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

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IN RE: *
LOESTRIN 24 Fe *
ANTITRUST LITIGATION * MDL NO. 13-2472
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* JUNE 27, 2014
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HEARD BEFORE THE HONORABLE WILLIAM E. SMITH

CHIEF JUDGE

(Warner Chilcott's Motion to Dismiss)

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THE COURT: Good afternoon, everyone. This is the matter of In Re: Loestrin 24 Antitrust Litigation. We're here on Defendant's motions to dismiss, so let's begin by having you put your appearances on the record.

MR. SOBOL: Good afternoon, your Honor.

Tom Sobol, S-O-B-O-L, Hagens Berman Sobol Shapiro, LLP, for the Direct Purchasers.

MS. JOHNSON: Good afternoon, your Honor.

Kristen Johnson, Hagens Berman Sobol Shapiro, LLP, for the Direct Purchaser Class Plaintiffs.

MR. SORENSEN: Good afternoon, your Honor.

David Sorensen, Berger Montague, also for the Direct Purchaser Class Plaintiffs.

MR. RICHARDS: Good afternoon, your Honor.

Doug Richards from Cohen Milstein for the End-Payor Plaintiffs Class.

MR. TARANTINO: Good afternoon, your Honor. John Tarantino. I represent Actavis, and I represent the Warner Chilcott entities; and with me today is Rob Milne and his colleague, Bryan Gant. Mr. Milne will be arguing.

MR. MILNE: Good afternoon, your Honor.

THE COURT: Good afternoon.

MR. BLAD: Your Honor, Leiv Blad, Bingham

McCutchen, for Lupin.

MR. LEVIN: Good afternoon, your Honor.

S. Michael Levin on behalf of the Walgreen Plaintiffs. With me today is Anna Neill from the firm of Kenny Nachwalter.

THE COURT: Who else wants to enter an appearance?

Okay. The rest of you are just observers, huh?

All right. I know you wrote me some correspondence about how to structure the arguments. I usually don't structure things quite as formally as you suggested in your correspondence, but I'm open to whatever you want to suggest in terms of how to move forward from here.

MR. SOBOL: Good afternoon, your Honor. Tom Sobol for the Direct Purchasers.

I think that from the Plaintiffs' perspective we will follow the lead of the Defendants. To the extent that they take a short period of time on an issue, we're going to try to keep our time to that amount of time as well. To the extent that there's a more developed argument and longer period on that issue, we'll probably follow their lead on that and do the same. So I would yield to Mr. Milne in terms of how much time he expects for all of the arguments.

I should also indicate that from the Plaintiffs' perspective, we're going to be dividing the arguments among three of us. I'll be dealing with the broader antitrust issues. Ms. Johnson, if it's acceptable to the Court, of course, will be addressing the relevant market and statute of limitations issues. Mr. Richards for the End-Payors, there are discrete issues on these overall matters that they have that do not affect the Direct Purchasers; in particular, matters related to Lupin, an acceleration clause and an over-arching conspiracy. And Mr. Richards and I have spoken and again will follow the lead of the Defendants. To the extent that they address those issues that are unique to Mr. Richards, he will take a relatively similar amount of time.

THE COURT: All right. That makes sense.

MR. RICHARDS: Your Honor, I agree with that with one additional point I'd make. Also on state by state law analyses, which really is a discrete subject, so I would suggest that we argue both sides of the broader antitrust issues first so that you can remember what people said about things a little more clearly when the rebuttals come and put off the argument about state by state laws until we finish up the rest.

THE COURT: You mentioned that in your letters, I think, and that seems to make some sense.

MR. MILNE: Your Honor, and from the Defendant's perspective, first of all, I represent Warner Chilcott/Watson and my colleague, Mr. Blad, represents Lupin, who his client is only implicated in some of these very specific issues raised by the Indirect Purchaser Plaintiffs, Mr. Richards' clients.

So I expect to take the lead on most issues here, but Mr. Blad will need some time to address issues from the Lupin perspective.

And then generally, your Honor, the proposal that we made was aimed toward focusing things on the substantive arguments that are being made here with respect to the various agreements and also the statute of limitations issues, which we think are important.

