IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

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IN RE:	JANUARY 13, 2017
LOESTRIN 24 Fe ANTITRUST LITIGATION	PROVIDENCE, RI
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BEFORE THE HONORABLE WILLIAM E. SMITH

CHIEF JUDGE

(Defendants' Motion to Dismiss)

APPEARANCES:

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13 JANUARY 2017 -- 10:00 A.M.

THE COURT: Good morning, everyone. This is the matter of In Re: Loestrin 24 Fe Antitrust Litigation. We're here on Defendants' motions to dismiss, so why don't we have counsel identify themselves for the record first.

MR. KOHN: Your Honor, my name is Peter Kohn. I don't think we've had the pleasure to meet yet. I'm one of the co-lead counsel for the Direct Purchaser Class Plaintiffs. I'm from Jenkintown, Pennsylvania.

THE COURT: Thank you very much.

MS. JOHNSON: Good morning, your Honor. Kristen Johnson, also for the Direct Purchaser Plaintiffs.

MR. SHADOWEN: Good morning, your Honor. Steve Shadowen on behalf of the End-Payor Plaintiffs.

MR. PERWIN: Good morning, your Honor. Scott Perwin on behalf of the Retailers.

THE COURT: Thank you.

MR. MILNE: Good morning, your Honor. Rob Milne with White & Case on behalf of the Allergan and Watson Defendants, and with me is my colleague Bryan Gant also from White & Case.

THE COURT: All right. Thanks very much.

MR. BLAD: Leiv Blad for the Lupin Defendants.

THE COURT: Thank you. So I had an e-mail sent

to you all yesterday, I believe, on how we were going to structure these arguments; so have you decided amongst yourselves how you're going to split that time up?

MR. MILNE: Yes, your Honor.

THE COURT: Okay. What is it going to be?

MR. MILNE: For, well for the Defendants, and we're the movants, we, on behalf of the Watson Allergan Defendants, I'll take the lead for the first about hour, if we have an hour and 15 minutes, and then my colleague, Mr. Blad, will address the Court for the remainder of our time on the opening.

THE COURT: I think that's a little more than I gave you.

MR. MILNE: I thought it was -- what was the total time we had for the opening portion? I thought it was an hour and 15 minutes.

THE COURT: Is that right? An hour and 15 minutes, take a break for 15, and then another hour and 15 minutes, and 30 minutes for rebuttal. That's how I structured it. So you're going to take about an hour?

MR. MILNE: I'll take about an hour, and then my colleague will take about 15.

THE COURT: All right. That works.

MS. JOHNSON: Your Honor, we have four attorneys

presenting on five different topics to track what the Defendants have outlined in their presentation. We are expecting that each attorney will take 15 minutes per topic.

THE COURT: That sounds good. So let's get going.

MR. MILNE: And your Honor, we have some slide materials that I believe you've heard we've provided those to our adversaries here. They should show up on the screens. If you need more copies, we have more.

THE COURT: Okay. Thank you.

MR. MILNE: Well, your Honor, thank you for taking the time to hear argument on this case.

From the standpoint of the Defendants here, as your Honor knows, there are three major categories of claim now asserted in the case: We've got the reverse payment *Actavis*-type claims, we've got the product hop claims, and then we've got the fraud on the patent office claims; and obviously we have moved to dismiss with respect to all three.

But before I get into the specifics of the individual claims, I'd like to spend a little bit of time talking about an issue that cuts across all of the claims, and that is the allegations relating to market power and monopoly power. If we could go to the first

slide there.

So, your Honor, the Plaintiffs in these cases are basically, these are antitrust cases and they are alleging restrictions in competition in a relevant market; and what the Plaintiffs are trying to allege here is that the market here is basically one product, the Loestrin product with this particular combination of chemicals, the ethinyl estradiol and the norethindrone, over a 24-day course of treatment. And that is -- they're trying to say that that is a market onto itself as to which the Defendant Warner Chilcott exercised monopoly power.

Now, they make that allegation despite the fact that there is no dispute in this record that we're talking about oral contraceptives here. And if we could go to the next slide, Bryan.

That even if you're just talking about the same molecules, the ethinyl estradiol and the norethindrone, there are over two-dozen branded products in the marketplace of this type. And that's just branded products. If you expand that to include generic alternatives to the branded products -- and if we could go to the next slide, we put together some pictures of what that entails -- and there we're talking almost 50 generic alternatives to those branded products.

And then if you take it a step further and you say oral contraceptives that use either norethindrone or ethinyl estradiol in combination with another molecule, you have dozens of additional products beyond that, so many, many interchangeable products. And the courts themselves, your Honor, have acknowledged this.

And the next slide that we have, slide 6 in the hard copy set, sets forth some of the cases, and we cite them in the briefs, in which the courts have acknowledged the very crowded nature of the oral contraceptive marketplace.

THE COURT: Let me ask you about these cases you cite on page 6. These decisions, how many of these decisions were in the context of a motion to dismiss as opposed to a motion for summary judgment?

MR. MILNE: If we could go, your Honor, and I'll address that this way. If we could go, Bryan, to slide 8 in the set.

There are multiple courts, your Honor, that have dismissed on the pleadings in drug product cases complaints where the plaintiff has tried to allege a single product market and the court has recognized on the pleadings that it's implausible because of the presence of other competitors of other functionally-interchangeable products.

And if we could go to the next slide, Bryan. This one is particularly pertinent because it involves oral contraceptives. It's the so-called Yasmin/Yaz case, and in that case, your Honor, it was a counterclaim that was being brought, but the court dismissed on the pleadings a claim where the allegation was very similar, where the allegation was in some form of delay of generic competition, and the court dismissed on the pleadings and found that the allegations of monopoly market power were implausible. Why? Because the plaintiff had overlooked dozens of functionally-interchangeable products. And so that is -- and you'll hear from the Plaintiffs that it's a factual issue, it's very factually intense, we should have discovery.

But where it is clear that products have been left out, the courts look very skeptically on those kinds of claims. And it's not just pharmaceuticals. We cite cases beyond pharmaceuticals where you're talking about -- where the Plaintiff is trying to define a market or characterize monopoly power being exercised over something that looks like a single product, where they're using common sense, which *Twombly* and *Iqbal* tell us we need to do, it's easy to see that there are alternatives out there.

THE COURT: Don't the cases suggest that it really matters whether the market is a well-functioning market, I think the term is, versus markets in the context of pharmaceuticals where you have doctors prescribing and patients who aren't paying or insurers who are actually doing most of the paying; is that a real sort of well-functioning market, and are you conflating those things?

MR. MILNE: Your Honor, first of all I would not agree with the characterization that the pharmaceuticals market is not well-functioning. It is not a typical market for the reasons you mentioned.

THE COURT: I might not use the right terms, so, and you're all in this business all the time, and I'm not so I might not get the terms exactly right. Not a typical market, is what I'm getting at.

MR. MILNE: Understood, your Honor. But for this purpose the key is what are -- when we know there are functionally-interchangeable products out there, regardless of who the decision-maker is, clearly in pharmaceuticals it is the doctor who has to prescribe the product, and to some degree third-party payors, insurance companies involved in that decision-making as well.

But the key is the difference between a

situation where you have one or two products that are functionally interchangeable versus dozens, scores of products. Those products are available to those decision-makers; and it is that issue which defines whether somebody can exercise market power, monopoly power.

Now, the Plaintiffs -- and as I say, we cite cases to you in which courts have dismissed on the pleadings antitrust cases in the pharmaceutical context, Yasmin/Yaz being one, but the others we cited on the slides before and in the briefs where they have done that in the context of pharmaceuticals. So that that is not uncommon.

Now, what the Plaintiffs' main argument seems to be is that we're not even trying to define a relevant market here. That's not what we're trying to do. We're establishing -- we're trying to plead and prove our case through direct evidence, they call it. And it kind of comes down to almost a syllogism, what they argue.

What they say is that before generic entry in the pharmaceutical space, you have a branded product out there and let's say it's selling for a dollar a pill. Now the generic comes in, and it comes in at a lower price; it comes in at 50 cents a pill. And so

the argument is, well, it's a lower price so that must mean that the branded company before that was pricing at a supracompetitive level and therefore must be deemed a monopolist and therefore by just sort of establishing these things we're showing the exercise of monopoly power or market power directly.

Now, they haven't cited one case in which a court actually found market power, monopoly power, in a pharmaceutical setting based on evidence like that. There is no case in which that has actually been found by a court.

There are plenty of cases where courts say you may be able to prove monopoly power through quote-unquote direct evidence; but even in that context many courts say if you're going to try to prove monopoly power through direct evidence, you also have to show -- you have to have some kind of relevant market that you're saying that that power was exercised within so we can have some context.

THE COURT: Let me stop you there because this is a point that frankly I was left a little bit confused about in reading all of the materials I've read, and really two questions.

It seems like the arguments go in a circle, and I'm trying to figure out what is it that -- what's the

order of decision? Do I decide, does a court decide what the relevant market is and then look to either direct or indirect evidence of market power; or, do you look to direct or indirect evidence of market power to determine what the relevant market is? And honestly I couldn't find a really sort of simple answer to that fairly straightforward question.

And the second is what's the definition of a supracompetitive price? And how does a price of a branded drug factor in both the cost of manufacturing plus the cost of research and development, profit margin, limited length of a patent?

MR. MILNE: Right.

THE COURT: And how does that fit into, or does it, some kind of a formula to determine what a supracompetitive price is?

Could you address those two things.

MR. MILNE: Yes, your Honor. Well, to take them in order, the first step is to evaluate whether the Plaintiffs have put forward plausible facts to either suggest that there is some kind of plausible relevant market as to which you can say that this product has a significant share; have they alleged plausible facts to do that.

The second part of that is to the degree that

they are trying to go on the basis of direct evidence, have they put forward plausible facts to support a direct evidence case? And that would include some plausible pleadings about what is the backdrop, what kind of relevant market are we talking about.

So the key is at the threshold pleading stage what have they alleged here? What kind of facts have they alleged?

Now, as to the relevant market part, we all know that the inquiry is, well, what are functionally-interchangeable alternatives. We look at those sorts of things. And what the courts have said is that when you leave out obvious alternatives, that's a problem, and that can be basis for dismissal alone.

Now then the question becomes, well, what about this direct evidence thing, and what kinds of allegations are needed for that? And the questions that you raise in the second part of your inquiry go to that issue. And here again the questions become, well, what has been pled here and what do you have to plead?

Now, the courts give us some guidance on this, your Honor -- and Bryan, if we could pull up slide 12 -- and the First Circuit has said, your Honor, that when we're talking about direct evidence and what is monopoly power, one of the key issues or the key

issue is do you have power to raise prices by restricting output? And output is a key, key factor here. So that the monopolist, what the monopolist does when it's doing anticompetitive things is restricting output. There's fewer of the product in question out there in the marketplace. That's how you raise prices. When you restrict output you tend to raise prices.

So a key issue is, well, the Plaintiffs say that in a world without the generics that's an anticompetitive world. So is output less during that period versus when the generics come in? And we know that in the pharmaceutical industry very often that is not the case. Very often what happens when the generics come in is that output goes down. It goes the opposite way. And part of the reason for that is because the brand company is no longer educating doctors, going out and doing the detailing that the marketing people do for this particular molecule because it knows the generics are just going to, you know, take the sales because of automatic generic substitution laws and the like. So very often you see output going the other way.

And on that syllogistic reasoning that I talked about, the courts say that you have to think about the costs, the differing costs. The mere fact that a

branded company prices at a higher level than a generic company in this industry in particular, but it can be the case in other industries as well, is that the cost structures are so different.

And we cite more cases in the papers, but in the Second Circuit case on this slide, the court is saying what you need to do, you can't look just look at a price differential. You have to look at the relative costs to be able to say, well, was that branded company a monopolist before the generic came in.

And in the pharma industry the deck is kind of stacked in some ways against the branded companies because they have to incur all the research and development costs to bring the products forward. They have to go through and pay for the safety and efficacy studies with the FDA that can cost millions if not billions, take years and years, and then they have to go out and educate, assuming they get their approval, they have to go out and educate the medical community about the product. The product just doesn't sell itself. They have to go out and educate the world about that product, and that costs money, lots of money.

The generics come in; they get a free ride on all of that, according to Hatch-Waxman. They don't

have to do their own R&D. They get to just say, well, I'm the same as the brand. They don't have to, and the way the state generic substitution laws are set up, they don't have to necessarily market their products, because if there's a brand prescription written it will automatically be substituted for the generic unless the doctor fills out additional paperwork and does extraordinary things. So the cost structure for a generic is substantially lower. And so the idea that you can tell because the brand is priced up at a level than the generic that there was monopoly power here is just implausible.

So these are the kinds of things that you need to be thinking about as a threshold matter on the pleading.

And by the way, in these cases where in the pharma context claims were dismissed on the pleadings, these same types of arguments were made that you'll be hearing from the Plaintiffs today. That we -- that direct evidence establishes monopoly power, et cetera. But the courts have said no; we have to look at the facts and the pleadings and how plausible is it in the context here that -- because the implication, don't lose sight of the implication. And the Remeron case and a few others that we cite in our papers note this,

that if the Plaintiffs are right in what they're suggesting, then literally every branded pharmaceutical product is its own walking monopoly, at least until a generic comes in.

And so just taking the oral contraceptive marketplace, you've got these dozens of branded competitors. In their conception of the world, each one is a monopolist, even though we all know that people can switch in between oral contraceptives.

And so this issue, your Honor, is a critical issue, it's a threshold issue, and it cuts across all other issues in the case.

And I do need to move on just because of the timing, but there is one more slide I want to put up. And that's the one, Bryan, with the market background, slide 11.

I mentioned this before, your Honor, that the courts have said that even if a plaintiff is seeking to rely upon so-called direct evidence, there still needs to be some kind of context of what is a cognizable relevant market as to which this direct evidence of monopoly power is supposedly being exerted. And so the courts have said you need to have that; it's not a complete end run, saying direct evidence is not a complete end run around having to define what a market

is here.

