UNITED STATES OF AMERICA

BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Joseph J. Simons, Chairman
Noah Joshua Phillips
Rohit Chopra
Rebecca Kelly Slaughter
Christine Wilson

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

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ORAL ARGUMENT

Reported by: Josett F. Whalen, Court Reporter

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P R O C E E D I N G S

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CHAIRMAN SIMONS: Good afternoon everyone and welcome.

The Commission is meeting today in open session to hear oral argument In the Matter of Impax Laboratories, Inc., Docket Number 9373, on the appeal of complaint counsel from the initial decision issued by the administrative law judge.

The respondent is represented by Mr. Ted Hassi.

Complaint counsel are represented by Mr. Chuck Loughlin.

During this proceeding, each side will have 45 minutes to present their arguments.

Complaint counsel will make the first presentation and will be permitted to reserve time for rebuttal.

Counsel for respondent will then make his presentation.

And complaint counsel will conclude the argument with a rebuttal presentation.

Mr. Loughlin, I understand you want ten minutes for rebuttal; is that correct?

MR. LOUGHLIN: Correct.

CHAIRMAN SIMONS: Perfect. And the bailiff will note that.

Mr. Loughlin, would you like to introduce your colleagues at the table?

MR. LOUGHLIN: Yes.

With me at counsel table is Maren Schmidt, Brad Albert and Markus Meier.

CHAIRMAN SIMONS: Welcome.

And Mr. Hassi, would you like to introduce your colleagues?

MR. HASSI: I would. Thank you, Mr. Chairman.

With me from O'Melveny are Mike Antalics, Steve McIntyre and Mr. Ben Hendricks.

CHAIRMAN SIMONS: Perfect. Welcome.

So, Mr. Loughlin, you may begin when you're ready.

MR. LOUGHLIN: Thank you, Mr. Chairman, Commissioners.

The initial decision in this case found that Endo paid Impax a large and unjustified reverse payment in exchange for Impax agreeing not to market its generic product until January of 2013.

The initial decision found that this restraint resulted in exactly the type of anticompetitive harm described by the Supreme Court in Actavis, a large

payment to prevent the risk of competition.

Now, despite this harm, the initial decision dismissed the complaint. The initial decision found the reverse payment agreement justified because the settlement agreement contained a license to patents that Endo might acquire in the future. That was error.

There is no dispute in this case that any benefits from a license to Endo's future patents did not flow from the challenged restraint.

The challenged restraint in this case is Impax' agreement not to enter until January of 2013 in exchange for a large and unjustified payment. The initial decision found that at page 99 of its decision.

Importantly, Impax did not assert in this case that any benefits from a license to Endo's future patents flowed from the challenged restraint, and the initial decision did not make any such finding.

And so the question on appeal is whether Impax needed to show that its procompetitive benefits flowed from the challenged restraint. Standard rule of reason case law says yes. But the initial decision did not require that. And that decision should be reversed.

Now, in Actavis, the Supreme Court addressed

the impact of reverse payment agreements on generic competition, taking into account the statutory scheme of the Hatch-Waxman statute, the FDA approval process, and the patent laws. And the Supreme Court explained that reverse payment agreements are problematic because they allow the branded incumbent to co-opt its generic competitor by sharing monopoly profits that are preserved from this avoidance of competition.

And Actavis makes that point clearly at 570 U.S. at 154. It says, "Payment in return for staying out of the market simply keeps prices at patentee-set levels, potentially producing the full patent-related monopoly ... return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses."

So under a reverse payment agreement, the brand is better off because it avoids the risk of what could be devastating generic competition, and the generic is better off because it gets certain revenue that often is more than it could earn by competing. The losers are consumers, because consumers are deprived of the possibility that generic entry might occur if the competitive process was allowed to play itself out.

And this case fits squarely into those concerns that were addressed by the Supreme Court in Actavis.

This reverse payment agreement was reached just days before Impax was set to get FDA approval to market its generic version of Opana ER.

Endo had sued Impax for patent infringement in 2008. That suit triggered a 30-month stay of FDA approval.

After that 30-month stay, the FDA was allowed to approve the generic version of Opana ER even if the patent case was still ongoing, and that's what happened here.

In mid-May of 2010, Impax got what's called tentative approval, which means that a month later it would get final approval.

Endo read about that in the papers, understood that it meant Endo [sic] was on the verge of getting final approval, and so it quickly contacted Impax to discuss settlement.

The parties negotiated very quickly and had a signed settlement agreement by June 7, 2010. This was about a week before Impax was expected to get final approval.

Under that settlement, Impax agreed not to

launch its generic version of Opana ER for two and a half years, 30 months, until January of 2013.

In other words, just as the 30-month stay under the Hatch-Waxman Act was expiring, Endo secured another 30-month stay. But it wasn't entitled to a 30-month stay under the Hatch-Waxman Act or under FDA regulations, so it bought that 30-month stay from Impax through a no-AG agreement.

COMMISSIONER PHILLIPS: Counsel, is it your position that they could have launched at that point, at the point of the entry into the settlement agreement?

MR. LOUGHLIN: That Impax could have launched?

COMMISSIONER PHILLIPS: You said they bought 30 additional months.

MR. LOUGHLIN: Yes. Impax -- well, Impax -- at the time of the settlement, they didn't have final FDA approval to launch. They got that a week later. But as of mid-June -- I think it was June 14, 2010 -- they had FDA approval to launch and they could have launched.

COMMISSIONER PHILLIPS: Legally, but --

MR. LOUGHLIN: Legally, correct.

Whether they would have launched is a different story. We don't know the answer of whether

or not they would have launched.

What we do know is they were doing active preparations to launch. They had filed for FDA approval. They had engaged in a patent case. They had gone out to customers to get letters of intent that they -- customers would buy their generic product.

They had gotten approval from the DEA to purchase oxymorphone, which is a controlled substance. It's an opioid product. They had formulated that into pills and put it -- packaged it into bottles, so they were -- they were on the verge of potentially launching.

COMMISSIONER PHILLIPS: For purposes of assessing the impact of the eliminated risk, which is sort of our theory of harm, right, under Actavis, what's the time frame at which we're looking?

MR. LOUGHLIN: We're assessing whether there was an elimination of the risk of competition as of the date of the settlement, because that's the time when the elimination occurs. That's when the anticompetitive harm, again, the elimination of the risk of competition, occurs.

When that settlement happens as of June of 2010, the risk of competition is gone, so long as Impax

abides by its agreement not to enter until January of 2013, which of course they did.

COMMISSIONER SLAUGHTER: Counsel, I think what my colleague is pointing to are the points in the initial decision that make very clear, in the view of the administrative law judge, that Impax would not have launched at that point, not that it could not.

But the question I have for you that I think is important is, the information that we might have now about whether Impax was about to launch or not, was any of that information that Endo had access to in assessing the risk of launch?

MR. LOUGHLIN: Yes.

Certainly Endo was well aware that Impax had filed with the FDA for approval of its generic version. Endo knew that Impax had gotten tentative FDA approval and therefore was about to get final FDA approval on June 14, 2010.

It's uncertain -- unclear whether Endo knew about Impax' internal operations in terms of preparing for launch. There's no evidence that they did know that.

But we do know that Impax was going out into the market to get letters of intent from customers. Again, I don't know whether or not Endo knew that.

There's nothing in the record that suggests Endo knew that one way or the other.

But what we do know is that Endo was planning internally that it would launch in July of 2010 in response to Impax's launch, so it was fully expecting a potential launch by Impax in the summer of 2010, and it was preparing its own response -- its own responsive launch afterwards.

Endo was doing its own preparation for creating generic versions of its product, putting those in bottles, getting itself ready to launch what's called an authorized generic in July of 2010.

COMMISSIONER CHOPRA: So even if we believe that it was very unlikely or extremely unlikely that Impax would launch at risk, are you arguing that we should only consider the fact that Endo was paying and Endo perceived that there was a risk of competition, and therefore, that's the point of analysis?

MR. LOUGHLIN: That is the primary point of analysis, is did Endo perceive a risk of competition and did it pay to avoid that risk of competition.

Now, we believe the risk of competition was real, that Impax in fact had made preparations, including filing with the FDA, going through that process, all the way up to getting -- almost to getting

FDA final approval.

So there was a real risk to Endo that Impax might launch. Whether or not they actually would have launched is not part of the analysis.

COMMISSIONER CHOPRA: So what should we use, real risk or perception of risk?

MR. LOUGHLIN: I think the key is perception of risk, but that perception has to be based on something, and here it was based on something.

There was in fact a risk to Endo because Impax was on the verge of getting FDA approval. It had -- it had gotten tentative approval and was a week away from getting final approval, which would have allowed it to market its product. Endo knew that and was preparing.

So there was a real risk to Endo that this product would come in in competition with its branded product.

CHAIRMAN SIMONS: And so that's the thing you focus on even if it had been the case that Impax's board had determined absolutely, positively never to enter at risk?