The state by state -- these various state law theories, as you know, the briefing is voluminous. There's a whole lot of case law being cited. And you know, from our perspective, we would be content with standing on the papers with respect to that state by state, you know, Consumer Protection Act in Alabama versus New York or that kind of thing, standing on the papers on that or coming back at a later point if your Honor thinks it's appropriate and having a more full-blown argument on those issues. Because at a high level, if you agree with us that the Plaintiffs haven't stated federal claims here, I think it's fair to say that the state law claims will go the same direction because they're basically claiming -- trying to fit antitrust conduct into various state law theories, so you could almost view that piece of it as being off to the side, at least for now, and could be addressed later.

THE COURT: What do you think of that?

MR. RICHARDS: I don't think it would be a bad idea. I really would be guided by your Honor's sense of what to do about that.

One thing I would mention is that the Lipitor case, a similar case, we addressed this in a similar manner. We came back another day to argue the state by state issues. We came back and argued for 40 minutes on each side, and I think Judge Sheridan appreciated that because it reduced the scope of what she had to focus on.

THE COURT: I like the idea and I think I'd be a lot more comfortable with it. And frankly, the real focus on my attention has been on the larger antitrust arguments and the Actavis arguments.

And as you point out, the playing the field on those issues may change a lot if I end up agreeing with the Defendants.

So why don't we do that. Why don't we -- I'll certainly reserve for you the opportunity to have oral argument on those issues. I'm not going to cut it off. If either party wants oral argument on them, we'll do that, but why don't we focus on the main issues in this argument.

MR. RICHARDS: I do think I'd say we would like to argue those issues, because I think you would benefit from having oral argument on those issues, but I do think if you add them all on top of the Actavis-type of issues it becomes a lot to get your mind around at one time. It's better for everyone if you narrow the focus a little bit.

THE COURT: Right. Okay. Well, then let's get going.

MR. MILNE: Your Honor, we have some PowerPoint slides, which I believe were handed up for you and your clerks, and we've provided copies to our adversaries. I guess we'd like permission to be able to turn it on and so everyone can view the slides as appropriate.

THE COURT: Sure. Absolutely. Go ahead.

Okay. Come on up to the podium. I noticed in Chief Justice Roberts' dissent the line where he says, "Good luck to the District Courts."

MR. MILNE: We think it's a straightforward issue here, your Honor.

THE COURT: Well, you've got competition that -- pretty stiff competition in Chief Justice Roberts on that.

MR. MILNE: That's right. Well, we think in this case it's relatively straightforward, because we think what the Plaintiffs in this case are trying to do is to take what are routine patent settlement agreements and routine business agreements and trying to take that square peg and pound it into the round hole of Actavis and turn it into some kind of antitrust violation. And we think even at the pleading stage that there are major deficiencies in what they're trying to do here and that's what I'd like to talk to you about today.

Your Honor, as you know, there are the two sets of Plaintiffs here; and as was alluded to, they're not asserting completely identical claims. They're overlapping claims, but not entirely identical claims.

So the Direct Purchaser Plaintiffs and the Indirect Purchaser Plaintiffs are both challenging various agreements that Warner Chilcott entered into selling patent litigation and entering into business arrangements with Watson, a generic company called

Watson.

And then separately, the Indirect Purchasers are challenging various patent settlements and a business agreement entered into between Warner Chilcott and Lupin, another generic company, and those agreements were entered later in time.

So what I'd like to do today, if possible, is first focus on the Warner Chilcott/Watson agreements, the ones that are challenged by both sets of Plaintiffs, and talk to you about the issues and the deficiencies with that piece and then move over to the Lupin agreements. And you'll see there is some overlap in terms of the types of arguments but just to keep them logically separate because they really are.

So if that's acceptable --

THE COURT: That's fine. Go ahead.

MR. MILNE: So focusing on the agreements with Watson --

And if we could go to that first slide, Bryan.

There are four agreements that really are put at issue here, your Honor. All were entered on January 9th, 2009. And at that time, Warner Chilcott entered into patent settlement agreements with Watson basically achieving global peace between the two companies with respect to then patent-pending litigation.

So they entered into two patent settlements, one relating to Loestrin 24, a Warner Chilcott contraceptive product; and another relating to a different product, different patent, different court, different issues relating to Femcon Fe.