So unless your Honor has questions, I --

THE COURT: No. I think you should keep moving because I want to make sure you get to touch on a lot of things, and I do have a lot of questions, so go ahead.

MR. MILNE: Okay.

MR. SHADOWEN: Pardon me. Steve Shadowen.

I just raise the question whether it might be more helpful to your Honor if we do this by segment. Would you like to hear from the Plaintiffs on market power while --

THE COURT: No. I think I'd like to just move right through. Thank you.

MR. SHADOWEN: Okay.

MR. MILNE: Then what I had next, your Honor, was the reverse payment *Actavis* issue, since I think that is the set of issues we began this case with.

THE COURT: Yes.

MR. MILNE: So, your Honor, as we all know the First Circuit remanded after your Honor's decision, which was a narrow decision focused on the issue of whether cash was the only form of consideration that could qualify as a reverse payment under *Actavis,* and the First Circuit said no and remanded back to this

Court to consider the other arguments that were advanced, as the court said, in the first instance.

THE COURT: Uh'huh.

MR. MILNE: So the court directed that we look at these issues, basically look at what *Actavis* means from the ground up.

Now, I want to say a word about the Nexium decision from the First Circuit, and I want to be clear here that the Nexium decision does not decide the *Actavis* issues that we are here to discuss with you, your Honor. The issues that were presented to the First Circuit did not include the fundamental questions of whether the consideration, especially as pled here for a 12(b)(6) motion, was adequate or qualifies under *Twombly*, both under *Twombly* and under *Actavis*.

The issues that were before the court in that appeal had to do with causation. Obviously it was after a jury trial and the focus was causation, and so it was at the very back end of the set of issues that need to be decided in this type of case.

Now, to be sure, earlier on in that case the district court had made decisions about whether the case could go forward, and it included an exclusivity term, a no-AG provision that is at issue here. But the issue of whether that could or should qualify under

Actavis did not get presented to the First Circuit on the appeal. It was a jury verdict for the defendants. The plaintiffs chose to raise issues around the causation aspect of the verdict.

So nothing has disturbed the First Circuit's direction to you to look at these issues in the first instance, to take a fresh look at them. And so what does that -- how do you do that?

THE COURT: Well, I don't want to interrupt the flow of your argument, but I do have some specific questions; and maybe you'll catch them as you go, but maybe it would be good if I started to fire a few at you.

MR. MILNE: Absolutely.

THE COURT: It seems to me, and I just want to see if this is your view. It seems to me from the cases I've read that the large and unjustified payment standard, that the formula for determining that is cost of litigation plus value, and that's it; and if it exceeds that then it's arguably a reverse -- a large and unjustified reverse payment. Do you agree with that formula?

MR. MILNE: I respectfully do not agree.

THE COURT: Then I want to ask you about that. Tell me why that formula is wrong.

MR. MILNE: Okay. Did you want to give me other questions?

THE COURT: I'll take one at a time.

MR. MILNE: Okay. Well, so there are multiple questions I feel embedded in your question, and the threshold question, which I'd like to circle back to, is what kind of consideration qualifies to be counted to begin with --

THE COURT: Uh'huh.

MR. MILNE: -- under the words of the Supreme Court in *Actavis*, and I want to circle back to that because I think that's a critical, critical question, but I also want to address your Honor's more specific question about large and unjustified.

THE COURT: Okay.

MR. MILNE: So if we assume that there has been some cognizable payment, something that counts, if you will, under *Actavis* then, as your Honor says, a threshold issue is, is it large; is it large within the meaning of *Actavis*?

And the Plaintiffs, of course, they do argue, and some courts, some district courts have seemed to agree with the idea the only metric is, for assessing large, is whether the payment, if you will, is even one penny or one dollar more than avoided litigation cost.

Now, if that was what the Supreme Court intended, it would have been very easy for the Supreme Court to say that directly. But the Supreme Court did not say that directly. And Bryan, if we could go to slide 37 in the deck here.

In *Actavis* the Court identified at least three different metrics for assessing "large." One was large in relation to, you know, does it exceed avoided litigation cost. Another was to assess the, assess size as a proxy for confidence in the resolution, the outcome of the patent case from the perspective of the branded company.

So if I'm willing to pay -- if I have, say, five years left on the patent and it's a $1 billion a year product, so I have $5 billion in patent-protected sales remaining in the product; if I pay $4 billion to have a settlement, well, that implies I don't have much confidence in the outcome of the patent case. If I pay $10 million, then a small fraction of what is being protected, those patent-protected revenues and profits, then that implies significant confidence.

And that is such an important factor, your Honor, because that goes to the heart of what the Supreme Court was concerned about in *Actavis*.

What it was concerned about was large payments

being made to in effect prop up patents that might be vulnerable, and so that is a metric that you cannot ignore. And I think that if you go to -- and Bryan, I'm not sure we have a slide on this.

But, your Honor, 2237, I believe it is, of the *Actavis* opinion itself, it's the wrap-up, it's where the court is wrapping up on its analysis, and it says the "likelihood of a reverse payment bringing about anticompetitive effects depends on its size, its scale in relation to the payor's anticipated future litigation cost, its independence from other services for which it might represent payment, and the lack of any other convincing justification."

So the court has the first two factors, size, and then independently does it exceed litigation costs. So the court is saying, is speaking about this size separate and distinct from avoided litigation costs.

And I think the only fair reading of that language together with the earlier analysis of the court is to say, okay, if there is -- again, if we're talking about cognizable payments, if you have a payment that doesn't exceed litigation costs, well, then that clearly is not going to raise concern. If you want to call it a safe harbor, you can call it a safe harbor. But it goes to the whole issue of is the

brand sacrificing anything; and in a situation where is it out of pocket, well, if I'm going to pay $10 million to litigate and I'm paying $10 million to settle, I'm not really out of pocket; I haven't sacrificed anything. So that's a safe harbor, and that's what the court is identifying in that second clause.

But size is separate. So if you have a payment that goes beyond avoided litigation cost, it doesn't mean automatically it's large and now we have to go to a massive rule of reason case, treble damages and all of that. It means that we don't have to think about -- and have the Plaintiffs plausibly alleged that this payment is large, relevant to these other metrics.

THE COURT: Then I come back to my question. If litigation cost is one element, why is the second element, where the court talks about other explanations that could justify it, why isn't that point directed to the value, the value of whatever the exchange is?

Now, in *Actavis* it was easy because it was dollars, and whatever the amount was I forget. Here it's complicated because it's a set of deals.

So isn't the task to identify what the value of those deals is, plus the litigation costs, and then to assess the amount or the degree to which that, how that measures up against the perceived strength or weakness

of the patent, and does it exceed the value of the deals, if that makes sense.

MR. MILNE: I think it does, your Honor, if I'm understanding. And what I would maybe commend to your Honor are the decisions of Judge Sheridan in the Lipitor and Effexor cases because I think this is the issue that he was going to in dismissing the claims in those cases.

And we're at the pleadings stage, so the question is have the Plaintiffs alleged facts to make plausible the valuations here such that we can even begin to decide whether it's plausible that the payments, if there are any that are cognizable -- and I want to circle back to that question -- whether any of those on their face seem plausibly large. And what Judge Sheridan found based on the pleadings, which we would submit are very similar to the pleadings here, is that the plaintiffs hadn't done that, that they hadn't alleged enough facts to give us context on the value.

And you mentioned that final factor of, you know, other considerations, and we are in a rule of reason context to be sure; and the court said this is a rule of reason case, like any other rule of reason case.

And so I think that's another factor

underscoring that it's not just one factor, avoided litigation cost, and now we -- if you have a payment that's $1 more than that.

In the Plaintiffs' view of the world, everything shifts to the Defendants. We show a payment, it's $1 more than avoided litigation cost, now the onus is on the Defendants to justify the whole thing.

That, your Honor, I would submit, is exactly what the Supreme Court rejected in *Actavis*. It was the FTC was coming in, and the plaintiffs as amici were arguing that there should be a presumptive illegality, that aside from avoided litigation costs, if there was any kind of reverse payment shown then the burden shifted, there would be a presumption that you had a payment that was unlawful, and now the burden shifted in a kind of a quick look rule of reason to the defendants to defend the whole thing and justify the whole thing, and the Supreme Court said no. The Supreme Court said it's a rule of reason case like any other rule of reason case. And as a rule of reason case, the Plaintiffs have burdens to plead facts that make plausible the allegations that are important.

And here, the largeness is an important element to this rule of reason inquiry, and they have to allege facts to get to that. And we would submit they haven't

done that. And it's not a talisman, this avoided litigation cost. I don't think you can read *Actavis* fairly in that narrow way. And --

THE COURT: It just seems to me that, it strikes me that the burden that you're attempting to put on the Plaintiffs at the pleadings stage is almost an impossible burden because how would a plaintiff know or be able to calculate all of the relevant pieces of this calculation? They would have to know with specificity what the additional profits are that the brand is going to obtain by keeping the generic out of the market. They would have to be able to identify that with specificity, under your formula. They would have to be able to identify what the foregone litigation costs are. And then they'd have to be able to identify with specificity what the fair market value of all the deals are that were part of the settlement. And it seems to me that every one of those things is subject to expert testimony.

And ultimately what you say might be sustained on summary judgment or trial, but at the pleading stage, how in the world could a plaintiff come up with that information?

MR. MILNE: Well, your Honor, just to be clear, we're not saying that they have to plead it down to the

dollar or the penny that you kept saying with specificity. That is not what we're saying. But I think you have a plausibility, a common sense plausibility obligation in any case.

And so with respect to these business transactions, really what we're talking about is have they alleged any plausible facts to make us believe that these deals were somehow outside the norm of what's normally done in the pharmaceutical, or are they sweetheart in some way, are they different from what pharmaceutical companies normally do. Those are the kinds of allegations that don't need to be, you know, the excess over what would have been a fair value deal is exactly this amount. No.

But they have to plead something to make it plausible, otherwise the kind of chilling effect, if all you need to do is plead, okay, there were some business deals done alongside a settlement; there was value to the generic that the settlor, that came from that and that's enough to get you in a rule of reason case, the burdens of which we're all living through right now, what companies are going to do that?

And the Supreme Court -- and this is getting to the issue of what qualifies as cognizable payments. But the Supreme Court clearly was not saying that any

and all consideration flowing to a generic, a settling generic in a Hatch-Waxman settlement can qualify as an unusual reverse payment. It wasn't saying that. And one of the things that the Supreme Court specifically called out were fair value business deals done alongside a patent settlement.

And that's so commonplace across industries. You know, you and I are in patent litigation, we're in some kind of litigation, we're at loggerheads, we're not going to reach resolution; so, but is there a win-win business deal that we can do that might, you know, allow us to bury the hatchet and have a settlement?

And the Supreme Court, if the Supreme Court intended to make all of those kinds of agreements unlawful, it would have been a very different opinion. They could have and would have written a very different opinion.

THE COURT: I think you're just saying to me essentially what I said in my order which got reversed by the First Circuit. I said things very similar to what you just said.

MR. MILNE: Well, but --

THE COURT: But the First Circuit said that's wrong and it really can be these other --

MR. MILNE: Well, your Honor, I respectfully would disagree. I think you're selling yourself short there because I think you were focused on a more narrow issue, that is, whether cash, whether the only form of consideration could be cash.

So the court has told us no, it can be something more than cash, now go back and look at *Actavis* and see what the court really meant. And Bryan, if we could go to slide 16.

This slide, your Honor, and I want to try to stick to the words of *Actavis* as much as I can because that's what we're really focusing on here.

THE COURT: Uh'huh.

MR. MILNE: The court was struggling with trying to draw a distinction between what it called unusual reverse payments and then those kinds of payments that come out of traditional or commonplace patent settlements and trying to strike that balance to say that the former are problematic and should be subject to rule of reason and the latter we shouldn't be worried about.

And so that first sub-bullet there is the court from 2223 and 33 of the opinion in various ways talking about what is an unusual payment, so the court says, (Reading) In reverse payment settlements the ones that

are unusual, as the bottom quote indicates, the defendant walks away with money simply so it will stay away from the patentee's market. That is something quite different.

Now the First Circuit said money doesn't mean cash, it can be other forms of consideration; so we got that.

But then in the lower quotes the court is then going on and saying but, however, (Reading) Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, then there is not the same concern of anticompetitive effects flowing.

And so the court with that fair value piece is bringing in this idea that you can do deals like this. You can settle litigation like this.

THE COURT: I think we're all in agreement on that. But how do you get to an understanding of fair value without expert testimony --

MR. MILNE: And what I would --

THE COURT: -- and typical discovery?

MR. MILNE: And if we have to we'll go down that road, your Honor, but I think there is *Twombly*. There are the requirements of pleading a plausible claim under *Twombly*. And simply saying, as the Plaintiffs do

here for many of them, really all of the alleged payments saying that, uttering the words above market and just reciting one side of the -- reciting the financial terms, well, this called for this payment or that payment, but not putting it in a context to say, well, this is outside the norm and here is why because the typical deal -- and there is a lot of industry statistics out there, your Honor.

THE COURT: I understand your frustration, I really do, and I think it's a frustration that judges and lawyers alike share, and I tried to express some of that in my earlier opinion, and I think Chief Justice Roberts expressed it in his dissent. But it is what it is, and we have to try to figure it out as best we can, and we're all trying to do that.

I have some very specific questions that I want to zero in on before your time runs out on this point.

MR. MILNE: Okay.

THE COURT: You suggest in your briefing the side deals, the so-called side deals have to be analyzed individually under a sort of large and unjustified standard and not as an aggregate, at least I think that's what you're arguing. And I'm wondering, it seemed to me all of these deals were done at the same time, they cross-reference each other; and what

authority is there that says that when parties do a series of business deals or side deals, that the Court should analyze them discretely as opposed to as an aggregate?