MR. LOUGHLIN: That -- those -- that of course were not the facts. But Endo's board had not made that determination. In fact -- or excuse me. Impax'

board had not made that determination. And in fact, Impax' management was letting the board know that it might come to it later to make a recommendation of a launch.

But the point isn't what was going on with Impax specifically in terms of how real was the risk. There was a risk. And if there was a risk, Endo cannot pay to avoid their patent risk. That's the anticompetitive harm under Actavis.

COMMISSIONER WILSON: Let me talk for a minute about the payment.

How would you characterize the payment that Endo made to Impax? Is it the no-AG provision? Is it the no-AG provision plus the Endo credit? Does it also include the broad license?

MR. LOUGHLIN: The payment is certainly the no-AG agreement backed by the Endo credit, because the Endo credit ensured that one way or another Impax was going to see value through this payment.

Our view is that it also includes the $10 million payment as part of the development and co-promotion agreement for this product IPX-203.

It is not our contention that the payment includes a license to future patents. That is not a payment under Actavis.

COMMISSIONER WILSON: Would a no-AG provision from here on out, in your view, always constitute a payment, or are there circumstances under which a no-AG provision would not be viewed as a payment?

MR. LOUGHLIN: It's hard to know whether or not in all cases a no-AG would be a payment. It might always be a payment. Whether it would be a large payment probably would depend on the circumstances.

As I sit here, I can't think of a reason why a no-AG agreement would not be a payment, but it's certainly possible it might not be a large payment.

COMMISSIONER CHOPRA: Why don't we look at all forms of consideration given, including the broad license, including all the exchange of value?

MR. LOUGHLIN: Because at issue isn't consideration or value transfer. It's whether or not there is a payment in the shape of a sharing of the brand's monopoly profits from the avoidance of competition.

COMMISSIONER CHOPRA: So how do you disaggregate that? Isn't it all fungible?

MR. LOUGHLIN: No, it's not all fungible.

In a reverse -- in a settlement agreement without any payments in it, the brand and the generic are in opposition to each other, and they are going to

work out a compromised entry date based on their respective views of the strength of the patent merits, in opposition to each other.

With a reverse payment that shares the monopoly profits, their incentives are now aligned. The generic no longer wants to erode a patent monopoly because it's benefiting from that monopoly through a sharing of the profits of that monopoly.

Now, by contrast, a license to future patents doesn't align incentives. It doesn't provide the generic with a sharing of monopoly profits. It's just like a split of a patent life. It's just there's more patents involved.

And so it's -- the generic only gets value by competing against the brand, by putting its product on the market, eroding the monopoly power of a brand, and so it's not a sharing of brand monopoly -- it's not a sharing of those brand monopoly profits through the avoidance of competition. It's a value that's been created because of competition, so it's not a reverse payment under Actavis.

COMMISSIONER PHILLIPS: So we get how sitting here today we can look at different provisions and apply the rule you're talking about, in particular, if we get to tie particular provisions to the limitation

of when Impax could enter the market. But they're all part of a deal, right, and they're all value that flow at the same time to Impax. And with respect to the freedom to operate, that helps guarantee Impax the benefit of the bargain; right? They get to be safe in selling their generic moving forward.

So why -- how do we get to take them out of the that bucket, right, how do we dissociate them in the way that you want us to do?

MR. LOUGHLIN: Because the question under the rule of reason is what is the challenged restraint and do the procompetitive benefits flow from that challenged restraint, are they supported by that challenged restraint.

So, for example, in Realcomp, there was a multiple listing service that had procompetitive benefits. That was found in the decision. But the Commission challenged a specific part, a specific provision of that multiple listing service set of rules and regulations because it focused on a provision that restricted access to the multiple listing service by discount brokerages.

And what it found was there was -- the benefits of the multiple listing service as a whole did not flow from that restraint. In other words, that

restraint did not further those procompetitive benefits.

The same is true here. There is no suggestion by Impax that its agreement not to enter until January 2013 in exchange for a large and unjustified payment benefited consumers, that that was procompetitive in any way. It said that we got a license as part of a settlement and that the settlement as a whole contained that license, but there's no connection that Impax makes or that was found in the record --

CHAIRMAN SIMONS: How about this? Suppose it were the case that there would have been no settlement at all without the payment. Isn't that -- in that case, is it your sense that the freedom to operate or the licenses to those other patents then becomes more relevant?

MR. LOUGHLIN: No.

Your question was whether there would be no settlement without the payment?

CHAIRMAN SIMONS: Yes.

So there's no settlement without the payment, right, and that settlement includes the freedom to operate, the license to those other patents.

MR. LOUGHLIN: No, that -- that doesn't change

the analysis at all.

Again, the payment to avoid the risk of competition is anticompetitive harm.

So if the settlement wouldn't have occurred without that payment -- this is discussed in Cipro -- Cipro says, well, that's fine. Then we don't have anticompetitive settlements. That's a good thing.

Now, had that happened, we don't know what would have happened. It could be the parties would have litigated and Impax would have come on sooner. It could have meant they would have reached a different agreement with the same license there, the same license to future patents in it, but no payment.

We don't know what would have happened. We don't need to probe what would have happened. That's an injury question, not a violation question.

The point here is that what we know is that the settlement did include a reverse payment in exchange for Impax' agreement not to enter --

CHAIRMAN SIMONS: Let me stop you there for a second.

So this is a case in which it turns out, in hindsight, that the license to those other patents was really important, because Endo managed to exclude every other generic manufacturer with those other patents

subsequently.

And so if you're talking about a situation in which there is no settlement and Impax gets no license to those other patents, then Impax is not in the market once those patents are exercised.

MR. LOUGHLIN: Well, no --

CHAIRMAN SIMONS: Isn't that something we'd want to balance off of the earlier entry?

MR. LOUGHLIN: No. No. Because we don't know if that's true.

CHAIRMAN SIMONS: Well, it's kind of probabilistic, right, so it's probabilistic for those additional patents, but it's also probabilistic for whether earlier entry would have occurred, so it's the same type of effect.

MR. LOUGHLIN: Right. But the Supreme Court is not looking at whether entry would have occurred. The harm is not delayed entry. The harm is the prevention of the risk of competition. It's the corruption of the competitive --

CHAIRMAN SIMONS: No. I get that.

So it's the corruption of the risk of competition from the delayed -- potential delayed entry. But then there is a potential procompetitive effect as well, and you know, even if it's not a

hundred percent or even if it's relatively low, it may be significant nonetheless, so don't you want to compare the probabilities and the magnitudes of those two things, the access to the market afterwards based on those additional patents versus the loss of the entry based on the original patent that comes from the settlement agreement?

MR. LOUGHLIN: No.

For purposes of determining whether there's an anticompetitive effect, whether complaint counsel has satisfied its case in chief, the question is whether or not there was a payment to avoid the risk of competition at the time.

Here, we know that happened. There were in fact possible speculative procompetitive benefits from the license, but the first step in the -- the second step in the rule of reason after you find an effect is do those benefits flow from the restraint. They didn't flow from the restraint.

CHAIRMAN SIMONS: Well, they might flow from the restraint if in fact what's going on is the only reason you get that settlement with those types of licenses occurring is because of the payment. If there's no -- if the only way to get that kind of a settlement is through a payment, then isn't -- it seems

to me that the licenses are a direct result of the payment.

COMMISSIONER SLAUGHTER: To follow on the Chairman's comment and question, isn't it also the case that Impax sought similar licenses in other settlements that didn't include payments?

I think that was in the record that they had -- that it was established that they had similarly sought freedom-to-move licenses in other settlements of litigation.

COMMISSIONER WILSON: And then to follow on to that set of questions, the record shows that the ALJ found that when the new negotiators arrived on the scene, all they wanted was a simple settlement involving only a date. Endo rejected that and went back to the original package that had been negotiated, and the new negotiators for Impax said, We're not going to take that without a broad license.

And so they seemed to require, based on the findings of the ALJ, a broad license to induce them to settle, and so I'm wondering what those facts say about ancillarity here.

COMMISSIONER PHILLIPS: Not to interrupt to interrupt to interrupt, but those facts also include -- and this is in your brief -- Impax being aware of the

fact that Endo had pending patent applications, so they get the concession and they know something is coming.

MR. LOUGHLIN: So -- yes. Impax -- the record shows that Impax tries to get licenses to future patents in every settlement that it does. Their lawyer came in and put that evidence on the record.

In terms of -- Commissioner Wilson, in terms of your question, the facts are not quite the way you described them.

After Impax's representatives asked to go back to a license with no payments, just an earlier entry date, what Endo did was put more money on the table. They said, No, but we'll give you more money in the DCA.

Subsequent to that, the parties -- and Impax also said, Oh, by the way, we also would like a license to future patents, and that was included in the settlement agreement.

Now, there is no Impax -- excuse me. There is no evidence in the record that Impax needed a payment to settle. They have not made that argument in this case. There's no finding that they needed a payment to settle this case.

