEW related to IPX-066 if you knew that the product was no longer under discussion; correct?
A. That's correct.
Q. Now, looking at CX 1208-002, do you see that this says "Evaluation: Kevin Pong"?
A. Yes.
Q. Does that mean Dr. Pong prepared the OEW?
A. It means he was the primary author. Yes.
Q. And you would have reviewed it and edited it; is that right?
A. Typically. Yes.
Q. Was Dr. Pong the lead evaluator for IPX-066?
A. He was, yes.
Q. Now, when you're reviewing an OEW, you rely on

your colleagues, who are experts in their specific areas, to make assessments and determine the appropriate information to go into the OEW; right?

A. Where there's time and we don't have that expertise ourselves, yes.

Q. So, for example, you don't consider yourself an expert in forecasting; correct?

A. No, I do not.

Q. So you don't generally make an assessment of forecasting in the OEW.

A. No, I do not.

Q. Could I ask you to turn to CX 1208-013.

A. Okay.

Q. Do you see the page is entitled Deal Terms and Valuation?

A. I do.

Q. And under Deal Terms do you see it says "Option fee (upon signing of option agreement): $10 million"?

A. Yes.

Q. And then there's a $5 million milestone payment?

A. I see that.

Q. And this again is for IPX-066; right?

A. That's correct.

Q. Now, you weren't involved in coming up with

those deal terms; correct, Dr. Cobuzzi?

A. We talked about the valuation before. I would have had a discussion around these deal terms.

Q. WereBDCDC 3 0 T mmerms.We talked about the valuation before Spa,pan

right?

A. That's correct.

Q. And there are a number of different permutations of ester structures; correct?

A. Yes, correct.

Q. And Endo, at the time of doing the deal with Impax, didn't know what ester form Impax would settle on; correct?

A. We didn't, correct.

Q. And Endo didn't know whether an ester form of levodopa would work; correct?

A. We didn't have precise data to support that. No. We had assumptions based upon what was available.

Q. And I believe you testified earlier that it's generally important for a new product to provide some improvement over existing products. Do you recall that?

A. Yes.

Q. You didn't evaluate whether IPX-203 was actually going to be an improvement over existing products, did you?

A. What do you mean by "evaluate"? That would imply that we conducted a clinical study and/or some other study to determine whether it was better.

Q. Were you asking me a question? Or was that an

answer? I couldn't tell.

A. It was a question back to you about your question to me.

Q. Yeah. Okay. Let's answer your question.

A. I'm not sure I follow you. I was asking a question to clarify what you were asking me.

Q. Okay. All right. That's fair.

You didn't evaluate in terms of conducting a clinical study or some other study to determine whether IPX was better or going to be an improvement over existing products; correct?

A. We had to make an assumption it was going to be better. That was the premise behind doing the deal and based upon the, call it, target product profile that was set forth for the product. But there's no way to evaluate whether it was better until an actual clinical trial was conducted.

Q. And you're aware that Impax never successfully formulated an esterified version of levodopa plus carbidopa, aren't you?

A. No, I'm not aware. That was a question that was asked earlier, and I don't stay with these programs after they're moved forward, so I don't have any firsthand knowledge of what actually happened.

Q. Could I ask you to turn to RX 282 in your

binder, sir.

Your Honor, this document, RX 282, has been admitted as part of JX 2. It is partially in camera, but I'm using a redacted version, and I don't intend to ask anything about in camera material.

Do you have it there, Dr. Cobuzzi?

A. I do.

Q. Could I ask you to turn to the second page of this document, RX 282.0002.

A. Okay.

Q. And do you see the bottom e-mail from Alan Levin to Chris Mengler, copied to you, dated June 3, 2010?

Do you see that?

A. I do.

Q. And it says, "Just a quick reminder that Bob Cobuzzi, Endo's head of business development, is still looking to speak with one of your R&D colleagues in order to progress our due diligence efforts on IPX-066a."

Do you see that?

A. I do.

Q. IPX-066a is what was later called IPX-203; correct?

A. That's correct.

Q. Can I ask you to turn back to the first page of RX 282.

A. Okay.

Q. Do you see the second e-mail from the bottom, it's from Michael Nestor to you and others, dated Friday, June 4 at 9:42?

A. I do.

Q. And it says, "Bob, Can you send me your contact information and Suneel Gupta, our CSO on the brand side, and I will give you a call."

Do you see that?