MR. MILNE: Well, your Honor, if we conveyed the impression that you have to look at each alleged payment, decide whether it's large and if it's not large it doesn't count anymore, that was not --

THE COURT: That wasn't your intent?

MR. MILNE: No. That wasn't our contention.

THE COURT: Maybe I misread. I thought that you did --

MR. MILNE: But how that could have come up, or how you could have perhaps I guess gained that impression is that I do believe that what you need to do is look at each alleged payment and see what are the allegations, are they plausible as to whether this is first of all cognizable at all; but, if it is, to what extent have they plausibly alleged the payment exceeds fair value. And then you basically look at them in total and say, well, together do they plausibly amount to something that's large.

THE COURT: I thought you were arguing that something in the language of Nexium that talked about looking at the individual agreements, I thought you

were trying to stretch that into saying you have to look at them individually. But look, if you're not, that's fine.

MR. MILNE: No, no, your Honor.

THE COURT: We talked about market power. Another point that you make is your suggestion that the five guideposts of *Actavis*, you want me to treat them essentially as a five-part test, and my reading of the cases is that that's not correct; and is there any authority that suggests that they should be seen that way?

MR. MILNE: Well, your Honor, again, I guess maybe just to be clear what we were doing there with the five guideposts is -- I wish the Supreme Court would have drafted things much more directly than it did. But we understood that the question that you have to grapple with here is looking at *Actavis* and deciding based on the pleadings is what the Plaintiffs alleged here enough to go forward.

And what we tried to do was to kind of go through the opinion and look for the things that the Supreme Court seemed, you know, viewed as important, and to articulate those as -- we didn't call it a test; we called them guideposts, and then we tried to analyze through that lens, through those lenses what the

Plaintiffs have alleged here.

THE COURT: Okay. But they're not a test.

MR. MILNE: They're not a test. But your Honor, I think what we tried to do is really tether those to the language of the opinion itself, and so I think they can form a useful basis of thinking about *Actavis* and evaluating the allegations, and that's really our purpose here.

THE COURT: Okay. So a couple more specific questions, and maybe this is a different way of coming at the issue I was trying to get at earlier.

Are you arguing a no-AG agreement cannot be a reverse payment?

MR. MILNE: We believe that a no-AG agreement should not qualify as a reverse payment. We do.

THE COURT: Hasn't the First Circuit said it can?

MR. MILNE: I believe that the First Circuit has not held that, your Honor.

THE COURT: Okay.

MR. MILNE: It did not hold that in the decision in this case. And in the Nexium decision, as I mentioned at the outset, the court was not presented squarely with the issue.

All of the arguments that we're talking before

the court, meaning the First Circuit, was not presented with the arguments that we're making to you here today about why a so-called no-AG provision does not qualify under *Actavis*.

The court kind of accepted the idea because it was in the background of the Nexium case and kind of talked about it in the background before it got to its analysis.

THE COURT: All right. Now let me jump -- I don't mean to jump around, but I'm trying to push you through this.

MR. MILNE: Yes.

THE COURT: You do have a limited amount of time, and I do want you to spend some time on product hop.

But one other question on this valuation that is leaving me a little confused is from what perspective does the Court look at value? Does it look at value from the standpoint of the patent holder or value from the standpoint of the infringer, or is that a distinction without any difference?

MR. MILNE: It's a huge issue, your Honor.

THE COURT: Okay.

MR. MILNE: I think it needs to be looked at really from both sides. But what's ignored here is the

critical, in many ways the most important perspective is from the perspective of the patent holder. And if we could go to slide 19, Bryan, because I think that that addresses this issue. It's really that first of the guideposts that we talk about.

I think the Supreme Court clearly spoke in terms of the brand company, the patentee, where you have an unusual payment sharing; what's a characteristic of that, a profit sacrifice of some kind, sharing of monopoly -- not monopoly, but patent-protected profits with the settling generic, as opposed to doing a fair value business transaction.

And even the Third Circuit decision in Lamictal agreed that reverse payment had to be costly to the patent holder. And some of the academics that the Plaintiffs themselves cite talk about that as well. And it only makes sense because for there to be something that should be suspicious, got to be thinking, well, is the innovator going out of pocket in some way?

THE COURT: So does that mean, not to be too simplistic, but does that mean the bigger the pharmaceutical company is that holds the brand, the more profitable it is, the bigger the value has to be in order to be large and justified? I mean how do you

measure it?

MR. MILNE: Well, there are two things there. One is for there to be a profit sacrifice it doesn't matter how big or small you are. If I do a win-win business deal with you, a fair value business deal, there may be payments involved, but I'm expecting to get some return; so if it's fair value I'm not out of pocket. I'm not sacrificing, it's not costly in that sense. So it doesn't matter how big/small I am if I have a deal like that. So that's one thing.

With respect to "large," and the factor of does the size of the payment, how does it reflect on confidence in the patent, then the size of the patent or the success of the patent will be relevant.

As I said before, you know, if you have five years left, it was a billion dollar a year product, you pay $10 million to settle that, that suggests great confidence in your patent. If your product is only a $20 million a year product, and you pay some number in the single, in the tens of millions, then it may not because it's relative. "Large" is an inherently relative term. So I think that's what we need to be thinking about.

And again, it comes back to the plausibility of the allegations the Plaintiffs are making. And we're

not asking for evidentiary specificity; it just has to be, it has to be plausible within commercial common sense.

And one of the things I mentioned before is that one thing about this pharmaceutical industry is that there's a lot of information out there. There is a lot of information about the kinds of deals done, what is the norm. These Plaintiffs are very sophisticated, and they know how to plead things if they can.

And that's the inherent role that *Twombly* plays, and I think it's a particularly important role here because the consequences of going down the road of a massive rule of reason case are huge. And I do think that the reason you don't have as simple an opinion as some people might have liked or that the Plaintiffs might like with a simple bright-line rule that says any payment above, any consideration one cent above avoided litigation costs is presumptively unlawful and now we have to do rule of reason. The court didn't say that. It didn't say that because it recognizes there are whole categories of settlements that shouldn't qualify.

And I think that a part of what the court was doing was setting those out, those traditional kinds of settlements out so that when courts now do their *Twombly*-type screening they can factor those

considerations in and say have the plaintiffs alleged facts that make it plausible that this settlement is unusual versus traditional. That's the -- that's your challenge. That's the Plaintiffs' challenge and your challenge as a District Court.

THE COURT: I'm watching the clock here so I really want to move you to -- and by the way, these slides, they're very helpful and I appreciate them and I'm going to go through them because I know you haven't touched on many of them.

But I want to get you to product hopping because --

MR. MILNE: May I make one more point before we leave, and then we'll go right to product?

There's another issue here that really makes this is case different than *Actavis* that I'd like to flag for your Honor. And Bryan, if we could put up slide 26.

This is just a kind of diagram of the Warner Chilcott-Watson settlement and agreements, and these were done back in 2009. And one thing that has been kind of washed under by the Plaintiffs is that you had two litigations going on. There was litigation involving Loestrin and there was litigation involving Femcon; separate product, separate patent issues.

And the parties and the public policy says let's try to resolve patent -- let's try to resolve as many issues out of court as possible, so they entered into a global settlement and alongside those settlements entered into the license and supply agreement and the co-promotion agreement referenced there.

The Plaintiffs say that those two agreements qualify as reverse payments in return for, they say, delay by Watson in the entry of generic Loestrin 24. They're just assuming that if we have any cognizable payments at all that these payments are not in respect of quote-unquote delay for the Femcon product.

Why is that? What plausible facts are there that would allow us to assume that?

And that is another factor that goes into the mix of deciding have they plausibly alleged anything that is a large, could qualify as a large payment in respect of delay with respect to Loestrin, which is the focus here. So I just wanted to make that point before we moved on.

THE COURT: Okay.

MR. MILNE: I'm happy to begin on product hop, but if your Honor has questions, it may be the most --

THE COURT: Well, I've looked at all the cases involving the, well, all the cases that I could

involving the product hopping, and it just struck me that the cases where we can identify on the ends of the spectrum what is a violation, Sherman Act, what isn't.

On the no violation end of the spectrum is a soft switch that involves the change in marketing strategies but that doesn't hold the product, the brand, the product from the market. I think that's the Prilosec cases, an example of that.

And then, on the other end, I think you've got the *Actavis* case in New York --

MR. MILNE: Yes, the Namenda case.

THE COURT: The Namenda case involving a hard switch kind of situation, and it involved things like, you know, pulling the product from the market, discontinuing plans for marketing, notifying caregivers and health care providers to discuss switching products with the patients and, you know, and pulling the product all the way out of the market, you know, so very aggressive.

This set of facts seems to fall somewhere in between, and I'm trying to figure out where to place it. It seems a little closer to Mylan, maybe to Suboxone? I'm not exactly sure, and I just want you to kind of zero me in on this.

MR. MILNE: Sure. Happy to address those

issues, your Honor.

And I would agree with you that this case is very similar to the Mylan case, what we call the *Doryx* case where the Third Circuit just issued its ruling. And one of the key factors there, and not to belabor this, is that the court found one of the decisive things that the court found there was the lack of any plausible evidence of monopoly power, because there you had a very crowded therapeutic category, just like we have here. There were antibiotics that were used for acne. But it was a very similar situation.

THE COURT: But one distinction, factual distinction that struck me was that in *Doryx*, that the brand destroyed some of their inventory. They withdrew or brought back some of the inventory.

MR. MILNE: Yes.

THE COURT: That didn't happen here, did it?

MR. MILNE: No, it did not. And so in some ways, that was what I was going to say, is that if anything the facts as alleged here are more toward the dismissal side of the world than they were in *Doryx* for that reason.

I think if you distill the cases, your Honor, what they're saying is that this kind of claim, which is a kind of unusual claim because you're talking about

the bringing in of a new product and discontinuing an old product, which is the kind of thing that happens across industry all the time. And to put on that type of decision, the possibility of trying a treble damages case like this is the kind of thing that many courts have said we have to be really careful about doing and have it be only in the rarest circumstance that that could happen.

And so what I think in the pharma context what the courts have, if you try to distill -- and, you know, the First Circuit hasn't spoken to this issue, the Supreme Court has never spoken to this issue, so the case law is sparse.

But I think trying to distill the cases, I think it's clear that a claim like this needs to be dismissed where there's no plausible claim. The customer choice in a material way has been compromised as a result of what transpired. And I think when you look at the Namenda case --

THE COURT: I'm not sure -- oh, you mean in the other cases?

MR. MILNE: Right. Looking across the cases, so you make the Prilosec cases at one extreme or *Doryx*. In those cases I think what the court said is that, look, either because the brand never withdrew the

original product, the older product, or because there were plenty of other therapeutic, close therapeutic alternatives to the product in question -- and, by the way, generics for the old product came in and managed to, you know, find a good place in the market. Where you have that kind of situation, plenty of customer choice, then we're not going to impose any trust liability for a company's decision to withdraw a product or add a product to the marketplace.

On the other extreme is where, and Namenda is an example where you have a very heavy -- and by the way, we disagree with the Second Circuit's, respectfully, with the Second Circuit's decision. We think it's totally distinguishable from what the situation is here.

But in Namenda, what the court found is that first of all you had a very unique patient population. It's early onset Alzheimer's, very vulnerable patient base. The branded product was held to be a monopolist. There were no branded alternatives. So when the old product was removed, there was really no choice. You couldn't switch to another brand of the twice-a-day. There was nothing, no place to go, and the generics were not yet in the marketplace.

So the court found that where you have a product

withdraw, a so-called "hard switch," together with other factors to indicate what the court called coercion, lack of customer choice, then it might be a problem. And there, you know, because of the uniquely-vulnerable patient base there was this factual finding that those patients really were not going to be that good candidates to switch back anyway. So a very different situation.

And then some of these other cases like the TriCor case and even Suboxone involve other conduct being claimed that's not at issue here, things like disparaging the old product; I withdraw the old product and now say it's unsafe. Or taking the old product off the market and withdrawing the NDA or withdrawing the NDDF codes that are used in the background to effectuate generic switching.

So we have no allegations like that here.

THE COURT: Does it matter to the evaluation of the product hop that the, sort of the nature of the switch, in this case it seems pretty simplistic, that is, the changing it from a swallow tablet to a chewable and adding some flavoring doesn't seem like a major switch and it's, you know, it seems that that could be designed to be just enough to be therapeutically different. Does that matter?

MR. MILNE: Well, I think what the courts have said that we ought to be extraordinarily careful -- and Bryan, if we could pull up slide 45.

We need to be extraordinarily careful over having courts become arbiters of whether a new product is sufficiently enough of an improvement. I think what the courts say is the marketplace decides that.

And maybe if we could go to the picture slide, Bryan. I don't have the number right in front of me, the one with the apple.

Just by way of a couple of kind of maybe silly examples but, you know, Advil Migraine is out there in the marketplace. It's got 200 milligrams of ibuprofen. It's out there being marketed this way.

Should Pfizer have to worry about whether that's enough of an improvement? What if it decides to pull regular Advil off the market? Has it committed an antitrust violation now? If the market decides they love to buy Advil with this particular labeling, that's the market's decision.

And here, to the degree that the degree of the improvement is relevant at all, there's no question that it mattered. And even the Plaintiffs have conceded this at various points in their complaint, that Loestrin was not able to be promoted as chewable.

And we know, and the Plaintiffs have conceded, that doctors had been advising patients to, if possible, chew their oral contraceptives.

Now, it is true that Loestrin is capable of being chewed. It is. But it matters a lot if you're allowed to go out and educate doctors about that. And under the way Loestrin had been approved, that wasn't legally possible. With Minastrin, the second generation of product, Warner Chilcott was permitted to do that.

And I think if we -- one of the core issues here that makes this case different from cases that have been allowed to go forward is that there's no plausible argument that choice has been limited, because it is true that Loestrin was taken off the market.

But Bryan, if we could go to the --

THE COURT: I need to bring you to close here because I want to give Lupin a chance to say what they have to say, and so wind it up.