But the key point again for the rule of reason

is not whether or not there would have been a settlement without this license. Under the rule of reason, the question is, is the challenged restraint, which, again, is the agreement to pay Impax in exchange for this January 2013 entry date, is that restraint procompetitive, does that restraint have offsetting procompetitive benefits that benefit consumers. There's no evidence that it does.

COMMISSIONER SLAUGHTER: So can I -- and can I go back to -- the Chairman was asking don't we have to look at the benefits that actually flowed from that freedom-to-move license with the benefit of hindsight. I'd pose the question the other way.

We want, I think as a general public policy principle, parties to know at the time they enter into an agreement whether that agreement is legal or illegal, right.

So if we base the magnitude of the benefits on facts that develop after the agreement is made, don't we then create a long-term risk of uncertainty both for the parties and a situation where parties can't actually know whether the settlement into which they're entering will be legal or not legal?

MR. LOUGHLIN: Yes. That is completely right.

But I want to go back to something you started

with, which is the question of whether or not we have to look at whether the freedom-to-operate license had procompetitive benefits or not.

The answer is we don't have to look at that because the procompetitive benefits that matter are those that flow from the challenged restraint. Here, they did not.

But you're absolutely right. Even if we did look at those --

COMMISSIONER PHILLIPS: Sorry. Finish your answer.

MR. LOUGHLIN: Even we did look at those, you would end up with a legal regime in which the settlement might be unlawful if a patent was found invalid at the district court and then found lawful again if the appellate court found the patent was valid, and then it would be unlawful again if the district court found that the product was not infringing. That doesn't make any sense.

I mean, there would be no certainty, and that's not the way antitrust law is designed to work.

COMMISSIONER PHILLIPS: What I was going to ask is this.

The restraint as you describe it is paying for delay; right?

MR. LOUGHLIN: No. I would not agree with that.

COMMISSIONER PHILLIPS: I'm sorry. Forgive the characterization.

It's the money flowing, right, in return for eliminating the risk.

MR. LOUGHLIN: Correct.

COMMISSIONER PHILLIPS: Those are two aspects of a broader agreement, but the agreement doesn't -- it's not like the DCA, where we have kind of one side and the other side.

I don't -- what I'm having trouble doing is delinking other aspects of the agreement, in this case the freedom to operate, which flowed to Impax as part of the deal. Why isn't that consideration just like the rest of the payment is consideration? Other than this ex ante description that we like it or we don't, how do we decouple them?

MR. LOUGHLIN: The freedom-to-operate license is consideration, but that's not the relevant question. The relevant question is whether or not the challenged restraint, which here is the payment to eliminate the risk of competition, whether that restraint supports the procompetitive benefit that Impax is proffering.

Impax is proffering a procompetitive benefit of a freedom-to-operate license. But Impax has never made the assertion that it needed to be paid to accept a license that benefited it. There's no finding to that effect, and there's no finding that the payment to avoid the risk of competition benefited consumers, so you don't need to get to that analysis.

Now, to your question, if your question is why isn't -- if your question is why isn't that a reverse payment, why isn't the license a reverse payment, the answer is that under Actavis, a reverse payment is the sharing of monopoly profits through the avoidance of competition.

Again, the license didn't do that. The license to future patents doesn't share monopoly profits. It only creates value when Impax competes and erodes monopoly profits.

COMMISSIONER SLAUGHTER: Can I ask, what would be the procompetitive benefits that would flow, some examples of procompetitive benefits that would flow from a restraint specifically?

MR. LOUGHLIN: In this case?

COMMISSIONER SLAUGHTER: Yes. In this case or as a general matter.

If we're only looking at the challenged

restraint as the agreement to -- as a payment to avoid the risk of competition, what would be the procompetitive benefits that could flow from such a restraint?

MR. LOUGHLIN: In terms of reverse payment agreements specifically, it's hard to come up with a procompetitive benefit that flows from a reverse payment agreement.

Certainly the Supreme Court identifies certain possible justifications, that the payment was simply for offsetting saved legal expenses and therefore helped with settlement, that the payment was not for the agreement to avoid competition but was in fact for some other deals and side deal that benefited consumers by the creation of a new product, for example. And the Supreme Court identifies other potential -- says that there are other possible justifications. It doesn't identify any.

Impax hasn't come up with any, and so what I -- and maybe I don't -- I don't know the answer to that question.

COMMISSIONER WILSON: So Hatch-Waxman struck a fantastic compromise between incentives to innovate and encouraging competition, and I think one of the incentives embedded in Hatch-Waxman is a preference for P-IVs that would put the patent at issue and then

allow earlier entry than otherwise. But in exchange for the cost, the transaction cost, and the litigation uncertainty, Hatch-Waxman provides to the generic 180 days of exclusivity if it is the first to file.

And so could we think about a no-AG provision as a clause that allows the generic to have exclusivity during that first 180 days, which in turn continues to incentivize generics to go the P-IV route instead of the P-III route, which improves competition generally?

MR. LOUGHLIN: I don't think that's the proper way to think about the 180-day exclusivity period because Congress and the FDA regulations do not ensure that the 180 days are exclusive. It allows brands to launch authorized generics.

And when the brand agrees not to do that, it is effectively creating a generic monopoly during that 180-day exclusivity period, and it is sharing profits that it would earn as an authorized generic with the generic, so it is a sharing of profits from an avoidance of competition, and therefore it's a reverse payment. It's not a benefit.

COMMISSIONER WILSON: Is that payment then different from a sharing of monopoly profits during the latter, in other

words, before the generic enters?

MR. LOUGHLIN: It's different in the form in which it's occurring, but it is still a sharing of benefit from the avoidance of competition rather than --

COMMISSIONER WILSON: But this time it's the generic that's avoiding competition, not the brand.

MR. LOUGHLIN: Well, in the 180-day exclusivity period, it's the brand that's avoiding competition, right, it's the -- the generic is avoiding competition from the brand, yes.

So the brand is giving a benefit to the generic in the form of its avoidance of competition, which allows the generic to earn higher generic prices than it otherwise would had the authorized generic come in and competed, and so the brand is shifting to the generic the value that it would otherwise earn through competing to the generic through this no-AG agreement. That's why it's a reverse payment.

COMMISSIONER WILSON: But you've told us that the categories of value are not fungible. And I think at the beginning we were talking about how the payment is a sharing of the monopoly profits that the brand would earn through avoidance of competition and now we're talking about the value that the generic would

get from avoiding competition.

Do you view those two things as fungible?

MR. LOUGHLIN: I'm not sure if "fungible" is the right word, but they are both -- I view both of them as reverse payments in the sense that they are both payments flowing to the generic from the avoidance of competition, as a result of the avoidance of competition. Whether it's the generic's avoidance or the brand's avoidance, they are both the value that has been created from not competing rather than from competing, and that's the reverse payment.

COMMISSIONER CHOPRA: So what if Endo -- let's put aside the cash payment and the no-AG clause.

What if Endo had given a basket of other patents, including the broad patent license for the drug at question? Would that be a reverse payment?

MR. LOUGHLIN: No. I don't think so.

If Endo had simply given to Impax an agreement to come on the market with a compromised entry date plus rights to additional patents that Endo might get in the future, I don't think that would be a reverse payment.

COMMISSIONER CHOPRA: But by that logic, wouldn't it be indirectly sharing monopoly profits?

So if they're getting the delay, and on

ancillary patents that are completely unrelated to the drugs they're providing value to Impax, why isn't that using -- their offsetting revenues from those patents, assuming they're royalty-free, why wouldn't that be a payment?

MR. LOUGHLIN: Again, because it's not a sharing of profits from avoiding competition. That benefit only accrues to Impax if it actually puts a product on the market and uses those patents to compete with Endo.

So its benefit is coming from competition, not from the avoidance of competition. That's the difference between a reverse payment and other forms of consideration, which are included in an agreement, but which are not problematic forms under Actavis.

COMMISSIONER CHOPRA: It just seemed like you're blurring --

CHAIRMAN SIMONS: He's out of time.

COMMISSIONER CHOPRA: Oh.

CHAIRMAN SIMONS: Mr. Hassi.

MR. HASSI: Mr. Chairman, Commissioners, Impax's settlement with Endo is procompetitive. It was procompetitive at the time it was signed, and it's procompetitive today.

There's no dispute that Impax sought and

obtained the earliest entry date it could. Impax' goal throughout was to get in and sell generic Opana ER as early as it could, but with meaningful protection against infringement.

CHAIRMAN SIMONS: So are you telling us that if Impax had gone to Endo and said "You know what, that no-AG thing, forget about that, we'll just take one week earlier" that they couldn't have gotten another week?

MR. HASSI: The record doesn't reflect that because complaint counsel never asked that question of Endo. There's certainly no evidence in the record that Impax could have gotten an earlier date.

With respect to the no-AG --

CHAIRMAN SIMONS: So for 23 or 33 million dollars they couldn't have gotten an extra week?

MR. HASSI: Respectfully --

CHAIRMAN SIMONS: Endo as a profit-maximizing institution, Endo wouldn't have gone for that?