A. I do.

Q. Did you have a call with Mr. Gupta and Mr. Nestor on Friday, June 4, 2010?

A. I don't remember.

Q. Now, the top e-mail on RX 282.0001 is from Mr. Nestor to you.

Do you see that?

A. I do.

Q. And it's dated June 4, 2010 at 4:41 p.m.?

Do you see that?

A. Yes.

Q. And he is sending you a slide deck on IPX-203; correct?

A. That's correct.

Q. Now, June 4, 2010 was the first day that Endo was able to do due diligence specifically on IPX-203; right?

A. On 203 specifically, yes.

Q. Can I ask you to turn to CX 1011.

And Your Honor, I'll note for the record that CX 1011 has been admitted as part of JX 2 and it is not in camera.

Are you ready?

A. I am.

Q. Okay. This e-mail is from Alan Levin, the CFO of Endo, to Chris Mengler.

Do you see that?

A. I do.

Q. Do you recall that Mr. Mengler was somebody at Impax?

A. I do.

Q. And you're copied on this e-mail.

Do you see that?

A. Yes, I do.

Q. And the e-mail is dated June 2, 2010.

A. That's correct.

Q. The second paragraph of Mr. Levin's e-mail says, "As part of the development of the IPX-066a compound, we would agree to an upfront milestone of

$10 million upon signing and a $5 million milestone payment upon successful completion of Phase II."

Do you see that?

A. I do.

Q. Now, again, IPX-066a is what became IPX-203; correct?

A. That's correct.

Q. And this deal structure of $10 million upon signing and then a $5 million milestone is the same that we saw a day earlier in your OEW on IPX-066; correct?

A. That's correct.

Q. And this was two days before June 4 when you got information from Impax on IPX-203; correct?

A. That's correct.

Q. Do you recall that the final development and co-promotion agreement between Endo and Impax for IPX-203 was signed on June 7, 2010?

A. Vaguely.

Q. Well, do you want to look at it? Would that help?

A. Sure.

Q. Okay. Can you look at RX 365 in your binder.

A. Okay.

MR. LOUGHLIN: And Your Honor, I'll note for

the record that RX 365 has been admitted as part of JX 2 and it is not in camera.

BY MR. LOUGHLIN:

Q. Dr. Cobuzzi, you're welcome to look at this. You'll see that this is a final version of the development and co-promotion agreement, and you can see the signatures at the back. If you want to take a look at that, you're welcome to.

A. Okay. Yeah, I see it. Thank you.

Q. And do you see at the front it says "Development and Co-Promotion Agreement dated as of June 7, 2010"?

A. I do.

Q. And this is three days after Endo first got materials from Impax on IPX-203; correct?

A. That's correct.

Q. Dr. Cobuzzi, could I ask you to turn to CX 3339 in your binder, please.

And Your Honor, I'll note for the record that CX 3339 has been admitted as part of JX 2 and it is not in camera.

And do you see the second e-mail on CX 3339-001 that's from you, dated Friday, June 4, 2010, at 11:04 p.m.?

A. Yes.

Q. And in the second paragraph of your e-mail, you say, "I will review the information tomorrow afternoon and begin working on the OEW tomorrow, but given some of the potential complexities of the ester both in terms of pharmaceutical development as well as clin pharm, I really would like to have Frank Diana and Steve Bai, respectively, review the information and opine for R&D. We would need opinions by midday Monday, if possible."

Do you see that?

A. I do.

Q. What is pharmaceutical development?

A. It's the ability to take and make a chemical effectively into a drug, a medicinal, in this case a pharmaceutic.

Q. And what is clin pharm?

A. Clinical pharmacology. It's the evaluation of how the drug behaves when it's taken up in the body and the evaluation of how the body behaves when it's exposed to the drug.

Q. And then the e-mail is forwarded by Ivan Gergel to Stephen Bai and Frank Diana.

Do you see that?

A. I do.

Q. And it was forwarded on June 5, 2010 at

12:54 p.m.?

A. Yes.

Q. That would be Saturday, June 5; correct?

A. Yes.

Q. And the message is: "This is the follow-on to 066. As you can see from Bob's note, there is a very rapid turnaround (Monday midday)."

Do you see that?