MR. MILNE: I will your Honor. And I guess --

THE COURT: You'll have a chance to rebut. You can use that half hour for whatever you want.

MR. MILNE: Yes. If I could just make one more point here. And Bryan, if we could pull up the table, the graph -- yes.

So here, your Honor, the facts are that Warner in August of 2013 discontinued selling and promoting Loestrin. And the blue line on this, this comes right out of the DPPs' complaint, this exact graph.

THE COURT: Uh'huh.

MR. MILNE: The blue line is Loestrin unit sales, and you can see it's trending downward over the years leading up to when Loestrin came off the market. So it was not on an upward swing, let's say. They discontinued it.

And the green graph is Minastrin. The red is generic forms of Loestrin. And these are the products that the Plaintiffs are saying had been constrained from the marketplace. And this is against the backdrop where we have dozens and dozens of branded alternatives and generic alternatives of these other forms of the product; and you have nothing about the patient base that is unique, that they can't switch, that they can't move in and out.

And by just over that period covered by the graph, at the end of the period the generic Loestrin sales, the very products that are supposed to have been impaired, have gained sales to be more than half of what the new Minastrin has been.

And there's nothing to prevent these generic

firms from -- they don't want to have to do it, but there's no legal impediment or financial impediment to them going out and promoting their drug. If they think that their drug is just as good as the new product, the new product isn't enough of an innovation, there's nothing preventing them from going to doctors and saying our product is otherwise the same, it costs half as much, you should, doctors, you should prescribe our product.

And basically what the Plaintiffs are trying to do in this context is say that there's some kind of perpetual duty, implied antitrust duty for this branded company to keep the old product in the market so that they don't have to lift a finger to market it themselves. So we would submit that this claim should be dismissed. It's kind of a tack on.

I didn't get a chance to address the Walker Process issues, your Honor, and maybe I can in the rebuttal period, or I otherwise stand on the papers.

THE COURT: Thank you very much, Mr. Milne.

All right. Let me hear from Lupin; 15 minutes, if you will.

MR. BLAD: Thank you, your Honor. Leiv Blad for the Lupin Defendants. We are not a Defendant in all of the cases. We are not a Defendant in the Direct

Purchaser case; just in the Retailer cases and the End-Payor cases.

I'm going to go over three points today. I'll rejoin in what Mr. Milne said both here and in the briefs.

The first point I want to make is that the settlement agreement between Lupin and Warner Chilcott settled two different patent litigations. One was the Loestrin litigation; the other was the Femcon litigation.

So in order for the Court to understand whether the payment for Loestrin in that settlement agreement was large and unjustified, we have to know whether it was for the Loestrin patent litigation settlement or the Femcon settlement.

In other words the Plaintiffs have to allocate the payments to one or the other cases. But they haven't done that. What they say is all of the payments, the alleged payments in this settlement agreement are for the Loestrin settlement. And there's nothing in the documents to suggest that is a plausible allegation. There is nothing suggesting that the Femcon supply agreement, for example, as opposed to the Asacol supply agreement was for the Loestrin patent settlement. If one would think that, they would argue

that the Femcon supply agreement was in settlement for the Femcon litigation, and the Asacol supply agreement was in settlement for the Loestrin settlement case.

They say that the Femcon agreement is not settlement for the Femcon litigation but for the Loestrin litigation, and there's nothing in the documents to suggest that.

So there's nothing on which the Court can base a conclusion about which payment was for the Loestrin litigation and what the value of that payment was.

The problem that they have is that the Asacol agreement at the time that it was signed had a potential value of zero. That is because that was a contingent agreement. It was contingent -- the agreement provided that Lupin could sell an authorized generic form of 400-milligram Asacol if and only if a third-party generic came into the market selling a 400-milligram version of Asacol. If that did not happen, then the value of that agreement to Lupin was zero.

If, for example, the branded company, which happens all the time, which is why we have product hopping claims, changed the formulation of Asacol away from 400 milligrams, then there would be no generic entry of 400-milligram Asacol and the contingency would

not be satisfied, and Lupin would never be able to sell the authorized generic.

So at the time that Lupin signed the agreement, there is a substantial possibility that it would never be able to sell a generic version of 400-milligram Asacol and the value to Lupin would be zero.

Now, that's exactly what happened. Warner Chilcott changed the formulation of Asacol away from 400 milligrams, no generic ever entered with a 400-milligram product, and the value to Lupin of that agreement turned out to be zero.

We would assert that where both the potential value at the time of the agreement and the actual value eventually reached is zero, that that agreement cannot be a large and unjustified payment under *Actavis*.

An overarching reason why the complaint should be dismissed, your Honor, is that the Plaintiffs allege that Lupin did not enter under the settlement agreement. The entry date that Lupin agreed to was July 22nd, 2014 for Loestrin. That the entry date Lupin had when it could enter the market was July 22nd, 2014. And they say, well, because you didn't enter before, that's an anticompetitive agreement and it's anticompetitive because the agreement did not permit you to enter prior to July 22nd, 2014.

Now, if Lupin could not have entered prior to July 22nd, 2014, wholly apart from the agreement, then the agreement did not impose the restriction. The restriction was imposed by something outside of the agreement. And there's no causal link from the alleged anticompetitive agreement and Lupin's inability to enter the market prior to the entry date.

Now, that is exactly what we have here because Lupin did not get FDA approval to sell a generic version of Loestrin 24 until October 28th, 2015. So wholly apart from the agreement, Lupin could not have sold a generic version of Loestrin 24 prior to July 22nd, 2014, which is the entry date in the agreement.

Under these -- we had almost these identical circumstances in the Solodyn case. In that case Judge Casper considered allegations that Lupin had agreed to an entry date that was anticompetitive with respect to some formulations of Solodyn.

We showed the court that Lupin did not receive FDA approval for those formulations until after the entry date that was provided for in the settlement agreement.

On those facts Judge Casper held that there was no causal link between the settlement agreement that

allegedly was anticompetitive and Lupin's inability to enter the market on those formulations, and so she dismissed the complaint with respect to those formulations. There was no antitrust injury, meaning an injury flowing from the alleged anticompetitive act.

The same thing is present here. Here, Lupin could not have entered prior to the entry date in the settlement agreement because it did not have FDA approval; and not having FDA approval until October 28th, 2015, that was the earliest date it could have entered the market. And so the allegation that it was the settlement agreement that imposed the anticompetitive effect is simply not the case. It was the lack of FDA approval.

So there's no antitrust injury in this case. The ability of Lupin -- inability of Lupin to enter before July 22nd, 2014 was unrelated to the provision in the agreement setting the entry date.

THE COURT: But at the time of the settlement agreement, Lupin wouldn't know whether it was going to get FDA approval or not; right?

MR. BLAD: Correct.

THE COURT: So isn't that eventuality, that isn't anticipated by the settlement agreement?

MR. BLAD: Well, your Honor, I would make two

points in response.

The first is the fact that Lupin didn't have FDA approval means that the value to Lupin of that agreement was compromised. If it had that FDA approval, it would know that it could enter on July 22nd, 2014. The fact that it didn't meant that it was a contingent agreement.

Point number two is that the question for antitrust injury is whether the injury flows from the anticompetitive act. If it does not, the causal link is broken and there's no antitrust injury.

That's the case here. It doesn't matter whether Lupin knew at the time it would get FDA approval by July 22nd, 2014. The question is whether under the facts as we know them now, the reason Lupin did not enter before July 22nd, 2014 was because of the agreement or was it because of some external fact. And here it is because of some external fact. It did not get FDA approval until more than a year after the date of entry provided for in the agreement.

THE COURT: So you're saying the perspective, the time to look at the question of antitrust injury has to be a retrospective look, not looked at for at the time of the entry or the making of the agreement.

MR. BLAD: Correct.

Now, if you go back to the Asacol agreement, the Plaintiffs argue that you have to look at the value of the agreement as of the time that the agreement was signed.

At that time the fact that it was a contingent agreement, contingent on a third party getting into the market, we know that at the time of the agreement that there was a possibility -- either if no third-party generic entered or if the formulation was changed -- that the value of the agreement would be zero.

So from that perspective at the time of the agreement, we know that the value to Lupin of that agreement was nowhere near the speculations of the Plaintiffs as to possible revenues or possible profits.

For antitrust injury we have to look at was the reason you did not enter prior to July 22nd, 2014 in selling a generic version of Loestrin due to the agreement or due to some external factor. And we know that that was an external factor because Lupin did not receive FDA approval until October of 2015.

THE COURT: So is anything in what you're arguing to me outside the scope of the pleadings?

MR. BLAD: Well, they did not point out in their pleadings that we did not receive FDA approval by 2015.

We put that in our briefs. You can take

judicial notice of that. That's what Judge Casper did in the Solodyn case.

THE COURT: Very good.

MR. BLAD: Thank you.

THE COURT: Thank you. So let's take our 15-minute break and come back at 11:45.

(Recess)

THE COURT: Let's proceed with Plaintiffs' argument.

MR. SHADOWEN: May it please the Court, Steve Shadowen on behalf of the Plaintiffs.

The question of market power in any antitrust case is fact intensive and is rarely amenable to resolution on a motion to dismiss the complaint. And as we'll get into a little bit later, there's especially good reason to deny such motions when it comes to prescription pharmaceuticals because of the price disconnect and other market structures that have already been alluded to this morning.

We've cited at footnote 612 of the Direct Purchaser Plaintiffs' brief, we've identified there at least a dozen cases in this industry where plaintiffs have pled a market that consists of a single branded product and its generic equivalents, and the courts have denied a motion to dismiss the complaint or a

motion for summary judgment or both.

Among those cases are the very recent decision by Judge Underhill in the *Aggrenox* case. That actually was not a motion to dismiss but a motion with respect to discovery. But what's important about the *Aggrenox* decision is that Judge Underhill goes into exquisite detail of both the facts and the economics as to why it's more than plausible, it's very possible and it's very likely that a single branded prescription drug and its generic equivalent constitute the relevant market. And in the *Aggrenox* case there were a dozen other brands that did the same thing, and the defendant said it also included in the market as doing the same thing was aspirin and all the dozens and dozens of makers and types of aspirin.

In the Nexium case Judge Young held on a motion to dismiss and summary judgment that plaintiffs plausibly alleged and adduced evidence to show that one of six proton-pump prohibitors that were what's called "me-too" drugs, they're essentially almost identical chemically, "me-too" drugs, there are six branded products and then four or five of them had, you know, six or seven generic competitors as well. He allowed that case to go to the jury, and we got a jury verdict that a single-branded prescription drug and its generic

competitors constituted a relevant market. So is it plausible? It's more than plausible. Judges believe it, and juries believe it.

The other side cites the Ovcon case. The Ovcon case actually supports us. That's the Meijer case, *Meijer v. Barr* out of the District of Columbia. That also was oral contraceptives. In fact, it's one of the drugs that these guys say is in this market. And there, the plaintiffs alleged that Ovcon and its generic equivalents constituted a relevant market, and the court there denied a motion for summary judgment.

And if I can just very quickly read the Court the quote that really summarizes what we're talking about here. This is on page 62 of the opinion. (Reading) Plaintiffs have marshaled evidence from which a jury could find that Warner Chilcott -- the same Defendant we have here, the same therapeutic class of drugs -- was not price-constrained prior to the entry of generic competition because physicians do not prescribe oral contraceptives based on price, patients do not switch oral contraceptives based on price, and there is an insignificant amount of actual switching between oral contraceptives.

And our complaints go into detail as to why that is. It's difficult for women to find the oral

contraceptive that is right for them that doesn't cause very significant side effects, headaches, and other things; but once --

THE COURT: But was that on motion to dismiss or a summary judgment?

MR. SHADOWEN: That was summary judgment, the Ovcon case. That's even a step beyond where we are now.

So we cited a dozen cases, many of them involving crowded therapeutic classes like you have here. And the Ovcon, they cite the Ovcon case for which it's factually true that there were 80 other branded products that did the same thing, functionally equivalent, and that court said those plaintiffs got to a jury on market power because of the specific nature of this industry.

Now, the other side, I'm going to actually -- the first slide I'm going to use is theirs. If we go back to their slide number 8, they identify three cases where they say courts granted motions to dismiss on similar allegations.

So they cite three cases. The first one you see right there in the brackets that they've inserted is "Prilosec OTC and its generic." The court there dismissed the case. That case did not involve

prescription drug market. It was an over-the-counter market. So you don't have what in fact creates market power in the market we're talking about, which is the price disconnect where the doctor does the prescribing and somebody else does the paying. Wasn't at issue in that case.

The next one they cite, *Shionogi Pharma* out of Delaware, that case was a prescription drug case, but there all the court did was say you have a wholly conclusory allegation; the plaintiffs just said it was the market. And the court dismissed the complaint with permission to replead, and that's all that happened in that case.

So the one case that they have, well, they have *Asahi Glass* here. *Asahi Glass* did not dismiss based on market power. It made a comment in passing. Judge Posner says you can't just assume that every drug is its own market; you have to plead it and prove it. We agree with that.

The one case that they do cite that did in a prescription drug context dismiss a complaint based on market power was the Yasmin case, which is on their slide 9.

And what happened in Yasmin, you read that opinion and the District Court goes through and

properly says here's the legal standard. You have to show that products are functionally interchangeable, as screen number one. And then also the second part though is you have to show those functionally-interchangeable products constrain the price of the subject product, that is, it's not just functionally interchangeable; you have to show there's substantial cross-price elasticity. And the court sets out the standard, and then the court applies that standard to the facts of that case.

And I don't know whether it's because the plaintiff did not plead it or whether they pled it and the court made a mistake and didn't address it, but the court goes through and says there are all these other functionally-interchangeable oral contraceptives and stops there and says there's a bunch of interchangeable, functionally-interchangeable products, therefore, this market is not defined by just the brand and the generic.

The court never does the price elasticity element, nor does the court look for direct evidence of market power that the price is substantially above cost.