On the same day, the companies entered into business agreements, a license and supply agreement under which Warner Chilcott licensed to Watson the rights to a product that was in late-stage development that eventually came to market as Generess Fe, which is a chewable contraceptive; and under that agreement actually Watson was to pay Warner Chilcott, not the other way around, in return for the rights to market that product were it to be approved as a branded product. So Watson would pay Warner Chilcott royalties and various fees associates with that opportunity. So that was the one agreement.

The other business agreement related to the hormone therapy product called Femring of Warner Chilcott's, and that was a co-promotion agreement under which Watson's sales representatives would go out and make sales calls on physicians to promote Femring and hopefully increase its sales.

So those were the agreements that were entered into that day in January of 2009. They were publicly announced by way of a press release that was issued on January 12th, 2009. The essential terms of the agreements were set forth in the press release. That press release was picked up in various press sources.

THE COURT: Let me just stop you, and I want to ask you a quick question just to make sure I understand.

Wasn't it also a term of the settlement that Warner Chilcott would not introduce an authorized generic during that six-month early entry period?

MR. MILNE: Yes, your Honor. So the terms of the two settlement agreements were-- we put the essential terms on the slide there.

So with respect to the Loestrin 24 settlement, it provided a license for Warner Chilcott -- from Warner Chilcott to Watson so that Watson could enter six months before the patent expired. And it was an exclusive generic license for that six-month period, basically exclusive in the generic field. The brand stayed on the market and there was no limitation on what the brand could do but with respect to that first six months it was exclusive. And there was no payment associated with that settlement agreement, no royalty running from Warner Chilcott to Watson, but it was exclusive for that six-month window.

The Femcon settlement involved a license as well, this one to permit Watson to come to market six years before the patent expired. Again, no payment from Warner Chilcott to Watson associated with that settlement. So all entered on the same day, all publicly announced, publicly known to the world.

So we don't have here a situation where there's an explicit cash payment or monetary payment associated with the settlement agreement. So the Plaintiffs have to look elsewhere to try to come up with something that they can call a reverse payment. So what they've done is -- and if we go to the next chart here, it tries to illustrate this. What they've done is they've first depicted the two business agreements as payments in return for delay, they say, with respect to Watson's entry with respect to Loestrin, the generic form of Loestrin 24.

They don't explain why or how or offer any facts to say why the arrows aren't pointing toward the Femcon patent settlement or one arrow going one way or the other way. They just assert that as a conclusion.

So their first, I guess, theory of reverse payment is that these two business agreements should qualify as payments in return for delay on this one patent settlement but not the other.

Then in addition, they claim that the exclusive, the exclusivity feature of the license should qualify as a reverse payment as well. And then they had the claim that I understand, based on seeing the slide that they provided us they have withdrawn, that there was a world-wide license provided by Warner Chilcott to Watson, not just a license focused on the United States. I believe they may have withdrawn that claim. I think it's completely refuted by the terms of the license itself, and we showed that in the papers.

But those are the claims of reverse payments here. We think they fail on multiple, multiple levels that I'd like to circle back to.

But before I do that, your Honor, I'd like to focus on the timeliness issue. We have multiple bases for dismissal here, and the next slide gives a quick overview on that.

So first is timeliness, and then we believe that the Plaintiffs have failed consistent with the requirements of Twombly and Actavis to plead a cognizable reverse payment, let alone one that is large and unjustified. And then in addition, we believe they've failed to plead an adequate relevant market here for purposes of a Rule of Reason antitrust case.

With respect to the timeliness issue, your

Honor, the relevant statute is four years. There's no dispute that the settlement agreement was entered into on January 9, 2009, publicly announced just a few days later. We have a little timeline here that shows when the first complaints were filed in these litigations.

So the Indirect Purchasers, the IPPs filed their complaint in April of 2013 and the Direct Purchasers in May of 2013, more than four years after the public announcement, and we believe that demonstrates that these claims are not timely.

And now, the Plaintiffs, they say, well, this is like a price-fixing conspiracy and so we should view it as a continuing violation. But the courts are clear, your Honor, in drawing a distinction between the kind of activity that's involved in a price-fixing case where you have the conspirators having to constantly coordinate with one another to just make sure that the conspiracy stays in place, make sure people aren't cheating, et cetera, et cetera. And it's in those circumstances that courts apply this continuing violation theory.