A. I do.

Q. And Monday was June 7; correct?

A. That's correct.

Q. That was the day the DCA -- excuse me -- the development and co-promotion agreement was signed; correct?

A. It is.

Q. Did you ever get opinions on pharmaceutical development and clinical pharmacology from Mr. Diana and Mr. Bai?

A. I don't remember.

Q. Do you recall discussing with Mr. Hassi information about risk mitigation that you decided to undertake with respect to IPX-203?

A. I do.

Q. Could I ask you to turn to CX 2534 in your binder.

A. Okay.

MR. LOUGHLIN: And Your Honor, I'll note for the record that CX 2534 has been admitted as part of JX 2 and is not in camera.

BY MR. LOUGHLIN:

Q. Are you there?

A. I am.

Q. Okay. Do you see in the bottom e-mail on CX 2534-001 there's an e-mail from Alan Levin to you?

A. I do.

Q. Sunday, June 6, do you see that?

A. Yes.

Q. And he's asking you for input on a potential argument from Impax, which is that Endo should pay $2.5 million if Endo terminates the co-promotion agreement after NDA acceptance but before FDA approval; correct?

A. That's what it says.

Q. In your response in the e-mail above it, Sunday, June, 6, 2010, the first line says, Alan: I think your term 'piggy' applies here."

Do you see that?

A. I do.

Q. And in the next paragraph, you say, "Given the porcine nature of the requests thus far, however, I

believe you are correct and they will ask again."

And what you propose is that, in return for this agreement that Impax is asking for, you say, "Specifically, I would ask them to refund a portion of our upfront (e.g., 2.5 million) if they cannot develop a clinically viable product that passes Phase 1 PK assessment."

Do you see that?

A. I do.

Q. Endo didn't get any sort of term in the contract allowing for any kind of refund of any portion of the $10 million; correct?

A. It's a negotiation. I don't believe we got that, no.

MR. LOUGHLIN: Your Honor, at this point I have one more segment to go and I need to go in camera for it.

JUDGE CHAPPELL: How long do you think this segment will be?

MR. LOUGHLIN: Ten minutes. Maybe less.

JUDGE CHAPPELL: Let's take a break before we do that. We'll come back, finish this witness and start the next one.

We'll reconvene at 4:55.

We're in recess.

(The following proceedings were held in in camera session.)

(End of in camera session.)

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(The following proceedings continued in public session.)

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REDIRECT EXAMINATION (continued)

BY MR. HASSI:

Q. Sir, you were asked some questions a moment ago about the OEW evaluating information from Endo's evaluation of IPX-066 when you moved on to considering IPX-203. Do you recall those questions?

A. I do.

Q. Is it unusual, in your experience, to assess one pharmaceutical aspect -- asset based on information from another pharmaceutical asset?

A. No. It's done all the time.

Q. Can you think of an example of a time where you've done it before?

A. Sure.

The example I cited earlier was a product called Belbuca, which is a buprenorphine-containing product, and buprenorphine has been an approved product for an extremely long period of time. Whether it was the clinical pharmacology of the drug or otherwise, we used that as the basis for both analyzing whether there would be a market and how it might work medically, clinically, commercially. Yes.

Q. And does having an existing compound like Belbuca give you an opportunity to assess the product that you're considering developing?

A. Sorry. Can you rephrase the question.

Q. Does it provide a -- does the information on an existing compound provide a benchmark of sorts for you to use?

A. Sure. We would use it as a predicate.

Q. And when you use it as a predicate, is that better than, for example, a new chemical entity where you don't have a predicate compound to work from?

A. It's much easier. Yes.

Q. Did having the work that you and your team had done on IPX-066 here help you evaluate IPX-203?

A. Tremendously. Yes.

Q. And you evaluated IPX-203 in a couple of days.

Had you spent additional time before that evaluating -- you and your team spent time evaluating IPX-066?

A. Yes. And we knew Sinemet from all of our prior evaluations.

Q. And with respect to the team that evaluated it, we've heard a number of names: Stephen Bai, Frank Diana, Ivan Gergel, Ernest Kopecky, Paula Clark, Kevin Pong, Charles Gombar, yourself.

Were there a number of people evaluating this product for Endo?

A. There were.

Q. Did you put significant resources into the evaluation of this product?

A. We put what we would typically put against any deal that has a short time frame.

Q. You were shown an e-mail in which you referred to Impax as being piggy and the porcine nature of their requests.

Have you ever been in a negotiation before where you felt the other side was maybe asking for too much?

A. Pretty much every negotiation.

Q. You were asked some questions from a slide from July 2010, so after the deal, but it showed a chart of the corporate development process. Do you recall that chart?