Now I have a theory as to why that was. The counterclaim plaintiff in that case was Sandoz. As a

competitor, Sandoz, a generic manufacturer, which is a subsidiary of Novartis, the brand name manufacturer, they're not going to be out there running around making the arguments that we're making about a lot of branded products had market power because they price substantially above cost.

So whether it was because of a strategic decision made by the plaintiff in that case or a mistake made by the district judge, the fact is all the District Court did in that case was look at functional interchangeability. And that's not the standard in this case or this circuit or any other circuit.

So they've got one case, and it's either wrongly decided or correctly decided based on the facts that were alleged and argued in that case.

So we have a dozen cases. They have one. And let me very quickly just explain to the Court why that is, why is it possible that especially in this industry there are lots of markets that consist of the brand and its generic equivalents. If we turn to slide 2, please -- I'm sorry, not slide 2. It's slide 55 in our deck.

This is the definition of market power. And the court asked a great question of my brother, and that is what's a supracompetitive price? And there's a

definition. A supracompetitive price or a price that reflects the exercise of market power is one that, according to the First Circuit, (Reading) Market power is the ability of a seller to set prices well above its costs.

And the court cites the Hovenkamp treatise. And Hovenkamp then goes on. It says, by the way, the costs we're talking about are marginal costs, that is, the cost of producing the next one. Sunk costs such as research and development don't count.

And so that's the definition of a supracompetitive price. That's the definition of market power. It has an economic, well-known economic definition.

Turn to the next slide.

THE COURT: Is there authority that -- I guess you're saying *Coastal Fuels* endorses that.

By the way, do you have copies of your slides?

MR. SHADOWEN: Oh, jeez, I thought you had them. I apologize.

THE COURT: Thank you.

MR. SHADOWEN: I apologize, your Honor.

THE COURT: That's fine. Thank you. So you're citing *Coastal Fuels* as endorsing the Hovenkamp treatise's explanation, --

MR SHADOWEN: Yes.

THE COURT: -- and that was obviously a nonpharmaceutical case and it's 1996, and the petroleum industry would be very different I think than the pharmaceutical industry in terms of measuring profits against marginal cost, I would think; maybe not.

But do you have any authority that sort of endorses this definition and the fact that it's a marginal cost that you measure against in the pharmaceutical industry?

MR. SHADOWEN: Yes. And again I commend to the Court's attention that Judge Underhill's recent decision in *Aggrenox* is really, I must say, one of the most lucid economic legal explanations of these difficult concepts that I've come across.

In addition to that I would direct the Court's attention to the Retailers' brief has a nice discussion of this at page 19 footnote 3. They go into the various case law and economic treatises that explain that you're looking at marginal cost and then why you're looking at marginal cost.

So that's the definition both in this circuit and frankly, as importantly, it's an economic definition. That's the standard economic definition of market power, the ability to price substantially above

marginal cost.

Let's look at why, why is that fairly pervasive in this industry. You look at our slide number 56.

THE COURT: I guess just to, and maybe you're going to address this, but just to come back. You're saying some costs are excluded from the calculation, and that's what I'm getting at with the difference between the petroleum industry and the pharmaceutical industry. Obviously producing the next gallon of gas or gallon of diesel, there's no difference in the research and development for the gallon of diesel that's sold today versus the one that was sold 10 years ago, but in the pharmaceutical market it's a very different ball game.

So I guess I can sort of see how you measure against marginal cost and not sunk costs if you're talking about a refinery that was built four years ago has the sunk cost. But in the pharmaceutical industry it's very different, so that's why I'm pushing you a little bit on that.

MR. SHADOWEN: Sure. First of all let me say in the pharmaceutical industry it may or may not be different. We will probably show in this case it's not different. That is, the research and development that went into developing Loestrin was done literally 20,

30 years ago. This is not their first product hop. We just caught up to them finally. But this R&D was done many, many years ago.

But your broader point is a good one; that is, how do you account for, as it were, the fact that this is a research-intensive industry. And again, the *Aggrenox* decision goes into this and it explains these brand manufacturers have a need to recover those sunk costs. But that's why they have patents that allow them. If the product is a commercially-successful product, we'll give them market power.

That is, the conclusion isn't that you don't have market power because you had to incur the costs; it's that the public policy is set up to give you market power to encourage you to accumulate market power legally through legal means so that you can recover the sunk costs.

THE COURT: Okay.

MR. SHADOWEN: But it doesn't change the economic definition.

THE COURT: You have a lot of notes coming your way.

MR. SHADOWEN: Wow, okay.

THE COURT: All right. So I'm not sure if that's saying anything other than sort of the circular

argument, isn't it?

So the patent gives you a monopoly. The monopoly allows you to charge more to recover your sunk costs. And then you were saying the monopoly price is supracompetitive because it's more than marginal.

MR. SHADOWEN: Right.

THE COURT: So therefore you have market power in every drug.

MR. SHADOWEN: Not in every drug because it's not the case that every drug patent, you know, gives market power. Important patents may and very often do.

But it's not circular in this sense, that is, nobody is saying there's anything wrong with having market power; it's just an element that the plaintiffs have to show that. And then the real question is did they either obtain or maintain that market power through exclusionary practices.

All it means is that because you are pricing way above marginal costs, you know, you are subject to the antitrust scrutiny to see whether it's legitimate that you're doing that, and that's all it is.

THE COURT: What about the, I forget -- the *Doryx* case. Isn't that one in which the court held that it was not a market of one?

MR. SHADOWEN: Yes, it is. If we turn to

slide 60, we have a slide there on the *Doryx* case.

First of all, initially that is procedurally distinguishable. That was on a motion for summary judgment, not on a motion to dismiss.

THE COURT: Uh'huh.

MR. SHADOWEN: And there the court very specifically said the problem here was, you know, the failure here was a failure of proof by the plaintiffs. The defendants had economists who came in and said there is substantial price cross elasticity among all these drugs, and the plaintiffs, I don't know what they did, I wasn't there; but the court said they didn't do anything, they didn't put in any contrary evidence.

And then specifically the court said when other products in that therapeutic class lowered their price, then *Doryx* lost sales. That's just an instance or an example of cross-price elasticity.

Our complaint specifically alleges -- you know, Mr. Milne showed you the chart with the other brands and generics that are in this therapeutic class.

Our complaint alleges when the generics of those other drugs came in the market and therefore the average price of those other molecules drastically fell, what happened to Loestrin 24 sales? They went up. What happened to Loestrin 24's price? It went up.

So there's no substantial cross-price elasticity here, but of course that's an allegation that will be fleshed out by the economists on summary judgment.

So with that, your Honor, unless you have other questions. But I do commend to you that these slides, we tried to really distill this thing down. And the Court, by the way, did use exactly the right phrase, well-functioning markets; and the Namenda court, the Second Circuit says because of the price disconnect these are not well-functioning markets. That's exactly the phrase they used.

Thank you.

THE COURT: Good to get something right once in a while.

MR. KOHN: Your Honor, I'm Peter Kohn, one of the co-lead counsel for the Direct Purchaser Class Plaintiffs. I'm going to be talking today about the reverse payment or the reverse payments.

I'm going to start by talking about what the standard is for measuring reverse payments; and you and Mr. Milne had some colloquy about whether the standard is the brand's saved litigation costs. Indeed that is the standard for measuring whether a reverse payment is large or not, and that standard is very clearly given to us by the First Circuit in this very case in

Loestrin.

The First Circuit said that the size of the reverse payment, particularly as it relates to potential litigation expenses, is central to the antitrust query and requires the reviewing court or fact finder to assess the value of the payment. So that is the benchmark.

And the saved litigation costs benchmark is also articulated in the leading antitrust treatise that exists, which is Areeda & Hovenkamp, and we've cited that. The Court can see it at Areeda & Hovenkamp 2046d6 and d5. And every court to have considered this matter also agrees that the benchmark by which to judge the magnitude of a reverse payment, is it large or not, is the avoided litigation costs of the payor, that is, of the brand.

THE COURT: Doesn't it also have to include the fair market value of the rest of the deal?

MR. KOHN: Absolutely, and I'm about to get to that. Once you get to the reverse payment by taking a look at what the brand gave to the generic -- and would you go to the first slide, please, Matt.

When you take a look at what the brand gave to the generic monetarily, you subtract out the fair value of any services, services that the generic performs for

the brand in respect of those payments. In fact, the First Circuit was very, very clear about that as well, and I will turn to that.

It said, and this again is the First Circuit, 814 F. 3rd at 549, "The Supreme Court recognized that a disguised above-market deal in which" -- and it defines what an above-market deal is -- "in which a brand manufacturer effectively overpays a generic manufacturer for services rendered" -- and the operative phrase there I think is "services rendered" -- "may qualify as a reverse payment subject to antitrust scrutiny."

And what I'm going to do with your Honor right now is I'm going to go through all three of the reverse payments in this case one by one. I'm going to show you how our complaint calculates, plausibly calculates, provides the inputs from which a calculation can be made for what Warner Chilcott gave to Watson for each reverse payment and, where available, if there were services that Watson performed for Warner Chilcott, which is only for one of the three reverse payments in this case, what that fair market value might have been.

And then from that we'll take a look at what the total is and we'll compare the total, that is, what Warner Chilcott gave to Watson, subtracting what Watson

gave back to Warner Chilcott, we'll take a look at that difference, that total, and we'll compare it to saved litigation costs. This is all going to be based on our complaint and nothing extraneous to the complaint.

So let's take a look at slide 4 which shows what the -- no, the first one. There you go.

Let's take a look at slide 3. This is the sum total of the reverse payments in this case. Our complaint alleges that the no-authorized generic clause provided Watson with $41 million approximately in incremental revenue.

Our complaint alleges that the Femring co-promotion payments that Warner Chilcott made to Watson, which are two kinds of payments -- and I'll get to those in a moment because we're going to take each one of these separately -- gave Watson $25 million in a reverse payment.

And then this Generess deal -- and I'm not sure if it's pronounced Generess or Generess, it could be one or the other, and if it's the second one I think it's kind of funny -- gave Watson $200 million approximately in a total reverse payment from Warner Chilcott.

We had pled tens of millions of dollars, but as you'll see the actual inputs for a calculation that

brings the sum total over $200 million is also contained in our complaint. You just have to do the simple arithmetic.

And we also plead what the saved litigation costs are in this matter which are, given by the literature, given by the Supreme Court in *Actavis,* which are six to $10 million total. Those are the total litigation costs that a brand would be expected to expend during the entirety of the course of a litigation.

Now, of course, at the time of the settlement of the '394 patent case, at the time that Warner Chilcott made the settlement agreement with Watson, and at the very same time simultaneously on the same day gave all of these reverse payments or the agreements memorializing them, most of the lawsuit had already been expended. Most of the six to $10 million had already been spent by Warner Chilcott. So we can look at these saved litigation costs of six to $10 million. They're clearly outstripped by the reverse payments, but they're even quite a bit lower than the six to $10 million.

Before I go on to the no-AG payment, I just want to say some things about the exactitude to which we are to be held. I think your Honor has already articulated

what that exactitude is.

Certainly the fair value of whatever marketing and promotional services Watson actually performed for Warner Chilcott -- and we don't actually know sitting here if Watson did perform those services; we just don't. Discovery will determine whether Watson actually did perform those services.

But the fair value of those services is really a matter for expert evaluation. Your Honor said that, and I think the Court is correct about that. But we do plead that those promotional payments from Warner Chilcott to Watson were above market, and I'll get to that in a moment.

The First Circuit says we do not require the plaintiffs to provide a precise figure and calculations at the pleading stage, but I'm going to do it anyway. And that's the First Circuit 814 F.3rd at 552.

The First Circuit also takes a page from Judge Underhill's book from the District of Connecticut in the *Aggrenox* case and says, citing Judge Underhill, "that very precise and particularized estimates of fair value and anticipated litigation costs may require evidence that is in the exclusive possession of the defendants," here, counsel for Watson and Warner Chilcott, "as well as expert analysis."

And as a consequence, as a consequence we simply cannot be held to the standard of precision that I think the Defendants are trying to hold us.

Even the Supreme Court had something to say about this exactitude issue in *Actavis*. The Supreme Court said at 2236 of 133 Supreme Court, it said that "Where a reverse payment reflects the traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement. In such cases the parties may have provided for a reverse payment without having sought or brought about the anticompetitive consequences we mentioned above, but that does not justify dismissing the FTC's complaint."

What the Supreme Court is saying there at page 2236 is even if, even if it turns out down the road that the payment that the brand gave to the generic, here, Warner Chilcott gave to Watson, in some respect -- and I'm talking mostly about Femring because there are no services that Watson provided for the no-AG payment, there were no services that Watson provided for the Generess payment.

The only arguable services that Watson provided

were for the Femring payments, which had to do with promotion. And the Supreme Court says that even the possibility that those services that were provided may have earned Watson every single penny of these $25 million, and that the $25 million are accounted for by those services and by nothing else, not delay, nothing else, even that possibility does not justify dismissing the FTC's complaint.

And of course what was in front of the Supreme Court was just that kind of a payment in *Actavis.* And Androgel was the drug, and the way that the money was funneled to the generics in that case -- which is currently being litigated -- was through these promotional agreements where the generics performed these supposed services for marketing and promotion of Androgel. And Solvay, the branded patent holder and the marketer of Androgel, gave them money purportedly to do that.

And the question in that case is was that money in excess of what the fair market value was and, if not, is it a reverse payment. And that's currently being litigated. It got over a motion to dismiss obviously. That's *Actavis*.

Let's take a look now at the no-authorized generic payment. What we've done here, your Honor, in

this slide is using just the complaint allegations that are listed at the bottom of slide 4, we've calculated what Watson's revenue would have been with the no-AG deal, and that's on the left, and then on the right what Watson would have earned in revenues for those same six months without an AG deal, that is, with Warner Chilcott marketing an authorized generic alongside Watson.

And these are just the averments of the complaint. In fact, your Honor may recall that the $41.34 million is the sum total of those revenues cited in the complaint.