MR. HASSI: Respectfully, Mr. Chairman, the no-AG was in there on the very first term sheet, and it was a March 2013 entry date. Impax negotiated and got earlier dates.

Hypothetically, could they have pushed terms off that sheet and gotten earlier dates? We don't

know, except, as Commissioner Wilson pointed out, toward the end of the negotiations, Chris Mengler, who was the prime negotiator for Impax, stepped away. Art Koch, who was the company's CFO, said that they need to forget all this mess, we'll take an entry-only settlement date, and Endo said no, they wouldn't do it.

So regardless of what Impax could have asked, they asked for that, and they didn't get it.

So an entry-only-date settlement was not made available to them. They settled on the terms that they got.

CHAIRMAN SIMONS: I'm sorry. It wasn't made available to Impax.

MR. HASSI: It wasn't made available to Impax.

Impax can't settle alone. It's being sued by Endo. That means Endo had to agree to these things. They put that on the table. They said, We'll take entry date only.

That was the very first settlement offer they made in the fall of 2009. It was the very last settlement offer they made in June of 2010 before they settled on the terms --

CHAIRMAN SIMONS: When they said, We'll take entry date only, what was the date on the table?

MR. HASSI: What was the date on the table?

CHAIRMAN SIMONS: Yes.

MR. HASSI: The first time, they asked for what the -- an entry date that Actavis got, which was an earlier entry date. I forget the date, but I think it was in 2011.

Endo said no. Endo said, We're not going to give you that date, forget it, it's off the table. We'll think about a date splitting between when the litigation would end and when the patents expire, which the patents didn't expire until the fall of 2013.

And Impax said, Well, maybe we'll just launch at risk. Endo laughed them off. And they didn't get there. They didn't reach a settlement.

The second time around, there wasn't discussion of an explicit date. They just said, We want an entry date-only settlement. I'm sorry. They may have said -- and I'd have to check the record. They may have referenced the Actavis date. But what I remember is, they asked for an entry date-only settlement, and Endo said no.

COMMISSIONER SLAUGHTER: But it matters, it matters what that date is, because it's not accurate to say they couldn't get any entry date-only

settlement. It's that they couldn't get the specific dates that you're talking about.

And you made another point that I think is important, that Impax explicitly, in the course of these negotiations, threatened to launch at risk, right, and Endo wasn't willing to settle, but Impax did make that explicit threat to Endo.

MR. HASSI: Any generic that wants to get a settlement is going to make the other side believe they're going to launch at risk. Absolutely. However, the ALJ found they were not going to launch at risk, and the record reflects that they were not going to launch at risk.

And furthermore, counsel relies on the Nexium case out of the First Circuit. And what the Nexium case says, if you want to prove a launch at risk, you also have to prove you're going to win the underlying litigation. And that's what Impax' condition was here. They would have considered a launch at risk had they won in the district court --

COMMISSIONER PHILLIPS: On that note, Counselor, Actavis says -- well, let me ask you, would you agree with me that complaint counsel's account of the harm described in Actavis is correct, in other words, it's the elimination of this risk of

competition? Is that a fair statement?

MR. HASSI: I would agree that Actavis says that. I would suggest to you that that was on a motion to dismiss. We're here after a full trial and -- and what you're struggling with is because that doesn't work under the rule of reason.

In other words, that's this theoretical harm. And it doesn't show harm to consumers. That's what these cases are about, is harm to consumers. And it's not --

COMMISSIONER PHILLIPS: Well, correct me if I'm wrong. We're into the rule of reason because of how the court viewed that harm.

MR. HASSI: Absolutely. Yes.

COMMISSIONER PHILLIPS: So if that's right, what difference does the fact that they were or they weren't or they probably were or they probably weren't going to launch at risk -- what difference does that make if the harm is this elimination of the risk of competition?

MR. HASSI: So respectfully, if you look back at the Commission's complaint, what the Commission said, under harm, they talked about harm to consumers. And in paragraph 95, what the Commission said is that but for the large payment Impax would have launched

before January 2013.

In other words, there has to be some evidence of a but-for world. There has to be some evidence that you're balancing consumers were harmed because but for this payment they would have launched earlier against the benefits that Impax got in this settlement agreement in the real world.

This risk of -- this risk of harm to competition -- look at it from Impax' perspective. Impax weighed those risks. It made a business judgment when it got to the settlement table. It knew, number one, it was not going to launch at risk. It knew, number two, that it was litigating a case with Endo and it was losing. As our expert --

CHAIRMAN SIMONS: You said Impax knew it was not going to launch at risk?

MR. HASSI: Impax was in a position to address those risks. They'd never launched at risk. And they weren't going to launch at risk. And the CEO -- and this is in the CEO's documents -- wasn't going to consider it until they won at the district court level.

CHAIRMAN SIMONS: But that's still launching at risk.

MR. HASSI: It is still launching at risk.

COMMISSIONER SLAUGHTER: And Endo -- did Endo know any of that?

MR. HASSI: No. Endo did not know that. But again, we're talking Impax is the respondent here.

Impax was evaluating those things when it sat across the table from Endo, because losing the litigation -- it had lost the Markman hearing across the board. It was losing the litigation. The litigation might well have taken -- to reverse the district court, go up to the Federal Circuit, come back down, that could take past January 2013.

They knew Endo was acquiring additional patents. They're trying to get in the market as early as they can. And they decided on a settlement that got them in before the patents expired. It got them a license not just to those patents but to the after-acquired patents. It got them freedom to operate that has them in the market today when no one else is in the market today.

COMMISSIONER CHOPRA: But doesn't intent matter here? Didn't they perceive the risk of competition that they were eliminating and managing now that they for their own future cash flows were able to get more certainty of it?

MR. HASSI: I don't think the record reflects

what Endo was thinking. I also don't think that Impax should be judged based on Endo's subjective intent.

COMMISSIONER SLAUGHTER: But does that mean that the legality of the deal is different with respect to Impax and with respect to Endo?

MR. HASSI: No. Respectfully, the legality of the deal should depend on the effects of the settlement agreement, was it procompetitive or was it anticompetitive.

COMMISSIONER WILSON: So, Counsel, can you share with me the best case that you can point to in which a court or the Commission got all the way to the balancing step in the rule of reason analysis and considered benefits that were not foreseeable at the time of signing but that actually happened subsequently?

And let me just add the factual backdrop here.

I think the record demonstrates that Impax foresaw that there would be an attempt to product-hop and that it was likely that Endo would not keep on the market the original Opana ER, and so it was I think foreseeable to Impax at the time of signing that there would be no brand and potentially no generics because it knew that additional patents were being added.

I don't know that Impax knew that the

reformulated Opana ER would need to be withdrawn from the market at the FDA's insistence, but, obviously, there are benefits flowing from having Opana ER as a generic on the market, particularly since the other version was pulled. So is there a case that supports capturing those benefits as well as the ones that Impax envisioned at signing when we get to the balancing step?

MR. HASSI: I think courts and this Commission take into account future benefits all the time. You certainly do it when you evaluate mergers.

I also can't cite you to a case where this Commission or any court ignored the real world and said let's not pay attention to what effects the agreement had in the real world and let's just look at the time the agreement was signed.

Indeed, if you look at your guidelines for collaboration with competitors, they say quite the opposite. They follow the Chicago Board of Trade language, which says, you look at -- if you have actual effects in the market, you look at those effects and you take them into account in balancing under the rule of reason. And you should do that here.

CHAIRMAN SIMONS: So let's do that here for a second and just follow this all through.

So what I'm interested in hearing your view on, what is the but-for world here if -- so we have a situation, as the ALJ tells us, where the freedom to operate, according to him, results in a situation where there's one competitor, right, which is just Impax.

And in the but-for world if no settlement had been reached, what would the but-for world have looked like? Just one competitor; right?

MR. HASSI: I'm sorry. One competitor to Endo?

CHAIRMAN SIMONS: No. One competitor selling Opana ER.

MR. HASSI: If Impax had not settled, yes, Endo would be the only -- would be the only party selling Opana ER. But, respectfully, the but-for world is in the province of -- we have the real world. We have an agreement.

CHAIRMAN SIMONS: And so the real world resulted in one competitor, and the but-for world would have resulted in one competitor.

MR. HASSI: But for a period of five years, from 2013 until the summer of 2017, Impax and Endo were both competing. And respectfully, this is the long-acting opioid market, so there are lots of

other -- there were lots of other competitors out there. But there were two parties selling Opana ER from January 1, 2013 until the fall of 2017, the summer of 2017, when Endo withdrew its product.

Had Impax not settled, it would have been just Endo during that period of time, and it's hard to say whether Endo would have withdrawn from the market or not.

COMMISSIONER CHOPRA: So you mentioned earlier that you relied on Nexium, but doesn't Nexium say you don't actually need any proof of delay?

MR. HASSI: Nexium accepted -- so Nexium was a civil plaintiffs case where the FTC put in a brief, and Nexium accepted some of the amicus arguments that the FTC put before it.