A. I do.

Q. Okay. You mentioned in response to several of Mr. Loughlin's questions about whether you would take those steps, and you said, We would do so in an ideal state.

Can you describe what you mean by that?

A. Yeah. Unfortunately, there is no ideal state

for a deal.

Big pharma company might have that opportunity where everything occurs sequentially. Unfortunately, the reality of any given deal, which is, environmental factors, internal factors, there's just so many different variables that affect a deal that almost never do you get to follow the perfect sequence for it. I can't honestly think of any instance where we followed the perfect sequence.

Q. Do you always have enough time to evaluate a deal?

A. Again, you're asking a scientist if they have enough time and enough information. No, I don't think there is, but we make the most of what's available to us.

Q. You were asked some questions about the structure of the deal and the $10 million upfront payment. Do you recall those questions?

A. I do.

Q. How is the risk in the development and co-promotion agreement allocated as between Impax and Endo?

A. So a couple things.

I made reference previously to the fact that we were using cash and not our P&L. For a company the

size of Endo, we're a big company, but we're not so big that we can loosely use the P&L from an accounting standpoint. That's in some instances much more meaningful than the cash, so that's point one.

Point two in that is, we weren't responsible for development and though we did have the ability through this joint development committee that was contemplated in the actual agreement to set forth and agree with Impax the criteria, given the caveats that were in there.

So we weren't going to have to use our P&L, we did have the ability for input, and basically it wasn't going to come to further monies having to be spent until proof of concept was established at the end of Phase II.

Q. And so when you say "proof of concept was established at the end of Phase II," if Impax failed to meet proof of concept, would Endo have to make any further payments?

A. There was a possibility it could happen, given the terms of the agreement, but it was a lower likelihood, and at the same time, our comfort level would have come from the fact that Impax themselves would have had to expend more money.

Q. Mr. Loughlin asked you some questions about

other deals and the upfronts -- upfront payments made in those deals.

What was different about those deals than this deal and the upfront payments made in those deals?

A. So the other early-discovery deals that we had done, there were a number of them, but they were in most instances for either novel targets or they were what we would have termed at that time to be fast followers, meaning, either a product had gotten to the market just recently with a novel target or one was in development and we knew of it.

But the point of the statement is that there was still a lot of risk inherent in the biology, the chemistry and other pieces, and we looked at this as again being carbidopa and levodopa.

Q. And with those other deals did Endo take on some of the development risk?

A. We did. We would have had to. Going back to that notion of expending our P&L, we would have had to have spent the money ourselves to actually conduct the development, so that hurt us from an accounting standpoint as well as from a risk standpoint.

Q. And in the deal with Impax, you didn't have any development risk; is that right?

A. Well, the development risk was there, but we

paid for it through upfront at least to the point where Phase II was complete and the milestones were realized.

MR. HASSI: Thank you, Dr. Cobuzzi. I have no further questions.

JUDGE CHAPPELef;6u,-Tr 12paiuw( )]JEMCrw( )] M sT02 Td[MRf

specifically if -- about completed deals, which is very different from deals that we looked at.

Q. Okay. Oh, I see.

So there are deals that you looked at but didn't complete, and so you didn't make any upfront payments; correct?

A. That's correct.

Q. Now, you mentioned in your discussion with Mr. Hassi that there was a short time frame with respect to IPX-203. Do you recall that?

A. I do.

Q. The reason there was a short time frame was that that's what you were given by Mr. Levin; correct?

A. That's correct.

Q. You're not aware of any reason for that particularly short time frame, are you?

A. I was told there was other work being done, but I didn't have all the details around it. But that's typical for a deal. There's a lot of circumstances.

Q. And there were no other competing bidders for IPX-203, were there?

A.

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here, Your Honor.

MR. LOUGHLIN: We're not beyond the scope, Your Honor. Talked about -- he asked about -- all about the short time frame for doing this deal. I'm asking this witness about the reasons for the short time frame.

JUDGE CHAPPELL: I thought you asked him about the short time frame on direct.

MR. LOUGHLIN: I didn't ask him. I did not ask him about the short time frame on direct, no. Mr. Hassi just asked about that in his redirect and I'm following up on it.

JUDGE CHAPPELL: The last question was whether there were competing bidders. He said, "I don't know," so that objection has passed.

MR. HASSI: Yes, Your Honor.