And you can see how we get to it by comparing the revenues with the AG on the right and without the AG on the left. Without an AG, Watson is making a lot more for those six months, quite a bit more, and we've been conservative in these calculations.

If you take a look on the right side, the 50 percent unit sales to Watson that Watson gets marketed along Warner Chilcott's AG, that's just the other side of the sacrifice coin; that is, that $28 million is or $29 million is what Warner Chilcott sacrificed by not launching an authorized generic.

Your Honor was wondering, well, what perspective should the payments be looked at from? And if the

Court would like to look at it from the perspective of Warner Chilcott's sacrifice, that $28.86 million is what Warner Chilcott's sacrifice was.

I want to say before I go to Femring and leave the no-authorized generic, Mr. Milne made a statement to the Court that the First Circuit in Nexium did not adjudicate the question of whether a no-authorized generic promise by a brand to a generic was actionable, an actionable reverse payment. I think that Mr. Milne was inaccurate when he said that to the Court.

This actually was argued in front of the First Circuit. In fact, the appellees in Nexium, the very last argument they made in their brief was a no-AG is not an actionable reverse payment. The Court can see those briefs for itself.

And the First Circuit disagreed, and I'll give the Lexis cite because I don't have the official reporter pagination. It's 2016 US at Lexis 20845 at star page 10. And so we think it's very clear because every single court, including the First Circuit in Nexium that considered the issue, considers a no-AG promise a payment.

Let's go to Femring. So the Femring deal was an interesting deal that is very much like the deals in Niaspan and Aggrenox, both of which were able to get

over a motion to dismiss.

Watson was to earn 50 percent of Femring net sales over three years over an annual $10 million floor regardless of whether Watson's promotion caused incremental sales or even if sales went down.

And so Watson's payment from the 50 percent of net sales was irrespective of Watson's efforts or its success. And that fact is what made the district courts in Niaspan and Aggrenox say that this is very suspicious, that this is a plausible reverse payment that is above fair market value.

And in Niaspan, Judge DuBois said that the royalty that Cos agreed to pay Barr was to be based on overall sales of Niaspan and Advicor regardless of whether the sales were generated by Barr, the generic there, its sales force. And it was on that basis -- and that's 42 F.Supp. 3d at 752-53 -- that that complaint was sustained.

Same thing in *Aggrenox*. Judge Underhill said that the fact that Barr was to be compensated on net sales regardless of whether its co-promotion generated any additional sales made the payments from Boehringer Ingelheim in that case, the brand, to Barr, reverse payments that were cognizable. And he sustained the complaint on that basis even over the defendants'

arguments -- I think it was Mr. Milne who argued the motion to dismiss in that case -- even over those arguments that the plaintiffs failed to plead with sufficient specificity the fair value of the services, that is, the excess of the payments over that value. The complaint nevertheless survived.

Let's go to the next deal, the Generess deal.

THE COURT: Before you get to that --

MR. KOHN: Yes.

THE COURT: -- what would be fair value then? How would you measure it?

MR. KOHN: So what would happen, your Honor, is there could be two potential measurements of fair value the Plaintiffs would seek through expert testimony to derive. Can we go back to Femring, please.

We would have the Femring deal, which is before the Court at ECF 193-3. We'd have that deal put in front of a licensing expert or a pharmaceutical promotion expert, and we would have that expert look at it and we'd have that expert, either based on his or her own fund of information and knowledge in the industry, or based on the availability of other like benchmark-type agreements -- some of which we'll be seeking in discovery from Warner Chilcott and Watson -- to determine whether having a promotional force paid

based on the net sales of the drug over three years, regardless of whether the promotion worked at all to increase those sales, whether that was the kind of deal that was commonplace or that would be considered fair value, or if that is consistent with industry custom and usage, or whether it's something that is remarkable in some way.

And in addition we would have that very same expert take a look at the second aspect of the Femring deal, this promotional fee of five-and-a-half million dollars a year for three years and say isn't that what was used to compensate Watson for the detail. In fact, I think it's called a detailing fee in the agreement. And so we would have that expert evaluate it, and that expert would have an opportunity through his or her report to address the Court and address the jury as well.

With respect to the Generess deal, and then I'm going to sit down, what we've done here is just the paragraphs of the complaint show what the deal netted to Watson. It netted $201 million. Watson didn't have to perform any services under this Generess deal. Watson wasn't given some authorized generic of Generess to market.

All Warner Chilcott did was it took a brand drug

that it was going to market and gave it to Watson. All Watson had to do was kick back a small 15 percent royalty before generic entry for Generess and pay Warner Chilcott at most a 15 percent supply price.

Even after deducting all of that, you still get a net $201 million payment from Warner Chilcott to Watson. What did Watson do for Warner Chilcott in exchange for this payment? Nothing. It did absolutely nothing. There was money for Watson.

Warner Chilcott even got the NDA approved by FDA for Generess for Watson, rather than going in and having Warner Chilcott sell the drug itself.

Thank you, your Honor.

THE COURT: Thank you.

MR. SHADOWEN: Your Honor, Steve Shadowen again on behalf of Plaintiffs.

I picked up from the Court's questions with respect to the product hop, some issues about the case law, so I want to jump right there. And we have a slide, it's slide 46, in which we have plotted here all of the cases that have addressed this issue, and they're across the top; and then down along the side we've identified the four key facts that we've alleged in the complaint and on which every one of these cases turns. And every single one of these cases, including

the ones that have thrown out claims with respect to product hopping, support our case here. And that's because even the ones that have thrown out product hopping have said it would have been different if the Plaintiffs had alleged X. And we have alleged the X in our case.

So what are the four key elements? Number one is a price disconnect market. And so what Mr. Milne was showing you about the aspirin or other over-the-counter drugs and computer electronics has nothing to do with this. Nobody is bringing product hop cases with respect to those products, because if the consumer is presented with a row of OTC products, the consumer is deciding which product to select and the consumer is paying, and so you have a unity of the product selection and the obligation to pay. So that price plays an appropriate role. same thing with respect to electronics and almost all other products. The pharmaceutical industry is not unique, but it's darn near unique in having this price disconnect. So that's element one.

Element number two, the Defendant cannibalized the original product, and that's unfortunately a term that the brand manufacturers and generics use in this industry is "cannibalize," that is, they take their own

prescription base. Let's say there's 9 million pills of Loestrin 24 a month being sold. Before the generics can come on to the market, the brand manufacturer takes its detailers out to the doctors and says stop prescribing Loestrin 24 and start prescribing Minastrin. And that's called cannibalizing. You're taking your own sales and then moving it to a new product. So you have cannibalizing. You have cannibalizing the property before the generic enters, and we'll see later that was a key fact that was missing in the *Doryx* case.

And then, as the Court already properly noted, a really key fact is whether or not the brand manufacturer during this period of time, before the generics enter, the brand manufacturer, while it's cannibalizing, in order to help make that happen -- because there may be doctors, there may be insurers, there may be others who would resist that. A doctor would tell you, Are you kidding me? Why would I take somebody who is already stabilized on this product, is not having side effects, has been taking it for five years, why would I move them to a new branded product? There may be resistance. And so the brand manufacturer withdraws the original product from the market and says to the doctors now you've got a real good reason to

move them, because you have to move them; we're withdrawing that product that they're stabilized on, that is not causing them any side effects and that they're happy with, we're withdrawing it from the market. So their product withdrawal, what is now being called, for shorthand called a "hard switch," is a key fact.

And every one of the cases and the commentators and the FTC have acknowledged that when you have those four elements, you've got yourself a viable product hop claim.

And then with respect to the last four cases on this chart, in every one of those cases there was missing one of these four key elements. And I think this would be a good guide for the Court as you look at this.

THE COURT: When you say withdrawal of the brand, there are distinctions, aren't there? In some of the cases they actually buy back the product that's still out on the market; in others they went out and said there were safety problems with them.

But neither of those things are present in this case; right?

MR. SHADOWEN: In neither of those two cases, so the case where they bought back the old product, that

was the TriCor case, the *Abbott Labs v. Teva* case, and the court there made very clear the discussion that this was actionable exclusionary conduct. They go through that, and the court says, it was Judge Gordon who sits on the Third Circuit said the key fact is the product withdrawal.

You turn the page of the opinion, then it says other facts in support of the claim. In other words a grab bag of other things that they did; and included in there was draining the supply chain, that they went back and made sure people didn't have two months' supply sitting around. That happened in that case, but it wasn't essential to the court's opinion.

The same thing, Judge Goldberg in the Suboxone case. That's the case where they also did product disparagement. That was not essential to the court's finding. He focused, like all the other cases do, on the product withdrawal.

THE COURT: So here you're saying there was product withdrawal.

MR. SHADOWEN: Correct.

THE COURT: So I guess a different way of putting it is what's your definition of product withdrawal?

MR. SHADOWEN: That they stop manufacturing the

product and selling it. And here's the key thing. During the six to eight month period of time before the generics entered the market, a woman comes in for a refill, or the doctor has a new patient, you know, that Warner has gone out and told the doctors this product is no longer available, don't write the script for that because that person will not be able to fill it at the pharmacy counter. And that's really the relevance of it.

THE COURT: So doesn't that really come down to saying that everything is a product hop unless you keep the brand, the old product on the market at the same time as you introduce the new product? Essentially what happens in AstraZeneca and Prilosec.

MR. SHADOWEN: No. These are very, very small -- there's actually literature on this -- a very, very small percentage of product reformulations.

In other words, Warner Chilcott comes to the court and says oh, it's helpful for some people to be able to chew this product. That's probably true. But what does that have to do with what they did?

Most manufacturers in this industry, when they're not doing something anticompetitive, they simply bring out a chewable form of Loestrin 24 that supplements it. They're not going out there to the

doctors saying switch from Loestrin 24 to this other product. They simply say here's another one; if you have a woman who wants to chew the pill rather than swallow it, here's another one. In other words, a line extension. So most reformulations of the product in this industry cause no problem whatsoever.

Other product reformulations, even when there is a hard switch, as there was in *Doryx*, are not made in anticipation of generic entry. The generic entry in *Doryx* had occurred years before. So *Doryx* was a case of a brand manufacturer responding to other branded competition in the therapeutic industry. It wasn't being wielded as a tool solely to impair generic competition. The generics had entered years before. And so it's not the case that every reformulation or even every cannibalization is going to incur liability here.

And under our view of the world, you have to have all four of these, and that's what makes our -- we have a limiting principle. It's not the end of the world; it's the very cases like this. And antitrust scrutiny is needed in cases like this because looking big picture, I want to make sure the Court gets the big picture here.

There's a price disconnect in these markets and

so they don't function well and a lot of branded products have market power. Congress and all 50 states then worked together to have automatic substitution at the pharmacy counter to support generics when the patent is no longer operative, obviously; right?

So if you legitimately have market power and a legitimate patent, that's fine; but when it comes to the end of that time, then we want generic competition, automatic substitution to get rid of the market power that you would continue to have as a result of the price disconnect.

And so then what happens is these product hops in these circumstances undo automatic substitution at the pharmacy counter and reinstitute or prolong the market power that's derived from the price disconnect.

THE COURT: I understand all of that, and I understand both in the abstract and as applied in this case. But how do you or what do you say then, while you're on the subject, to the graph that Mr. Milne showed just at the end of his --

MR. SHADOWEN: Yes.

THE COURT: I think it's your graph actually, isn't it?

MR. SHADOWEN: It is in our slide deck, your Honor, at 44.

THE COURT: So doesn't that undermine in the real world, the abstract principle that you're arguing?

MR. SHADOWEN: Not at all, and I'll walk you through why that's the case.

THE COURT: All right.

MR. SHADOWEN: So our slide 44 is the same as their graph, except we've added a line that I will explain. Are you with me? Do you have it?

THE COURT: Yes.

MR. SHADOWEN: All right.

THE COURT: I see it there. I'm just trying to find it in here. Go ahead.

MR. SHADOWEN: I believe it's 44.

THE COURT: Yes. Go ahead.

MR. SHADOWEN: Okay. So the blue line here is the unit sales, monthly unit sales, number of pills of Loestrin 24. And what you will see here is where you have that circle down the bottom, that was the expected generic entry date, because they had paid off the generics to stay out of the market until then. They knew what the generic entry date was going to be.

And so what they did was stop promoting Loestrin 24, the blue line; and long before the generics were scheduled to enter, on the green line, instead switched all those prescriptions or as many of

them as they could to Minastrin 24, which is the green line.

And there are two things now I want to show you. Where the circle is, that's when generic entry occurred. There were essentially zero, zero Loestrin 24 branded prescription available for automatic generic substitution for the most cost-effective means for the generics to compete. There was zero available. That's point number one.

Mr. Milne then shows you the red line at the bottom which is ultimately, over a long period of time, what's called branded generics, and they admit this in their brief, that these are not true generics; these are what's called branded generics.

The generics get the -- they go through the ANDA of the process, they just show bioequivalents to Loestrin 24, they put their own brand on it, and then they go out and market that product. So it's not a true generic, it's a branded generic, and we'll have to get into discovery to see whether this graph shows unit sales, not price. It may turn out that these branded generics were more expensive -- they typically are -- were more expensive than a true generic. But that's really a sad note to what we're talking about here.

Here is the key point is the red-dotted line

that we've added to his chart. Based on the allegations of our complaint, we say absent the product hop immediately within six to 12 months, 85 to 90 percent of these unit sales would have gone to the generic.

So the red-dotted line is the, what the economists call the "but-for" sales of the generic, and absent the product hop that's what the generic sales would have been. So that the key point isn't the red solid line. What actually happened in the real world, it's the difference between the actual sales of the generics and what we say and will prove are the but-for sales of the generic, which is the dotted line.