But the Supreme Court, just this term, in the American Express case, said the first step of the rule of reason is to prove consumer harm. That's a government case. That's the U.S. DOJ against merchants. Now, at the time it went to the Supreme Court, it was states. The DOJ had dropped out.

But consumer harm is the hallmark of these cases, and weighing -- balancing that consumer harm is what you're supposed to be doing under the rule of

reason.

COMMISSIONER PHILLIPS: So, Counselor, a lot of this, to me at least, seems to turn on a question of harm from what. And complaint counsel is citing Polygram and Hovenkamp and NCAA for the proposition that we're looking at what flows, harm and benefit, from the restraint, and you're saying from the agreement.

Are they misreading the precedent? I mean...

MR. HASSI: I think they are. Yes, sir. I think they are entirely missing the doctrine of ancillary restraints.

So the doctrine of ancillary restraints says, if the restraint is not required to achieve the procompetitive efficiencies, then we look at it alone.

So NCAA, that case, they put caps on how many games could be televised. That was a naked restraint. If you look at Hovenkamp, he says that, a naked restraint case -- in fact, the Supreme Court said it in Cal Dental -- NCAA, naked restraint case, you look just at the restraint.

If, however, it's not a naked restraint, if it is ancillary to the procompetitive purposes of the overarching agreement, you look at the benefits to the overarching agreement. And if you look at that --

that's in your competitor collaboration guidelines. And indeed, if you think I'm wrong about that, take a look at one of your consents, for example, the one that you just entered into two weeks ago, the Penn Gaming consent.

You have in there a two-year noncompete, right, under which you give the divesting parties this two years' freedom from -- a no poaching agreement, that says the merging parties can't take employees away from the divestiture party for two years.

That restraint is naked on its -- is -- excuse me -- not naked, but if you look at it alone, right, you can't justify that. If you look at it in the context of the overall consent, the overall decision and order, what you're trying to do, it's procompetitive because you're doing something procompetitive. You don't balance just the restraint, just the benefits from that restraint, unless it's naked.

COMMISSIONER SLAUGHTER: Can you apply that to -- yes, I was going to say apply that to here.

MR. HASSI: So here, we've been talking about the restraint as though it's the payment. The payment doesn't restrain anything. The restraint here, according to complaint counsel, is the fact that Impax

couldn't enter until January 1, 2013.

Now, importantly, even if -- if they hadn't settled, there would have been valid patents that extended past January 1, 2013.

So when you asked the question earlier, Commissioner Phillips, about whether it would be legal to enter in June of 2010, was it legal from an FDA standpoint? Yes. Were there a couple patents that prevented Impax from entering? Yes. Was Impax in litigation in front of a federal court with respect to those patents? Yes. If Impax had launched, how fast would they have been taken off the market by a judge? Like that (indicating). And they knew that.

But if you -- if you look at the overall -- the -- excuse me -- the overall scope, this agreement was procompetitive and the settlement terms -- excuse me -- the payment terms are part of the settlement. They're section 4.1(c) and 4.3. They're not in the same section of the settlement agreement even of the entry date.

So the January 1, 2013 entry date, that appears in the definitions section and it appears in section 3, which is the license section, which, by the way, also has the broad license. There's a -- separately, there's a covenant not to sue. You have to

take all of those together because that's what -- that's what Impax was negotiating for.

In fact, complaint counsel, they want to throw in the ten million that's from an entirely other agreement and they want to say that's in this, too. In fact, that has no --

COMMISSIONER PHILLIPS: In fairness to complaint counsel, part of their argument was that the no-AG commitment, the Endo credit -- leave aside the DCA because that depends on other facts -- the licenses both within the scope of the patent and then the freedom to operate, all of these flow in the same direction.

And so the question is logically, how do you have to tie them together if from the perspective of the other side it would have been better to give you less? Right?

Why are they so intimately tied together if it would seem that from Endo's perspective to drop one would leave Endo in a better position?

MR. HASSI: I apologize. I'm not sure I follow your question. I think they're tied together because they're involved in the same agreement that the parties reached following a negotiation.

Am I answering your question?

COMMISSIONER PHILLIPS: So complaint counsel -- I'm not going to quote directly, but they have a line or a couple of lines in their brief that as a matter of logic, right, if they would take a deal where they paid you, they would take a deal where they didn't pay you --

MR. HASSI: I see.

COMMISSIONER PHILLIPS: -- the same agreement in the same direction as the license. And so common sense tells you that there's something else available out there.

MR. HASSI: Well, respectfully, we're here after a trial. The time for using common sense, for making inferences is past. The time for evidence is here.

Indeed, if you could make those kinds of inferences from a payment, you'd have a quick look, wouldn't you?

And that's what the FTC asked for in the Actavis case. When the FTC went up before the Supreme Court in Actavis, they said, we think there should be a presumption, we think there should be a presumption that there's a payment flowing from the brand to the generic, there should be a presumption that that's anticompetitive, and then let the respondents sort that out.

And Justice Breyer said no, you prove your case as in other rule of reason cases.

And indeed, Justice Breyer, mind you, is the person in Cal Dental who wrote the dissent. Justice Breyer would have given a quick look in Cal Dental. And in that case, like in this one, the Supreme Court said, you can't do it based on a theoretical harm, you've got to show actual harm.

In Cal Dental, the FTC chose not to put on evidence of actual harm, they wanted a quick look, and Justice Breyer didn't give them a quick look, just as here -- excuse me. Justice Breyer would have given them a quick look. The majority did not. But here, Justice Breyer looked at it and said you don't get a quick look. You've got to prove your case as in other rule of reason cases. You've got to balance whether they're anticompetitive --

COMMISSIONER SLAUGHTER: So can I --

COMMISSIONER CHOPRA: Let's say we buy this. What if -- let's move the logic forward then on less restrictive alternatives, so Commissioner Phillips seemed to intimate this.

When we look at viability, in your mind, what are the factors we should consider in what's viable? Should we look at the possible, the probable, what

could have been put off the table? How should we think about this? Or should we just think nothing is viable?

MR. HASSI: And so I think less restrictive alternative is interesting in the sense that complaint counsel didn't touch less restrictive alternative, not during the trial, not until their post-trial reply brief did they come up with this sort of a common sense argument.

Less restrictive alternative is also a subject of evidence. The Supreme Court has said that, and perhaps the best example of that is the O'Bannon case out of the Ninth Circuit.

In O'Bannon, the plaintiffs came up with two less restrictive alternatives. The Ninth Circuit looked at them and upheld one and struck down one. And the reason they struck down one of the two is that there wasn't enough evidence.

Here, there's no evidence, none, on a less restrictive alternative.

They put two experts on the stand.

Roger Noll from Stanford University, he said, Don't have to do that, I don't have it.

They brought Max Bazerman down from Harvard, professor of negotiations, wrote the book on

negotiations, literally. He said, I don't have an alternative settlement here.

And so to come forward now and to say, There's a less restrictive alternative, here it is, we put it in our post-trial reply brief, without so much as a shred of evidence? There's no basis for that.

COMMISSIONER CHOPRA: So the back-and-forth on the negotiation, the material facts related to the -- let's call it the side agreement -- we can't consider any of that?

MR. HASSI: So, interestingly, the -- if what you're referring to as the side agreement is what they refer to as the side agreement, the DCA, development and co-promotion agreement, the facts are overwhelmingly in favor of Impax on that. There is no evidence that that was a payment.

I mean, I'll grant you, it was the only money that changed hands as of the time of -- as of the time of settlement. It was a separate agreement. It was negotiated by separate individuals.

But most importantly, there's no evidence that it wasn't an exchange of fair value for service. And the ALJ devoted 38 pages to showing you why it's an exchange of fair value for services. It's a drug that Impax is still pursuing today.

COMMISSIONER CHOPRA: But let me ask you the facts of -- oh, go ahead.

COMMISSIONER SLAUGHTER: Yeah. Because the question I wanted to ask you before was about the side agreement, too.

You had said just a second ago that we have to look at all of the elements and benefits of the SLA, the freedom-to-move license, in addition to the restraints, because it's all part of one agreement and they wouldn't have entered into it without it being part of one agreement. But in almost the same sentence you said but we shouldn't also then consider the side agreement that was entered into at the same time.

So my question for you is, isn't that a little inconsistent, but also wouldn't that lead to -- wouldn't that set up a road map in the future for a sort of structuring of transactions with moving pieces into side agreements versus main agreements in order to avoid potential liability that would be artificial in some way?

MR. HASSI: So lots of parties have tried to move lots of things in side agreements. I'm aware of the basis for your concern there.

The reason I said that here goes back to a

problem with the way complaint counsel has structured the rule of reason here.

The initial prong of the rule of reason, as set out in Actavis, is a large and unjustified payment. The Supreme Court said that a large and unjustified payment brings with it the risk of anticompetitive harm. And their prima facie burden is to show there's a large and unjustified payment.

We proved and the ALJ accepted that the DCA is not a large and unjustified payment, so my point is it comes out at that stage. It's not part of their prima facie case. It doesn't fall into the balancing of the rule of reason because, on its own, that agreement can be justified by the exchange of value, the profit-sharing rights that were granted to Endo in return for the opportunity to participate in the marketing of IPX-203.