BY MR. LOUGHLIN:

Q. The reason there was a short time frame was that this deal was being done in connection with settlement negotiations; correct?

A. As I understood it, yeah. There was a package of deals that were being done.

Q. And the package was the development and co-promotion and a settlement agreement; correct?

A. I know about the co-promotion agreement. I

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typical generic doesn't have a brand name associated with it.

Q. So you believe that Endo was selling Sinemet under the name Sinemet and not under a generic name?

A. Sorry. That's my recollection.

Q. Okay. And you discussed with Mr. Hassi a minute ago the need for IPX-203 to be superior to Sinemet. Do you recall that?

A. I do.

Q. If IPX-203 was not superior to IPX-066 or Sinemet, would that affect the market opportunity for IPX-203?

A. I'm not a commercial expert, but I believe so.

Q. Did information about IPX-066 or Sinemet indicate whether 203 would be better than 066 or Sinemet?

A. I'm sorry. Could you -- you mixed a couple of things there. Could you repeat the question, please.

Q. Sure.

Did the information that Endo had about IPX-066 and about Sinemet -- did that information indicate to Endo whether IPX-203 would be better than 066 or Sinemet?

A. It suggested it should be. 066 was a modified formulation, so it would change the time frame for

absorption of the product itself versus the immediate-release Sinemet. And then 203 would have -- if all things continued to move forward as planned, given the modification of the L-dopa component of the molecule, should have been better again than that was 066, so each should have been incrementally better than the other.

Q. And when you say "should," you mean in theory based upon what you expected IPX-203 to be; correct?

A. That's correct. We had no empiric data.

MR. LOUGHLIN: Okay. No further questions, Your Honor?

JUDGE CHAPPELL: Anything further?

MR. HASSI: No, Your Honor.

JUDGE CHAPPELL: Thank you, sir. You may stand down.

THE WITNESS: Thank you.

JUDGE CHAPPELL: Next witness.

MR. LOUGHLIN: Your Honor, at this time complaint counsel will have its rebuttal expert witness Mr. Hoxie. Do you want him -- you want him to start now at 5:30?

JUDGE CHAPPELL: Yes. That's why I said call your next witness.

MR. LOUGHLIN: All right. I just wanted to

make sure.

JUDGE CHAPPELL: Do you have a time estimate for the length of direct you're going to have?

MR. LOUGHLIN: About two hours, Your Honor.

So at this time, Your Honor, complaint counsel calls Thomas Hoxie, and my colleague, Lauren Peay, will handle the examination for complaint counsel.

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Whereupon --

THOMAS HOXIE

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

MS. PEAY: Good afternoon, Your Honor.

And may it please the court.

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DIRECT EXAMINATION

BY MS. PEAY:

Q. Good afternoon, Mr. Hoxie.

Can you please introduce yourself to the court by stating your full name.

A. Yes. My name is Thomas Hoxie, H-O-X-I-E.

Q. Mr. Hoxie, as you know, I'm Lauren Peay. I'm an attorney with -- for complaint counsel.

I'm going to be asking you questions about facts and evidence giving rise to complaint counsel's

lawsuit against Impax.

Do you understand?

A. Yes.

Q. Would you please introduce yourself and briefly explain your background.

A. Okay. I'm a patent attorney. My background is I started off as a scientist. Then I went to law school. I worked for a while in Baltimore as a litigator.

I then went in-house in the pharmaceutical industry at Sandoz in Basel, Switzerland, which Sandoz eventually merged, became Novartis. I was -- came back to the United States. I was head of Sandoz' intellectual property for North America and global head of IP litigation for Novartis, for the Novartis group.

I left Novartis in 2004, and since then I've been working -- I started a firm and I've been working at my own firm since then. And the firm specializes in patents in the area of pharmaceuticals, chemicals and biotechnology.

Q. Without getting into the details of your opinions, please tell us what you're here to testify about today.

A. I'm here to respond to Mr. Figg's report.

Q. And Mr. Hoxie, there's a binder of exhibits and

a bottle of water on the table next to you. No need to refer to the binder now, but we may -- I may refer you to exhibits in the binder during your testimony this afternoon.

A. Okay.

Q. Before we get to your opinions, Mr. Hoxie, I'd like to ask you some more details about your professional experience, education and training that qualifies you to reach the opinions in this case.

Mr. Hoxie, where do you currently work?

paralegals and staff. We're located in Millburn, New Jersey, outside of New York City.