And the difference between those two lines, you know, you talk about the real world, that's hundreds of millions of dollars extra that women and insurers paid for this product. And we think this is very conservative because our economists may end up concluding that -- one of the things you'll notice is the huge drop between the blue line, the Loestrin 24 sales, and the Minastrin sales. They lost, you know, about a quarter, it looks like, of their sales in this transition. And but for that product hop, this red-dotted line may well have been far further up; that is, there would have been a lot more Loestrin 24 sales

available. So that's the key point. The key point isn't the red line; it's the difference between the red line and red-dotted line.

Thank you, your Honor.

THE COURT: Thank you.

MR. PERWIN: Good afternoon. I have some slides I'd like to hand up if that's okay, a few.

THE COURT: Sure.

MR. MILNE: Is there any copy for the Defendants?

MR. PERWIN: I'm happy to give one to you.

Your Honor, Scott Perwin, for the Walgreen Plaintiffs. I want to make a couple of brief points before I get to the Lupin motion, just a couple of brief points. First I want to add a footnote to the market power discussion, the market definition discussion.

Actavis says that the reason the Supreme Court reached the result it did in that case was because there's reason for concern that reverse payment settlements tend to have significant adverse effects on competition. And that's another `way of saying that there tend to be relevant product market consisting of a branded drug and its AB-rated generics, because if that wasn't the relevant market they wouldn't have

adverse effects on competition.

Think about this case. Suppose that there are 80 or a hundred oral contraceptives other than Loestrin. If all of those drugs were competing with each other on price and driving prices down, then branded Loestrin would be sold at marginal cost and nobody would care whether there was a generic version of it, and certainly Warner Chilcott would never pay anybody to keep the generic off the market. If they were stupid enough to do that, as I said, nobody would care because they would just be the hundred and first oral contraceptive, another drug sold at marginal cost. Keeping it off the market would have no effect.

So *Actavis* itself recognizes that there tend to be these narrow markets in pharmaceutical cases. It doesn't mean it's in every case, but it's certainly plausible. Not asking for summary judgment; we're just asking you to deny a motion to dismiss.

The second point I want to make, Judge, is just to remind the Court that we have alleged and argued in our brief that the no-AG agreement between Warner Chilcott and Watson was not merely a payment to Watson; it was also a horizontal market allocation agreement and therefore illegal per se under the longstanding, more than a hundred-year-old rule against

horizontal market allocation agreements.

The only difference between this case and the many cases that have been decided since 1899, which is when the *Addyston Pipe & Steel* case was decided, is that this was a geographic -- I'm sorry -- that this was a temporal market allocation agreement as opposed to a geographical market allocation agreement. It wasn't, We'll take all the customers west of the Mississippi and you'll take all the customers east of the Mississippi. It was, We'll take all of the customers from 2009 until 2014, when Watson was allowed to enter, and we won't compete with you during the next six months so you'll have a generic monopoly.

We say that that is not merely a payment; it's worse than a cash payment because a cash payment simply pushes the entry date out.

Under this kind of agreement, the restriction on competition continues after the generic enters because there's only one generic instead of two; so we say that's the reason that it should be put, it should be classified as a horizontal market allocation agreement and it should be held to be illegal per se.

Now let me move to Lupin, and let's start with the facts that we've alleged, which is the first slide. We've alleged that Warner Chilcott paid Lupin to stay

off the market until July 2014. We've alleged the payment consisted of two authorized generic supply agreements for Asacol 400 milligrams and for Femcon Fe. We've alleged that both of those were more favorable to Lupin than a typical authorized generic supply agreement. And the Loestrin settlement agreement explicitly says that Lupin's agreement to stay off the market until the expiration of the patent was in consideration for the other deals.

And Mr. Blad made the point that it's not just the Loestrin case that's being settled. It's also the Femcon case that's being settled, and that's true. The agreements show that on their face that all the consideration was to settle both cases.

We haven't brought a case on Femcon. We have brought a case on Loestrin. And if we are required to allocate the consideration between the two of them, the only way we can do that is by taking discovery and seeing if that was part of the negotiations. Based on what we know now, which is the settlement agreement itself, it was all for both.

All right. Lupin says in its motion to dismiss, well, number one, we never launched an Asacol 400-milligram authorized generic. They say our actual sales under the Femcon agreement are small, and they

say our allegations are threadbare, and they importantly, Judge, they do not mention causation. That was the third point that Mr. Blad spent a lot of time on when he was at the podium. That's not in their motion. They didn't raise that until their reply brief. I'll come back to that in a minute; but we have not had an opportunity to respond in writing to that argument.

If you go to the next slide, those arguments contradict both *Actavis* and our complaints. *Actavis* was quite clear, and other cases as well that we cited, that the issue is whether the generic was induced to abandon its claim by the agreement that was entered into to settle the patent litigation. An inducement has to depend on what the generic expects to receive under the agreements at the time of the agreement.

Generics certainly can't predict the future with certainty, so it has to be based on expectations. And, in fact, Warner Chilcott and Watson and all the Plaintiffs agree on this point, that the valuation of the deal has to be done at the time of the deal. Now, you can assume things are going to happen in the future if they're expected to happen, but if they're not expected to happen they have no role to play in the valuation.

It's true that the Asacol and the Femcon agreement were contingent because all authorized generic agreements are contingent. Nobody launches an authorized generic until there's another generic on the market. So the fact that it didn't work out the way they expected doesn't mean they didn't get value.

THE COURT: How do you measure value if it's contingent and in fact if it never happens?

MR. PERWIN: The fact it never happened is irrelevant. But it is contingent, and that is relevant. But as I said, all AG agreements are contingent and lots of deals that people make are contingent. Things can happen.

But these people negotiated a deal. They didn't go to all that trouble and paid lawyers to negotiate a deal if they didn't think there was a reasonable likelihood that there was going to be a need for an authorized generic.

THE COURT: Well, it could be that it's like buying a lottery ticket; right? I mean you buy the lottery ticket for a couple dollars. The percentage chances that it's going to have any value beyond a couple dollars are infinitesimal, but if it does it's a lot.

MR. PERWIN: But this wasn't a couple dollars,

Judge. They negotiated a complicated agreement. People do that all the --

THE COURT: I understand that. I'm just asking how do you put a value on it? If it's contingent and it has no stated value at the beginning, and at the end of the process it has zero value, you're saying it still has great value, and all I'm asking is just, okay, how do you come up with a number for what that value is?

MR. PERWIN: You do the best you can. We have put in our complaint what the size of the market was, what you would expect an authorized generic to get in terms of a share of that market, the profits they would earn, and that comes out to a big number, $100 million.

Now, you're correcting that that has to be discounted somewhat because it's not certain, but nothing in life is certain. So we would try, if we were at the summary judgment stage or at trial, to put some kind of valuation on how likely it was that there would be an authorized generic for Asacol at the time of the agreement, not based on what happened at the FDA years later.

So it's possible to do that, and I'm not disputing that you can't put a hundred percent certainty on that deal, on that hundred million

dollars; but the motion to dismiss stage is not the point we have to decide what the potential probability of that being earned was.

We have done the best we can at the pleading stage to use the figures that we know to come up with a valuation, and that's all we're required to do.

And in fact at the motion to dismiss stage these subsequent events are not in our complaint and they're not subject to judicial notice. I mean whether or not -- these are facts that have to be proven at trial, and at the moment we're at the pleading stage and we have not alleged that these things happened. So they're not subject to judicial notice; they're outside of the scope of the pleadings.

Turning to the next slide, our allegations are sufficient. The Loestrin case itself said that plaintiffs are not required to provide precise figures and calculations at the pleadings stage.

We have alleged, as I said, that they had an expectation of approximately a hundred million dollars on the Asacol deal, approximately $5 million on the Femcon agreement. We've provided the calculations. That's sufficient at the motion to dismiss.

The cases that Lupin cites are cases in which there was no attempt to put a value on the number; it

was just hundreds of millions of dollars. Now, some courts have said that that's okay, but we have done a lot more than that.

And just to move quickly to the next slide, we cite some language from the Lamictal case, Opana, Aggrenox, Solodyn, and Nexium to show that allegations like the ones we've made are sufficient at the pleadings stage to survive a motion to dismiss and allow to take discovery.

And then, Judge, briefly on the causation issue, as I said before, the caution issue is whether or not Lupin was kept off the market by the agreement or by some external factor like lack of FDA approval; not raised in their motion, not part of their motion, raised for the first time in the reply memo.

Second, discovery will show whether or not the FDA approval date was affected by the agreement. It's quite common for generics who enter into reverse payment agreements that mean they're not going to enter the market for five years will not push the end processing, or they won't respond to questions from the FDA, they won't do what they would normally do if they were seeking to get FDA approval quickly.

And we have no way at this point of knowing whether or not that date, the FDA approval date, was

influenced by the fact they had been paid to stay off the market until the middle of 2014.

And even if that discovery doesn't pan out, we have alleged an overall conspiracy between Warner Chilcott, Watson, and Lupin, which has not been challenged by Lupin; and under that theory even if we can't prove that Lupin was delayed, Lupin would be responsible of having joined a conspiracy for the delay caused by the Watson-Warner Chilcott agreements. So that wouldn't get them out of the case, even if we can't prove that Lupin itself was delayed.

And then finally, Judge, on the last slide I've just responded to an argument that was made in the brief, not orally, that the Court should phase discovery. We don't think that makes any sense. This case is already more than three years old. The only likelihood is that that would require two rounds of discovery, two rounds of depositions, and the Court should permit discovery to go forward on a claim, if the claim survives a motion to dismiss, to not phase the discovery.

Thank you, your Honor.

THE COURT: Thank you very much.

You're just about out of your time, so can you keep this fairly short.

MS. JOHNSON: I believe I have about eight minutes left. I will do my best to stick with that, your Honor. Thank you. Let's start with slide 9. I'll start talking.

The Walker Process theory, your Honor, requires the following. First, a material misrepresentation or omission; second, that that be intentionally made; third, but for that the patent would not be issued; and fourth, knowledge of the fraud by the entity asserting the patent. Plaintiffs also, in order to comply with Rule 9(b), must identify the who, what, where, and when of the misrepresentation or omission. If I may approach, your Honor.

THE COURT: Yes.

MS. JOHNSON: I realized last night when preparing we'd omitted a footnote from our brief that identified cases where courts had denied Walker Process allegations -- I'm sorry -- had denied motions to dismiss Walker Process allegations, and I wanted to provide that to the Court. We've given you seven cases here. There are others.

I'll also note that the Defendants cite to the Lipitor decision as denying Walker Process allegations, and that's true, it did; but that decision is on appeal. Lipitor also involved a prior determination

that there had been no inequitable conduct before the PTO; so the position there is very differently than this case where no court has yet ruled on whether any Walker Process fraud or inequitable conduct had occurred.

Slide 10, I guess your Honor will have to deal with the hard copy.

THE COURT: I'm looking at it.

MS. JOHNSON: Thank you. So let's talk about the patent. So what's claimed in the '394 patent is, "A method of female contraception which is characterized by a reduced incidence of breakthrough bleeding." It involves giving combination pills for 23 to 25 days and in hormone amounts, the one that's relevant here, of between 1 to 35 micrograms of ethinyl estradiol.

Someone trying to obtain a patent for Loestrin4 24 faced a serious uphill battle. Warner Chilcott already marketed a product called Loestrin 1/20 that included these same amounts of these same combination hormones. There were also known, in the prior art, regimens for birth control where you took active pills for longer than 21 days. Those two elements at minimum posed an obviousness challenge.

So one way that one might get past that

obviousness challenge would be to identify to the PTO an unexpected clinical benefit associated with their regimen, and that's what was done here. The specification as well as the claim articulate that, look, that the product described in the invention in fact reduced the incidence of breakthrough bleeding.

If you turn to page 11, the examiner here focused on to two things and only two things, your Honor. The examiner focused on the notion that this regimen in fact decreased the instance of breakthrough bleeding, and the examiner focused on the amount of hormones available in other drugs. And as I'm running short on time, your Honor, I'll do this quickly.

Our next few slides spell this out, but at the bottom line, Hodgen, the scientist prosecuting the patent application, his attorney, a Mr. Millen, and there was only one attorney, represented to the PTO that a monkey study showed a decrease in incidence. They did not disclose a study that Hodgen himself had done in 30 women prior to applying for the patent that showed quote "no significant differences in the amount of intermenstrual bleeding." There's no question, by the way, that Hodgen knew about that. He conducted the study.

Warner Chilcott tries to make some mileage out

of the fact that the study may have only included a placebo for seven days instead of three days, as the patent said, but if you actually look at the abstract, it refers to a shortened pill-free interval. But to the extent that's a factual dispute, your Honor, I'd suggest that's exactly why we need to move past summary judgment and get into discovery so that we can get to the bottom of it.

THE COURT: So does this mean that -- let's just assume I agree with you and I deny the motion to dismiss, and we get to summary judgment. But does that ultimately mean we have to try the patent case inside this case?

MS. JOHNSON: No, your Honor. It doesn't mean that we have to try the patent case. What it does mean --

THE COURT: If you survive summary judgment, then why not?

MS. JOHNSON: What it does mean is that a jury would have to reach a conclusion as to whether or not the Defendants engaged in Walker Process fraud or that the litigation was a sham. Now, that's a little bit different from a traditional patent infringement case; right? The burdens might be different. These are antitrust plaintiffs. There's some issues that may or

may not have to be addressed in the antitrust context. But yes, your Honor is correct that a jury would have to grapple with those.

The reality though, your Honor, is that if our agreement claim survives, there will be questions, there will very likely be evidence presented to the jury about the patent merits and about the weaknesses or strengths of the patent in relation to the settlement.

So as the First Circuit has said in the Nexium case, it has suggested that at least in some circumstances it may be necessary to present evidence about the patents, meaning the weaknesses, the strengths thereof, in order to make out a claim.

Now I won't agree today that that's necessarily the case here, your Honor, but I will suggest that at minimum it means that patent merits evidence will be part of discovery and very likely will play into what's presented at trial. So in that sense, adding an overarching scheme claim that includes Walker Process and includes a sham litigation theory is not adding much to the case.