And so that's the first prong of the rule of reason, is their prima facie case is to prove that there was a large and unjustified payment.

I've been talking about the Endo credit, which the ALJ found was a backstop to the no authorized generic. Those he did find were payment terms.

COMMISSIONER SLAUGHTER: But the freedom-to-move license was also not a large and

unjustified payment. I mean, we've been discussing here that it was consideration, but not a large and unjustified payment, so why is that consideration something that's part of the analysis but not the DCA consideration?

MR. HASSI: That's part of the procompetitive benefits of the settlement agreement.

So the DCA is a separate document, a separate agreement, and it falls out because the only reason it's in this case is because there was a $10 million payment associated with that, which they allege is large and unjustified. If you find that that $10 million is not large and unjustified, that entire agreement can be set to the side.

I mean, if you want to consider it, you're welcome to consider it. I would say it's on balance, it's procompetitive. Impax has demonstrated that. But it's, frankly, a distraction.

COMMISSIONER CHOPRA: And even if we don't -- even if it's not material, this DCA, I just want to ask a few questions on the facts on this.

So who is this -- is this the right pronunciation, "Dr. Cobuzzi"?

MR. HASSI: "Cobuzzi," yes.

COMMISSIONER CHOPRA: Who is that?

MR. HASSI: He was an employee of Endo. I don't remember exactly --

COMMISSIONER CHOPRA: Okay.

MR. HASSI: -- what his title was.

COMMISSIONER CHOPRA: So it's possible that he was head of business development?

MR. HASSI: I believe he was the person who negotiated the DCA. Yes, he was a business development --

COMMISSIONER CHOPRA: Okay. So you would imagine that he'd be involved in all sorts of licensing deals or speculative product deals; is that right?

MR. HASSI: He was involved in a great deal of business development, yes.

COMMISSIONER CHOPRA: Okay. So is it -- is it -- he was looped in quite late in the process about negotiating this, and the factual record shows that; is that right?

MR. HASSI: The factual record shows that the DCA was negotiated at a very time-compressed --

COMMISSIONER CHOPRA: Yes. In about two or three weeks; is that right?

MR. HASSI: That sounds about right.

COMMISSIONER CHOPRA: And what's the typical

time when he negotiates deals that he completes those deals? Has it been longer than two weeks?

MR. HASSI: I believe he sat on the stand right here and said there is no typical time. He said he's done them in shorter periods of time, but he's certainly done them in longer periods of time.

COMMISSIONER CHOPRA: And is it right that the $10 million was offered by Endo to Impax before there was even basic market information about the drug in development? Is that right?

MR. HASSI: I don't believe that's accurate, in the following sense.

IPX-203 is a follow-on to another drug, IPX-66. Endo initially wanted to license IPX-66 or perhaps both of them. Impax never wanted to license IPX-66. They were willing to negotiate IPX-203. They're in the same family. One is a tweak on the other, so --

COMMISSIONER CHOPRA: And the payment structure of it, so with speculative product deals, you know, cash flows, they tend to materialize when certainty increases, so isn't it strange that this agreement was mostly front-loaded and not back-loaded where there was more -- where most of the value came later?

MR. HASSI: Actually, most of the value did come later here. The -- most of the payment --

COMMISSIONER CHOPRA: But it wasn't realized; is that right?

MR. HASSI: They weren't realized, but most of the payments that were built into that agreement were only built in if Impax met certain milestones. Impax has recently met those milestones but only after Endo abandoned --

COMMISSIONER CHOPRA: So that's why you think we should consider all of these future events, but in this one we should not consider those future events?

MR. HASSI: Again, from my perspective, you shouldn't consider the DCA because there's no large and --

COMMISSIONER CHOPRA: Okay. And then the last question on this, do you know how -- Impax, obviously, gets audited financials.

MR. HASSI: Yes.

COMMISSIONER CHOPRA: And do you know how they accounted for this $10 million payment? Was it an extraordinary payment due to the settlement or was it accounted for just like other product deals?

MR. HASSI: It was not. The one piece of evidence that complaint counsel put in, they tried to suggest that it was treated as a settlement. They put that piece of paper in front of the CFO. He said,

Don't know what it is. He'd never seen it before. That piece of paper is floating out there in the record with, frankly, no evidentiary value.

COMMISSIONER CHOPRA: So do you know how it was accounted for though it's not in the trial record?

MR. HASSI: The CFO may have testified at how it was accounted for. My point is, is there was an absolute -- there was -- there's something that complaint counsel cites to that's a spreadsheet that they found in a million pages of documents that they couldn't tie to any witness that uses the word "settlement" in connection with the $10 million.

I suspect that that's what you're referring to in your question, and if you're not, I'm not sure. I'm happy to get back to you on how this --

COMMISSIONER CHOPRA: Okay.

COMMISSIONER WILSON: Can I just take us back --

MR. HASSI: -- I just don't remember.

COMMISSIONER WILSON: I'm sorry.

Can I just take us back to the less restrictive alternative for a moment?

On page 14 of your brief, you argue that Complaint Counsel's proffered less restrictive alternative, a settlement that includes the broad

license but not a large and unjustified payment, quote, "is no less restrictive of competition than the SLA." And you stated, "Impax would still have launched its product on the exact same date and given up its patent challenge in the exact same manner."

Do you mean to suggest that no matter what terms Endo offered, apparently even zero dollars, Impax would only settle for the entry date that it actually received?

MR. HASSI: No. I will say the record reflects that was the only -- that was the earliest date that Endo was willing to offer.

The point we were trying to make there is, complaint counsel keeps suggesting that the payment is the restraint. The payment is only a restraint if it's tied to an entry date. And the entry date in the less restrictive alternative is the same entry date as the actual entry date in the settlement agreement. It's not less restrictive, by definition.

Again, focusing on consumer harm, consumers get generic product on January 1, 2013 under either scenario.

COMMISSIONER PHILLIPS: Well, in fairness, isn't that kind of where Actavis leaves us; right? Actavis looks at the relation between the two, the date

and the payment, as a problem.

So how do we get out of -- how do we get to your point that it's the date, not the payment, that is the restraint?

MR. HASSI: I think if in this case if complaint counsel had proved what the Commission set out to prove, that in exchange for a payment -- had there not been a payment, Impax would have launched before January 1, 2013, it would be a very different argument. You'd meet what Actavis was looking for.

CHAIRMAN SIMONS: Is that a necessary requirement, that we prove that Actavis really -- that the generic would have launched earlier?

MR. HASSI: I think you have to prove some consumer harm, Mr. Chairman. I think you have to prove that somehow in the but -- that there is a but-for world in which consumers would be better off in that but-for world than they are in the real world with this settlement. That's the rule of reason test.

CHAIRMAN SIMONS: So it's not a probabilistic thing? I mean, suppose that it reduced the risk of competition by 10 percent. That's not enough?

MR. HASSI: Well, I like the probabilistic theory. I'm not sure how you apply it. But again, if you look at as of the date the settlement was signed,

I mean, that's essentially what Impax is doing. They're saying, “probabilistically, how do we make the most money for our shareholders, how do we get in this market the soonest?” Right?

They weren't going to launch at risk. They weren't going to win the litigation.

CHAIRMAN SIMONS: So basically -- I'm sorry. Basically, they fooled Endo? Endo didn't really need to pay this money?

MR. HASSI: In every negotiation, there's an element of bluffing, there's an element of getting the best you can.

Whether Endo needed to -- Endo didn't pay any money. I mean, let's be clear. The payment terms here were conditional. And as to the no-AG, they were only going to launch an authorized generic if Impax launched at risk. Impax was never going to launch at risk. It was the sleeves off their vest.

COMMISSIONER SLAUGHTER: But Endo did pay $102 million; right?

MR. HASSI: Endo did pay $102 million.

COMMISSIONER SLAUGHTER: So it's not accurate to say Endo didn't pay any money?

MR. HASSI: Yes.

And respectfully, to go back to a point

Mr. Loughlin made earlier, he talked about their interests being aligned. And as to the Endo credit, I don't agree with that at all.

The genesis of the Endo credit was Impax was concerned that Endo might engage in a product hop, that Endo might move the market away from them. Impax asked for a market acceleration trigger, something that, again, would benefit Impax, would benefit consumers, would get them in earlier. Endo refused.

And Impax said, “Well, you know, maybe we're at loggerheads. We're concerned here. You're going to move the market.” And Endo said, “We'll tell you -- we'll give you -- you know, we'll create a disincentive to move the market. We'll pay you if we move the market away, because we're going to grow this market.”

And they made us put in a royalty. And the royalty would have grown if they had grown the market. And the Endo credit grew if they shrank the market.

So our incentives were not aligned with Endo's on that at all. I don't know how you make the --

COMMISSIONER CHOPRA: On the bluffing piece, so if there's flow of value, are you trying to -- isn't a reasonable market metric Endo's perception of your entry?