Q. How long have you been with your firm?

A. When I left Novartis in 2004, so counting the Hoxie & Tso and Hoxie & Associates time together, about thirteen years.

Q. And Mr. Hoxie, what does your practice at your firm encompass?

A. As I said, my practice encompasses supervising the attorneys who work for me. Personally, I do a lot of work in the area of opinions for pharmaceutical companies.

I -- right now on my docket, if I think of things that I have to do, I'm going to Texas in a couple of weeks. I'll represent a company in a court-ordered mediation in a patent infringement case. I have a couple of opinions due for companies that are -- that are -- relate to investments in companies where people want to invest money in companies and want to know that they have adequate intellectual property to protect their products.

I'm just trying to think what else I have right now, but that's the sort of work that I do.

Q. Does your experience with your law firm relate to the opinions you intend to give in this case?

A. Yes, it does.
Q. How does it relate?
A. I'm -- I represent companies with respect to patent -- patent matters in the area of pharmaceuticals particularly, and so it -- it -- some of the issues -- issues similar to some of the issues that came up in -- came up in the patent litigation in this case are -- are similar to some of the patent -- the issues that come up in matters that I've handled and issues that come up in patents that I've drafted and prosecuted, so I -- it's relevant -- I have I think relevant experience in that way.
Q. Where were you employed prior to founding your firm?
A. I was employed at Novartis, Novartis Group.
Q. What is Novartis Group?
A. Well, Novartis is a large, Swiss-based employed prior to fe

Hexal. Biochemie. Gema. A number of -- there were a number of generic companies around the world that they handled.

So in working at Novartis I worked both with the branded pharmaceuticals, so the innovative pharmaceutical side, and I also worked on the generic side.

Q. And Mr. Hoxie, how long were you at Novartis Group?

A. About fourteen years.

Q. And what was the date range?

A. 19- -- beginning of 1991 to 2004.

Q. And Mr. Hoxie, did you hold multiple positions during your time at Novartis?

A. Yes, I did.

Q. What were those positions?

A. Well, I started in Basel, Switzerland as a patent attorney. After the merger, I came to the U.S. I became -- I was in charge of the seeds and egg biotech division, patents for that division. I worked in Research Triangle Park.

Then I came -- in 1999 I came up to New Jersey and to be in charge of the pharmaceutical patents group.

And in 2000, beginning January 1, 2000, I took

over management of the U.S. and North American patent and trademark operation. And then I -- I got additional responsibilities.

I became global head of intellectual property litigation for Novartis. And I was also in -- the deputy -- deputy head of pharmaceutical patents for Novartis globally. And I was also head of patents for pharma markets for Novartis globally, which meant I was responsible for all the agreements and patents relating to marketed products as opposed to earlier-stage products.

Q. In your first position with Novartis as a patent attorney, at a high level, what were your responsibilities?

A. I was responsible for preparation and prosecution of patent applications relating to pharmaceuticals and in particular therapeutic areas.

And I think I was -- I got that job and I think I was hired because I had background doing litigation. And at that time, they -- Novartis -- it was then Sandoz -- Sandoz was involved in some patent litigation. They hadn't actually been involved in much patent litigation in the U.S. before, and so I was sort of -- they wanted to have an American attorney there in Switzerland to explain this strange

level, in that role?

A. Well, my responsibilities were managing a group of attorneys that did preparation and prosecution of patents, reviewing contracts and licenses, negotiating contracts and licenses relating to patents in the area of pharmaceuticals, and managing litigation, again, in the area of brand -- in that case branded pharmaceuticals.

Q. You also held a position as head of intellectual property for North America; is that correct?

A. That's correct.

Q. And what were your responsibilities in that position?

A. So in that capacity I was head of a -- I took that job in 2000, beginning of 2000, and I was -- I was in charge of -- we had a group of attorneys in East Hanover, New Jersey. We had a number of -- some attorneys in Atlanta, Georgia. We had some attorneys at certainly one point up -- they moved a large group up in Boston and a group out in San Diego.

And so those attorneys reported to me, and I sort of was responsible for managing their work, for reviewing contracts and licenses, at least in major deals, and, depending on the case, getting personally

property -- that was me -- the head of HR, the head of finance, all the -- all the functions, so I -- I was on that. I was on that committee.