I'll note the FDA reached its own conclusion later in time that Loestrin 24 did not in fact reduce the incidence of breakthrough bleeding.

So let's jump to slide 16. And so here is an affirmative misrepresentation made during prosecution, your Honor. It was affirmatively represented to the PTO that all other combination formulations commercially available in this country all contain at least 30 micrograms of ethinyl estradiol, EE. And that's not true, because Loestrin 1/20 contained 20 micrograms.

And why is that so insidious? Because the examiner was focused on how much other products contained. He was drilling in on what the prior art showed in terms of how much ethinyl estradiol, what's the difference here, is that obvious, is it not obvious.

You'll note there also in that same affirmative representation, this is Warner -- sorry -- this is Hodgen and his attorney's words. They then direct the PTO back to their reduced incidence of breakthrough bleeding claim.

So what we have here, your Honor, is one omission, the failure to disclose the women's study, the failed study in women, and two misrepresentations. That's the affirmative misrepresentation about 30 micrograms of ethinyl estradiol as well as the affirmative claims repeated that the invention actually

controls unscheduled bleeding.

The Retailers also reference -- have alleged that the Molloy reference was improperly withheld. The Directs do not make that argument, but it is well-covered in the Retailers' briefs.

THE COURT: Okay. Very good.

MS. JOHNSON: And I think that brings us briefly, your Honor, to Mr. Boissonneault's knowledge, which is something that Warner Chilcott really hammers in their briefs, and in that instance I would say this. Mr. Boissonneault is the CEO of Warner Chilcott. He was previously the President of Warner Lambert. And in our complaint at paragraphs 143 to 145 we expressly walk through Mr. Boissonneault's role both in knowing about the failed study and obtaining the patent, the license to the patent -- excuse me -- the assignment of the patent. He was intimately involved. This is not a situation where we're trying to impute knowledge. Mr. Boissonneault was personally involved, and that more than covers the requirements under federal Rule 9(b).

We also have, your Honor -- I think I'm out of time, or do I have two minutes?

THE COURT: You're pretty much out of time, but reference me to what you want me to look at in your

slides, and I'll go from there.

MS. JOHNSON: Thank you, your Honor. I would point the Court to slide 30.

Separate and apart from our Walker Process fraud claim is our sham litigation allegation, and the allegation is this; that no reasonable pharmaceutical manufacturer in Warner Chilcott's position would have realistically expected to succeed on the merits, and I'll summarize it this way.

You could choose your own adventure in that litigation, your Honor. You could have claim construction go one way or have claim construction go another. The court could have found that there was fraud or that there wasn't fraud.

The point of slide 30 is that whichever path you choose, Warner Chilcott would have lost, whether because the patent was unenforceable for fraud, because it was obvious because the amount of hormones were in the prior art, as were 24-day regimens, or because Loestrin 24 does not in fact reduce the incidence of breakthrough bleeding.

Thank you, your Honor.

THE COURT: Thank you.

Okay. So Mr. Milne, just one second. Off the record for a moment.

(Discussion off the record.)

THE COURT: Let's go forward. You have a half-hour, and you can feel free to use less.

MR. MILNE: I'll do my best, and I'm sure my colleague, Mr. Blad, may have something he wishes to say. Okay.

THE COURT: You're sharing it, so.

MR. MILNE: All right.

Well, maybe since we ened with Walker Process, and I didn't get an opportunity to address it, I can begin briefly by discussing why the Walker Process claims don't pass minimum pleading standards.

I mean first of all I would just note, and I won't dwell on it, and we have a number of slides addressing this beginning at slide 51 in our package. I don't know if it's showing up on your screen now.

THE COURT: It is.

MR. MILNE: Your Honor, the standards here for Walker Process fraud are extremely high.
Walker Process is intended to be the kind of cause of action that is allowed to go forward only very, very rarely; and the reason for that is, as some of the case excerpts that we have here talk about, it's that it's very easy to take the routine back and forth that goes on in any complex patent prosecution and after the fact

try to make it look sinister.

And that's what the federal circuit said in the Northern Telecom case, that last sub-bullet on slide 51, taking a relatively routinely act of patent prosecution and portraying it as intending to mislead or deceive. So that, if we move up on that slide 51 one notch, the federal circuit has said that you have an extremely high level of misconduct that is needed to make out a Walker Process claim, and a Walker Process claim is an antitrust claim. And if we could go to slide 53, Bryan.

So in addition to fraud, you have all of the antitrust elements that need to be established, including that the fraud had an impact in some relevant market. So just to take a simplistic example, let's assume you had Walker Process fraud with respect to a patent protecting a product that controlled one percent of an adequately defined relevant market. Under the general rules of antitrust, that would probably not arise to an antitrust violation.

And that's what the Supreme Court said in *Walker Process* itself. That's what the federal circuit has said, is that even if, even if you could make out a claim of fraud you then have to say, okay, take that patent and put it in the context of the relevant market

and tell me if it makes a difference.

THE COURT: So don't we need to know what the relevant market is in the absence of Loestrin 24?

MR. MILNE: Well, exactly, your Honor, and it goes back to that first argument, and I will circle back to the issue of have the Plaintiffs adequately alleged a market here.

THE COURT: Isn't it a little bit different because this harkens back to the granting of the patent for Loestrin 24, so it has to be what the market was at the time that the patent was granted in order to figure it out, isn't it?

MR. MILNE: I think, your Honor, the way it works in this kind of situation is the patent was issued. We know that. Now someone is saying it was issued by fraud. So the fact of the product being in the market is there at the time the lawsuit is filed. And so the question that you're asking is did the enforcement of that patent, which arguably this is a purely hypothetical scenario, kept off the marketplace, a would-be infringer --

THE COURT: I get it. I get the point. So it's the same market because it's the enforcement in that market.

MR. MILNE: Exactly, your Honor.

THE COURT: All right.

MR. MILNE: And so that issue is very much in play here as well.

And the standard for establishing fraud, if we could go to slide 55, is very high. It needs to be plead with Rule 9 specificity, and so you have to plead and ultimately prove a material misrepresentation or omission. In other words you have to prove and -- plead and make plausible that but for this misrepresentation or omission, the patent wouldn't have issued; and you have to plead and prove that that was done, that the misrepresentation or omission was done with the specific intent to deceive the Patent and Trademark Office such that that is the only reasonable inference from the alleged facts.

And the specific intent has to be established independently based on facts alleged rather than by reference to the alleged materiality of the omission. So you have to have independent evidence of fraudulent intent.

Now, one thing that's a critical issue here, your Honor, is that the individuals who prosecuted the patent here were not Warner Chilcott employees. They were individuals associated with the Eastern Virginia School of Medicine. Warner Chilcott acquired this

patent years after it was issued.

And so ultimately to make out a claim against Warner Chilcott, the Plaintiffs have to allege to this level of demanding pleading and ultimately proof standard that Warner Chilcott had knowledge of this fraud and then went ahead and -- this claimed fraud, and then went ahead and enforced the patent.

And what they allege here -- and I won't, given time constraints I won't walk through it with you -- they allege two letters that were written by this Dr. Hodgen of the Eastern Virginia School of Medicine to Mr. Boissonneault, who at the time wasn't even an employee of Warner Chilcott. He was an employee of a different company and eventually became an employee of Warner Chilcott.

And I would submit to you, your Honor, that you will see nothing in those letters that would suggest an awareness of fraud, suggest that anything is attempting to be hidden from the Patent and Trademark Office, anything by which you could reasonably say, let alone to the demanding standards of Walker Process, that somehow Warner Chilcott was in on some malfeasance.

And so we're at the pleading stage here, but it is important to look at these allegations through the lens of *Twombly*. And the Plaintiffs put up examples of

Walker Process cases that have not been dismissed on the pleadings. We have cited cases where they have been dismissed on the pleadings, including the Lipitor case. And it all comes down to what's alleged, and I would submit to you here that what's been alleged doesn't come close to satisfying the test.

And I won't get into all of the details about the alleged frauds covered in the briefs, but just to speak to the one that was emphasized here significantly by Ms. Johnson, this issue about breakthrough bleeding and the incidence of breakthrough bleeding.

Now, they say that there was a study done, the so-called 1993 study which did not show a statistically significant reduction in breakthrough bleeding.

That is only a potentially material omission if that information would have been important to the patent examiner, but for it would have led to the patent examiner not issuing the patent.

So the critical issue is whether the issue of breakthrough bleeding was a claim limitation in that patent. And if it's a claim limitation on the patent, then that was important to the issuance of the patent. If it wasn't, then by definition it wasn't material.

And one court has already looked at this issue. This issue was litigated in one of the underlying

patent cases on the '394 patent. Judge Pisano in New Jersey, who is a very experienced Hatch-Waxman patent judge, they have a lot of those cases in New Jersey, looked at this issue and based on discovery, based on expert testimony that was before the court -- and we cite this in the briefs -- and Judge Pisano found that the issue of breakthrough bleeding was not material to the issuance of the patent.

Now Ms. Johnson -- and Bryan, if we could put up the excerpt from the patent -- she put up this same excerpt from the '394 patent and she highlighted that first clause about breakthrough bleeding.

And this is getting into patent. I'm not a card-carrying patent lawyer, your Honor, so I'm faking it a little bit here. But from patent law it's clear, and we can cite you references to the Chisholm treatise and whatnot that makes this clear. The beginning part of a claim in a patent is called the preamble, and the claim really begins after the magic words like "which comprise" or "comprised of" or words to that effect.

So the language here about contraception characterized by reduced incidences of breakthrough bleeding is the preamble. And then the claims go on to say "which comprise," and we go on to issues about the

levels of the various active ingredients, the dosage regimen.

Basically the invention here was low dose of the ethinyl estradiol and the norethindrone over a longer dosage regimen, 24 days. That was the invention. And you don't see anything in the claims after the preamble relating to breakthrough bleeding. And in essence that's what judge -- that was the basis for Judge Pisano making the ruling that he did in the underlying case.

Now, we're not saying that's collateral estoppel or anything like that, but what we are saying is that it's incumbent on the Plaintiffs to plead facts making plausible that this was wrong.

THE COURT: I got that argument.

MR. MILNE: And I think I will stop there with Walker Process because of time, but we address the other issues in the papers.

I'd like, if I could, to circle back to the market definition and the monopoly power issues.

THE COURT: Does Mr. Blad want any time?

MR. BLAD: No.

THE COURT: Okay. Then go ahead.

MR. MILNE: And a couple of things that you didn't hear from the Plaintiffs' side. I put up some

of the language from the *Coastal Caribbean* case from the First Circuit that spoke in terms of output effects. And the First Circuit has been very clear in saying that if you're going to think about what is monopoly power and you're thinking about direct evidence of monopoly power, it is the ability to control prices by reducing output.

They make no allegations in their complaint that there is an output effect as a result of whatever patent protection may exist here with respect to Loestrin. They don't, and that is a key problem for them.

Now, they did say that they have allegations in their complaint relating to cross-price elasticity and whatnot with respect to defining a market, and they made it sound like there were lots of facts alleged.

I commend to your Honor just to review the complaint, but around I think this is the, I'm looking at the End-Payors' complaint; but basically what they assert on cross-price elasticity is essentially a legal conclusion. They just say a small but significant nontransitory price increase in the price of Loestrin 24 did not cause a significant loss of sales. It's just about as plain vanilla as one could imagine. They don't put any color on that at all. It's a legal

conclusion; it's a buzz word.

And the courts that -- what it really comes down to, your Honor, and I will say they mention that there are a lot of cases that have gone forward where these single product pharmaceutical markets have been allowed to proceed.

Not every case involves the defendant calling the plaintiff out on it at the motion to dismiss stage. Many times these cases just move forward without the defendant making a motion at that level, and then you're into discovery and the issue gets litigated.

We have done that. Some of the other courts that have done it have looked at it, and I think Judge Posner's comment in *Asahi* is a very important thing for the Court to keep in mind, is that when you have -- we shouldn't just presume that a single product, just because it has a patent and just because it's a pharmaceutical, functions as a monopoly.

And here, with respect to this particular category, the Yasmin/Yaz case I think was decided exactly correctly, and your Honor should follow it here.

There was talk about marginal cost and pricing above cost and what is the proper measure and whether it should just be pricing above marginal costs or

whether you need to consider R&D factors and, your Honor, I would commend to your Honor the *Eastman Kodak* case from the Second Circuit which we cite in our brief where the court talks about deviations between marginal costs and price such as those resulting from higher fixed costs are not evidence of market power.

So the courts are -- and we cite a number of other references in our papers; the Neurontin case from the District of New Jersey where the court looked at sunk R&D costs as part of making that type of assessment.

And so these are the factors that would have needed to be pled, not down to the penny, of course. But if you're going to say that I'm going to make a big antitrust case go forward where you have obviously dozens of other functionally-interchangeable products in the marketplace, you have to come forward with some kind of facts to make it plausible why we should think of that individual product as a single monopoly among all the others. And I think when you look at the cases you'll see that the courts do recognize that you have to take into account not just the cost of producing the next widget if you're going to go down that road at all.

THE COURT: Okay. Why don't we bring it to a

close there.

MR. MILNE: Okay. Your Honor, may I just address one or two *Actavis* issues, or are we --

THE COURT: I think we're done. Thank you.

MR. MILNE: Very good. Thank you, your Honor.

THE COURT: While we're on the record and then we'll go off the record, I'm going to -- you can go ahead and sit down.

I'll try and endeavor to get you a decision as quickly as I can. There's a lot to cover, but I am going to work on doing this expeditiously so you can keep this case moving and understand where it's going, but there is a lot to do.

And so I just want to thank you for the excellent briefs and your excellent slides, they were not boring or tedious, and your excellent arguments. So let's go off the record.

(Discussion off the record.)

(Adjourned)

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

I, Denise P. Veitch, RPR, do hereby certify that the foregoing pages are a true and accurate transcription of my stenographic notes in the above-entitled case.

/s/ Denise P. Veitch
Denise P. Veitch, RPR

January 31, 2017
Date