I mean, there's also a series of facts in the public domain about potential entry, the filing of certain applications, among others, so isn't that our best piece of evidence of the probability?

Rather than what -- rather than Impax's own perception of what the probability was.

MR. HASSI: Well, again, complaint counsel talks about the risk of competition. Impax is that risk. Who better to evaluate that risk?

I mean, Endo has a perception of Impax's risk, but it could be bluffing. It could be real. Impax knows what it is.

I mean, in Delaware, they have something called the business judgment rule. And we trust executives to get the best deal for their companies. That's what Impax did here.

Could there have been a more procompetitive deal? Maybe. Could there have been a deal that was better for Impax and consumers? Maybe. Impax did the best it could, and Impax got the earliest entry date it could.

COMMISSIONER WILSON: So does Impax normally launch at risk after taking all of the steps that it took here?

MR. HASSI: Impax had at that point in time

never launched at risk. And as the record reflects, they always take the steps they took here.

In other words, it's -- and they're a prudent company that says, six months out from when we think we're going to get approval, we're going to start doing these things. That way, if something happens, we get to come to market. We're ready to come to market.

They also always go to their board. They didn't go to their board here. They -- this is a -- this would have been a bet-the-company risk for them. They weren't going to bet this company.

COMMISSIONER WILSON: Do you have a sense for how frequently Impax pursues P-III versus P-IV filings for its ANDAs?

MR. HASSI: I don't. I know of other P-IV filings they've pursued, but I don't know whether they've pursued P-IIIs. And I can get that information, but I don't know the answer to that.

COMMISSIONER WILSON: And particularly, within the context of an opportunity to be the first to file.

MR. HASSI: I can look at that. I mean, I don't know the answer to that.

One of the other areas that we haven't talked about but I think is important here is market power,

because the ALJ's opinion has about two pages on it. I don't think either side agrees with that approach.

But the market power approach that complaint counsel has pursued here would essentially make every brand-generic pair a market. They basically say that the generic, which is a copy of the brand, as you know, has a price effect on the brand because of that unique relationship, and therefore, you should look at those two as a market.

And literally, their expert, Professor Noll, eyeballed a bunch of charts, literally -- he didn't do any econometrics. He just looked at charts that were prepared for him by the FTC and said, “I see the effect on prices or I don't see an effect on prices, and I see an effect when the generic Opana ER comes in here, I don't see an effect when other long-acting opioids -- and that's the market here -- come into the market.” And so --

COMMISSIONER SLAUGHTER: But, Counselor, doesn't it matter, both in thinking about consumer choice and the substitutability of products, consumers as patients don't usually have a choice about which drug, which brand or generic version of the brand -- they usually have a choice between the brand and the generic maybe at the pharmacy? But at the moment the

prescription is issued, they take what their doctor prescribes them, which is not any long-acting opioid, it is Opana ER or a generic equivalent; right? Isn't that correct?

MR. HASSI: Well, prescribers have a choice and consumers have a choice. It's not uncommon --

COMMISSIONER SLAUGHTER: But the price incentive for consumers and prescribers is not the same. The prescribers are not paying.

MR. HASSI: The prescribers are not paying. What you heard in this case from the experts is that prescribers take into account what the consumers are paying. It's not the only thing they take into account, but they do take it into account.

You also heard the experts -- I believe both of them testified that there are people -- there are consumers that come to them with a particular drug in mind. There are also -- and in this case, both of them agreed, they sometimes have to switch patients from one to the other. Some long-acting opioids -- everyone is different. Some people react differently to one long-acting opioid rather than the other, and so they switch patients. They also --

COMMISSIONER CHOPRA: Isn't that therapeutic reason exactly why that there is not -- there's not

cross-elasticity, is that one product works for some patients versus other products within that class of drugs works for some other patients, so it's not -- does the patient get multiple prescriptions, and you know, you pick the one that feels best for you, or is it one at a time?

MR. HASSI: It is one at a time. But the experts agreed there's no basis for identifying that patient beforehand, so you can't price discriminate and say, “Aha, I've got this cohort of patients that can only use Opana, I'm going to charge them more.”

What they do is prescribe OxyContin because that's what the doctor is familiar with. If OxyContin doesn't work, they might try Opana.

We had a natural experiment we put into evidence here. It's the UPMC study.

So UPMC had a formulary, and OxyContin was on a favored tier in the formulary, and they moved it to an unfavored tier and they watched what happened. And the majority of patients moved away from OxyContin, some of them to Opana, others to long-acting opioids.

That's cross-elasticity. That's patients moving because of a financial incentive.

COMMISSIONER PHILLIPS: Are there precedents in the pharmaceutical drug context that show us a broader

way to look at the market here?

MR. HASSI: I think the Doryx case in the Third Circuit is one example, one example of such a precedent. Yes.

COMMISSIONER WILSON: Do we need to define a relevant market or would it be sufficient for complaint counsel to demonstrate in fact that the brand and the generic are very close in terms of substitutability and that there is a significant demand impact when the generic enters? In other words, can we look at that direct evidence as opposed to defining a market?

MR. HASSI: Respectfully, I think you need to define a market here.

I mean, that price difference -- so I'll use an example I used at trial. I eat Cheerios very often in the morning. And I go to the supermarket, and there are Cheerios and there's the store brand Oatios. And the store brand Oatios do not sell for the same price as the Cheerios, because nobody would buy them. And no offense to the ShopRites of the world, right, we're going to buy the General Mills Cheerios.

There's a price differential there. There has to be because it's a copy. That does not mean that Cheerios and Oatios are a market unto themselves and

that the Frosted Flakes and the Corn Flakes and everything else in that aisle, Raisin Bran and all the other cereals in that aisle -- pick your poison -- that they're not all in the same market.

And so, respectfully, this eyeballing and -- so yes. Is there a unique relationship between a brand and a generic? There is. And that has to do with our laws and substitutability at the pharmacy. And that does not mean that it's a market unto itself.

If it were, if it were, first, every brand and generic would be a market unto itself, and so, for example, the Third Circuit would have gotten it wrong in Doryx. And secondly, that's just one step removed from the per se case they want. They want to say “prove a payment, assume market power because it's a brand and generic, and we're done here.” That's it. That's per se.

COMMISSIONER WILSON: That's just actually step one I think, right, and then we get to offering a justification and --

MR. HASSI: On -- we'd like to limit that justification to --

CHAIRMAN SIMONS: Just on the market power, just on the market definition, you've got a situation where, when the generic enters, it takes a huge amount

of volume away from the brand and has virtually no impact on any other branded drug. Doesn't that tell you something?

MR. HASSI: It tells you that there are generic substitution laws that require that to happen at the pharmacy regardless of what the patient wants.

CHAIRMAN SIMONS: Can you point to any other product where that could be the case and those two products aren't in the market by themselves?

MR. HASSI: I'm not aware of any other regulatory regime like the one that exists for generic pharmaceuticals that causes that to happen. That's not happening because of consumer choice. It's not really happening because of price. It's happening because --

COMMISSIONER SLAUGHTER: But does it matter --

CHAIRMAN SIMONS: I know it's weird, but that's what we do for a living here, we take into account, when we do the analysis in a particular market definition, we take into account the relevant regulatory environment, and this is just -- this just happens to be the relevant, controlling regulatory environment; isn't that right?

MR. HASSI: It is the relevant regulatory environment, that's true, Mr. Chairman.

I'd like to -- complaint counsel didn't address it. They've got time on rebuttal. I'd like to address the remedy as I have a couple of minutes remaining. And we briefed this, but I think there are a couple of important points here.

Number one is, there's no basis for it. There's no basis for remedy here. I mean, this settlement was procompetitive, and it is procompetitive today, and consumers are benefiting today just as they started benefiting in --

CHAIRMAN SIMONS: If this case was very, very quickly done before the other patents were decided in court, would your analysis be different, or is it really focused on the fact that we know how that came out?

MR. HASSI: I'm sorry. I missed the last part of what you said.

CHAIRMAN SIMONS: So if we were sitting here today and it was -- I forget the date actually. Maybe 2013 -- and we're still in 2013, and so we don't know what was going to happen with respect to those other patents, would that -- does that change the way you would look at this?

MR. HASSI: It wouldn't, because those other patents had issued. Those other patents -- I mean,

number one, as of the time of settlement, Impax had a broad patent license. The patent -- a license that they gave it freedom to operate as against patents that are coming down the pike. Three of the patents by January 1, 2013 had issued, the Johnson Matthey patent and the two patents --

CHAIRMAN SIMONS: But they hadn't been ruled valid and infringed.

MR. HASSI: They had not been ruled valid, but they were presumptively valid, and they're valid going forward into 2018.

We're not relying on the fact -- should it affect your judgment? Yes. You should take into account the fact that the Federal Circuit and the district courts have all upheld those patents. But that's not the only thing.

If you want to talk probabilistically, that broad license was a benefit that nobody else got, and it was a benefit that gave them freedom to operate, and it was among the many benefits. I mean, there's a benefit to the fact that they got in before the patents-in-suit expired, so no matter when you look at it, this was a procompetitive settlement.