I was on the portfolio review committee, which was a committee that reviewed products that were in development and made determinations whether -- how to prioritize the development products, made -- was the committee that made the decision whether or not to launch products and, you know, just sort of tracked products that were in development prior to their commercialization and prioritized and managed those, those products, at a high level.

Q. And the products that the portfolio -cializatim -2.035 Td(

And so that involved a lot, lot of traveling, which is one reason that I wound up starting my own firm and staying home, but it was a very interesting job.

Q. And Mr. Hoxie, during your time in Novartis, what was your involvement in patent litigation?

A. Well, my involvement was basically to identify litigation risks at the very beginning, obviously.

Then if we did get sued or if we decided to sue somebody, you know, I would select the outside counsel. I would work with outside counsel in preparing the case, in providing discovery.

I would -- if there were briefs or motions to be filed or whatever, I'd review those and comment.

I'd typically go to the trials if we -- if the case went to trial.

If there were settlement negotiations, I would normally be the person negotiating. Normally, the way at least we did it at Novartis -- and I know my clients -- I have noticed that clients of mine in private practice also work this way -- typically, the negotiations would be handled by an in-house attorney or somebody acting sort of like an in-house attorney, in other words, not the litigators.

Typically, we want the litigators to focus on

winning the litigation and not be pulling their punches and not be tailoring their litigation to what was going on settling -- on the settlement side. And we would typically have parallel settlement negotiations, and I would usually be the person representing Novartis in those negotiations.

Q. During your time at Novartis, do you know how many patent litigations you were involved in?

A. Dozens.

Q. And did some of that -- were some of those patent litigations related to Hatch-Waxman litigation?

A. Yes.

Q. Do you know how many Hatch-Waxman litigations you were involved in during your time at Novartis?

A. At least a dozen I would say.

Q. While at Novartis did you have involvement in any patent litigations that went to trial?

A. Yes. I'm not sure exactly how many. Probably about a dozen went to trial I guess, some Hatch-Waxman, some not.

Q. And for those --

A. I mean in the United States I'm talking about. I'm not talking about outside the United States.

Q. And for those patent litigations that went to trial, what was your involvement?

A. Well, typically, in most cases that went to trial -- well, in ones where I was personally involved, I would go to the trial. I would -- in some cases I was the corporate representative, so I'd sit at the trial table and try by mind control to convince the jury to rule our way.

I'd -- I'd support -- typically I had a role in supporting the experts and the technical witnesses, sort of helping to prepare them, and so forth, and also sort of keeping the channels open with the other side for possible settlement discussions.

And then I'd also sort of manage the litigation in the sense of authorizing the outside counsel to make strategic decisions.

Very often, when you go to trial, it's very important to streamline your case and try to keep it simple, and that means jettisoning arguments. And that's not something outside counsel feel that they have the authority to do, so I'm like okay, it's perfectly okay to drop that argument, you know, and not, you know, waste a lot of time, try to keep the case focused, because typically these -- these patent cases are on -- most judges at this point put them on a clock and you don't have a lot of time, you have 40 hours a side or something, so you have to be very

focused.

Q. Mr. Hoxie, while at Novartis did you have involvement with negotiating patent licenses?

A. Yes, I did.

Q. What was that involvement?

A. It depended on the context.

If it was sort of a pure patent license or like a settlement agreement in a litigation or a freedom-to-operate license, I probably would have been the lead negotiator. In some cases it would be somebody reporting to me who would be the lead negotiator, and then I'd review the final product.

If it was a license in the context of a deal that had sort of maybe some non-IP aspects, like maybe there would be a manufacturing and supply piece of it and other pieces of it, then I'd be part of a team that would, you know, work together. And I'd sort of be responsible for the licensing piece, and somebody else would be responsible for the manufacturing and somebody else for the R&D piece, whatever, I mean, however it -- however the agreement was broken up.

Q. During your time at Novartis, how many patent licenses were you involved in negotiating?

A. A very large number. Many dozens I would say.

Q. And Mr. Hoxie, of the patent litigation -- the

patent licenses that were included as part of patent litigation settlements, were any of those in the context of a Hatch-Waxman litigation?

A. Some of them. Yes.

Q. Do you know how many of those were in the Hatch-Waxman context?

A. Yeah. I was trying to think about that earlier. I think probably about half a dozen.

Q. While at Novartis did you have any responsibilities related to making decisions whether to launch a new product?

A. Yes.

Q. What were those responsibilities related to making decisions whether to launch a new product?

A. Well, for -- for -- every -- at least when I was at Novartis, every product required a recommendation from the patent department on whether or not -- whether or not to launch, so the patent department, so the department I was running, was responsible for making a recommendation in every single launch on every single product.

There were certain times -- oftentimes the patent recommendation was simple and uncomplicated. Sometimes it -- if the situation was more complicated, particularly obviously when the litigation involved

more than that, then, you know, I might make a presentation to -- to the -- you know, to the board or to the committee or to the committee in Basel or in the U.S., people who would -- people who would be making the decisions.

Q. Mr. Hoxie, are you familiar with the concept of launching a product at risk?

A. I'm familiar.

Q. How would you define that?

A. Well, I mean, in a -- broadly speaking, every time you launch a product, it's at risk. It's at risk of all kinds of things. It's at risk of, you know, that the product will fail or that they'll -- and it's particularly at risk of patent infringement. And it costs $400 or whatever to file a lawsuit, so any time you launch a product, somebody might sue you.

But "at-risk launch" I think as it's been used in this case and in Mr. Figg's report, which I'm responding to, particularly relates to a situation of a generic company launching in the context of Hatch-Waxman litigation before they have a final Federal Circuit decision in their favor. That's -- it's specifically that context.

Q. And while at Novartis did you have responsibilities related to making a decision whether

to launch a product at risk?

A. Yes.

Q. Mr. Hoxie, does your experience at Novartis relate to the opinions you intend to give in this case?

A. Yes.

Q. How?

A. I think the experience that I had at Novartis working on, you know, different products on the branded side and on the generic side and also the sort of more general business experience and being involved with the decision-making from a business perspective gives me some background to interpret the -- the circumstances, the documents, the -- you know, the facts, as far as -- as far as I can ascertain them, of what was going on in 2010 when Impax and Endo entered into the settlement and license agreement.

Q. And Mr. Hoxie, where did you work prior to Novartis Group?

A. You know, prior to the Novartis Group, when I first graduated law school, I worked for a company called -- a law firm called Semmes, Bowen & Semmes. And it was located -- primarily I worked in Baltimore. I was admitted to practice in Baltimore and in -- in Maryland and in the District of Columbia, so I did some

Q. What are those?

A. I'm a registered patent attorney, so admitted to practice before the U.S. Patent and Trademark Office.

I'm admitted to the bar of Maryland, the District of Columbia and New Jersey. I'm admitted to the federal district courts in those jurisdictions as well.

I'm admitted to practice in the Court of Appeals for the Federal Circuit in the Fourth Circuit, the U.S. Court of Claims and the Supreme Court.

I think that's -- I think that's about everything.

I'm also -- well, was at one -- I mean, at one time I was admitted to practice in -- in -- as a solicitor in England and Wales and also -- but that's not active because I'm -- I don't maintain an office in England.

And I passed the examination to practice as a patent attorney in -- a European patent attorney, but again I'm not active, I'm not listed, because I don't live in Europe and I'm -- and also for the reason in that case I'm not a European citizen.

Q. Do you have any involvement in professional organizations related to your practice as a patent

attorney?

A. Yes. I'm involved in, you know, several professional organizations.

Probably the one I'm most consistently -- been most consistently involved with over the years is the Association of Corporate Patent Counsel, the ACPC, which is an organization of chief patent counsel and former chief patent counsel for large corporations, so it's a group that meets twice a year and then pretty much all the chief patent counsel from all the -- all the major -- all the larger corporations are members of that organization.

So it's a very interesting organization. There have been presentations, and it gives me an opportunity to meet with people in the industry and have a sense of their reactions and, you know, what the feeling is about legal developments and -- and in the area of patents.

JUDGE CHAPPELL: It's after 6:05. We're going to call it for today.

I would note that's just over 30 minutes of qualifications. That's enough. You need to get into opinions tomorrow.

MS. PEAY: Yes, Your Honor.

JUDGE CHAPPELL: Everybody note, we will start

tomorrow not at 9:45, we will start at 10:30 in the morning, 10:30.

We're in recess.

(Whereupon, the foregoing hearing was adjourned at 6:08 p.m.)

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thereafter reduc <<to t57 writing under my supervise /; that I am neither counsel for, relat <<to, nor employed by any of the paEMCes<to the BTe /Pin which these proceedings were taken;7and further, that I am not a relative or employee of any attorney or counsel employed by the paEMCes<hereto, nor f/Tyncially or