With respect to the remedy, number one, there's no basis for a remedy here.

Number two, this is not -- there's no cognizable danger of a recurrence here.

Complaint counsel hasn't attempted to show that Impax has done this again, would do this again. The only thing they cite in their papers is the Solodyn case. Respectfully, that was a case that was investigated by the FTC and it closed it, so that's not a suggestion that they would do this again. The settlement was, under the prevailing law at the time, lawful. Recall that this was settled in 2010 when courts at that point in time were thinking about the scope of the patent. Actavis hadn't been decided yet.

But perhaps most importantly, the remedy addresses a second agreement between Impax and Endo, a 2017 settlement, that was not the subject of any investigation. It was not the subject of any expert testimony.

They put the settlement in the record, and they put it in front of you and they say “take a blue pencil to it and remove some of Impax's rights with respect to that agreement.” On the basis of what? Certainly not due process, certainly not evidence. They simply want to take Endo's -- excuse me -- Impax's rights and take them away based on their look at that agreement and saying, “We think this is anticompetitive, too,” or “we think it's

somehow fencing in."

It's not a reverse payment. It's a royalty payment. And it shouldn't be addressed.

Unless you have any other questions, I cede my three or four seconds.

MR. LOUGHLIN: I'd just like to make a few points.

Mr. Hassi mentioned a number of times that the restraint here was the payment. The payment is not the restraint. The restraint is the payment in exchange for a deferred entry date.

And what we -- that's what we have here. We have a payment. The ALJ found a payment of at least 23 to 33 million dollars in exchange for the avoidance of the risk of competition.

There's no evidence that that payment was for a license to future patents. There's certainly no evidence that Endo was going to pay Impax to take a benefit. There's no evidence that Impax needed to be paid to take a benefit, that initial license that helped it.

And importantly, if we're going to have a rule that says the parties can look at a license to future patents included in an agreement that doesn't flow from the challenged restraint, we're going to create a

huge hole in Actavis, because licenses to future patents are common in the industry, and if parties can simply point to a license to future patents in their agreement that doesn't flow from the challenged restraint and say the entire agreement is procompetitive, then just about any reverse payment agreement can be justified.

A naked cash payment could be justified on the basis that the settlement overall includes a license to future patents.

If that were the law under the rule of reason, then Realcomp would have come out differently, NCAA would have come out differently, and National Society of Professional Engineers would have come out differently.

COMMISSIONER SLAUGHTER: Doesn't that depend on how you measure the magnitude or the value of that benefit, right, like doesn't that analysis depend on whether you measure the freedom-to-move license in the value we know today that it had given the five years Endo was on the market versus what the reasonable expectation would have been for Impax at the time that it was entered into?

MR. LOUGHLIN: No. Because that's essentially a balancing analysis, but you don't get to that step

unless respondent can show that the license to future patents flowed -- the benefit from that license to future patents flowed from the challenged restraint.

Here, it didn't. There's nothing procompetitive -- there's no procompetitive benefit from the license to future patents that is stemming from the restraint that --

COMMISSIONER PHILLIPS: Let's assume just for a minute -- we've been having a version of this I think back and forth for a while. Let's assume that we have to count --

COMMISSIONER CHOPRA: The broad patent.

COMMISSIONER PHILLIPS: Thank you -- the broad patent license. It's late in the day.

Can you still win?

MR. LOUGHLIN: Yes. Because, first, there's no -- we have a showing -- there's a less restrictive alternative here. It is plausible that the parties could have settled without the payments and still gotten the license to future patents.

Actavis itself identifies a license without payments in it as a plausible way of settling. We know from the Commission's reports on patent settlements that parties are able to settle without reverse payments all the time.

And here, a settlement without reverse payments would have benefited Endo in the sense that it wouldn't have had to make what turned out to be a $102 million Endo credit payment. Impax we know would have taken that deal because a license to future patents benefited it. It didn't need to be paid to accept that license.

So a license -- excuse me. A settlement without payments, without reverse payments, was absolutely plausible.

COMMISSIONER WILSON: Is there other evidence in the record besides the Impax offer for a date and simple settlement which Endo rejected? Is there any evidence in the record of a less restrictive alternative that both Endo and Impax would have found acceptable?

Because I think we can hypothesize that Endo might have been willing to forgo making payments, but I'm not sure that Impax would have been satisfied with a deal, with the exception of the one that it proposed and that Endo rejected.

MR. LOUGHLIN: What the evidence shows is that rather than agreeing to earlier entry, Endo, every time that was offered, put money on the table and Impax accepted it.

So there's -- it's not surprising that there isn't more evidence of negotiations, for example, over an alternative settlement, because that was quickly rejected in favor of more money.

COMMISSIONER SLAUGHTER: So isn't the less restrictive alternative then not the same deal but just without the payment but the same deal without the payment and with a slightly earlier entry date? Is that the argument that you're making?

MR. LOUGHLIN: That is likely the effect, but even a settlement with the same entry date and no-AG provision would benefit consumers, because the no-AG provision ensured that when Impax came on the market, it came on the market with a higher generic price because it wasn't getting competed against by Endo, and so that harmed consumers.

Consumers are better off even if there was the same entry date. Now, that's not likely. The payment -- the logic of the payment is that Endo was paying not to accelerate entry or get the same entry date but to get a later entry date. But certainly, even under your hypothetical, a less restrictive alternative here is a settlement without payments in it.

COMMISSIONER CHOPRA: But by that logic, don't

you -- if you prove your prima facie case that it was large, unjustified, among other things, won't you then always win with less restrictive alternative using that logic?

You're essentially saying that there's a theoretical less restrictive way to do it, and there would always be a theoretical one when there's delay.

MR. LOUGHLIN: The issue is, generally, these cases rise and fall not on the less restrictive alternative test but on whether or not there's anticompetitive harm or procompetitive justification for that.

Now --

COMMISSIONER CHOPRA: But we --

MR. LOUGHLIN: -- when we get to less restrictive alternative, it may be that there's alternative settlements, but it also may be that there may be some facts where there absolutely could not be an alternative settlement. I don't know what those would be.

Here, in this case, we do know that there were discussions of an alternative settlement which were rejected in favor of more payments. And we know that the Supreme Court identified these kinds of no-payment settlements as less restrictive alternatives in Actavis

itself.

COMMISSIONER PHILLIPS: Is that helpful for you or is it hurtful? Because they sort of say, look, they were rejected, they weren't an alternative, and you're telling us they were on the table. Like what's the level of proof you need to show something that was available as an alternative?

MR. LOUGHLIN: Under the less restrictive alternative test, we have to show that a less restrictive alternative could have been reached. We don't have to prove that it would have been reached. And there are cases saying that it's unlikely that the plaintiff is going to be able to show what would have happened in alternative negotiations.

So under a standard where we have to show that it could have happened, our burden is to show that it was feasible.

Here, it clearly was feasible. As I mentioned, a settlement without reverse payments would have been good for Endo and it would have been good for Impax, and it was on the table.

Now, just --

COMMISSIONER PHILLIPS: Sorry. One more question, and this is related to that issue.

The Chairman asked a question of Impax about

how its but-for world looked.

How does your but-for world look?

MR. LOUGHLIN: Our but-for world is the world before the settlement when there was a risk of competition. In other words, but for this agreement, there would be a risk of competition.

We don't know how that competition would have played itself out, but antitrust law does not dictate outcomes. Antitrust law protects competition so that the market can dictate outcomes.

Here, we don't know what would have happened had there not been a settlement. It could have been a different settlement. It could have been further litigation.

The point is, the but-for world here is the situation where there was in fact a risk of competition. That was ended through this reverse payment agreement.

And that's the problem that Actavis talks about. Actavis is talking about the payment being the thing that corrupts that competitive process that the antitrust laws are designed to prevent -- to protect. Excuse me.

Now, I wanted to make one point about the DCA agreement.

Commissioner Chopra, you asked questions about accounting documents.

There are in fact documents in the record that you were referring to, CX 2701, in which Impax' CEO -- this is a document created by Impax' CEO -- identified the payments from the DCA as an Endo settlement payment. That's CX 2701 at 004.

In addition, Endo created a memo, CX 1701-005, where Endo attributed the benefit from the DCA as adding significant topline revenue for Opana. It wasn't benefiting -- it wasn't identifying a benefit from a product that it was licensing. It was attributing a benefit from the license agreement to additional revenues from Opana.

That only occurs through the agreement on an entry date, not the license, so that tells you what this license was for.

CHAIRMAN SIMONS: Thank you, Mr. Loughlin. I'm sorry to tell you you're out of time.

That concludes our oral argument in this matter.

I would like to thank each of the parties for their presentations. I thought they were both excellent.

And we're adjourned.

(Whereupon, the foregoing oral argument was concluded at 3:37 p.m.)

CERTIFICATE OF REPORTER

I, JOSETT F. WHALEN, do hereby certify that the foregoing proceedings were taken by me in stenotype and thereafter reduced to typewriting under my supervision; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

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