In contrast, the courts are also clear that where you have something that's a discrete event like a contract, like a merger transaction, like some kind of discrete event, then that is the point that you use for purposes of saying when the limitations period starts, and you don't get to claim that the period continually restarts as a result of what the courts have called the inertial consequences of just carrying out that discrete event, that discrete contract, that transaction.

And in the First Circuit, the courts are very clear on this. I think the First Circuit has been very clear, if we go to this next slide here. The DelMonte case is a very useful case because there you had a situation where the allegation was that there was some kind of conspiracy to allow DelMonte, a large producer of fruit products, to acquire a plantation in Guatemala. And so the Plaintiff, which was a smaller fruit producer that lost out in that bidding exercise, claimed conspiracy but he brought his claim more than four years after the deal was complete. And the First Circuit was very clear saying you can't make the argument that there were continuing effects in the United States, higher prices, whatever it may have been, reduction in competition as a result of that prior event and expect the limitations period to keep restarting. You have to sue within the four years of that discrete event.

Same thing in the Doherty case. That was a criminal case but the Government was focusing on rigged civil service exams, which had the effect of allowing police officers to be promoted and make more money when they shouldn't have. The Government brought its case more than four years after the rigged exams but said, well, the defendants continue to reap the benefits. They're getting these unnaturally high salaries; and therefore, the limitations period should continue, should restart with every new receipt of that salary. And again, the Court said no.

And there's a very recent case, your Honor, we can hand up a copy of this opinion from the Sixth Circuit that just came down a few weeks ago in which the Sixth Circuit made a very similar holding where you have a purchaser in that case that was suing over the alleged anti-competitive effects of a merger transaction and brought his claim more than four years after the transaction was completed claiming competition has been reduced by continuing effects. And the Sixth Circuit said, no, it was a discrete event.

That's what we have here, your Honor. This is not like a traditional price-fixing case with a smoke-filled room and people conspiring to overcharge their widgets by five percent. These were contracts entered in the public domain settling patent litigation, and the mere carrying out of the terms can't qualify as the kind of continuing violation that the courts have focused on.

Now, the Plaintiffs in some of their opposition briefs make the argument that, well, the limitations period shouldn't begin until the generic got its FDA approval. In this case Watson. They say that happened later than January of 2009, and so we couldn't have been injured because the generic in the real world with the agreements did not get its approval until that later point and that's where the limitations period should begin.

THE COURT: Why doesn't the -- I want you to finish your thought but let me just interject. Why wouldn't the limitations period begin when the harm occurs? And the harm here, isn't that governed somewhat by when the Plaintiffs here, the ultimate purchasers of the product would have been able to benefit from the lower priced drugs?

MR. MILNE: Well, that's in essence the argument that I'm now discussing. So they're saying in effect we couldn't have been harmed before that date that the generic company, Watson, actually got its approval from the FDA. The problem with that, your Honor --

THE COURT: They would say that's the earliest point at which consumers could have been harmed.

MR. MILNE: And if you take that date and carry it forward four years, they say we're within that period. That's their argument.

The problem with that argument, your Honor, is that in all of these cases, and I think you see it in the complaints here, but what the Plaintiffs are complaining is that it was the entry of the agreement in the first place that created incentives. This is their theory. We don't ascribe to it, but it's their theory, and it's what they pursue in these cases. They say that when the generic promises not to come to market for the period called for in the settlement agreement, that changes the incentives; and in a world without the agreement, they say, generic entry could have occurred sooner. They will say the generic would have been more aggressive in securing its final approval. It didn't have to be so aggressive because it knew it had a longer time period because of the settlement. They say there might have been a victory in the patent case and that might have led to a path market earlier. They even speculate that there might have been a different settlement agreement that might have led to earlier generic entry.

So the harm, if they are consistent with the theory that they're espousing elsewhere in their complaints and in all of these other cases because it's many of the same Plaintiffs lawyers, very many of the same actual class representatives that bring these cases again and again, they make the argument that generic competition could have happened sooner. So it's the effect of the agreement that triggers things as far as they are concerned. And this goes to a policy issue underlying the whole reason why we have statutes of limitation, and it applies with real force when you're talking about antitrust cases.

You know, one of the leading treatises out there on antitrust is the Areeda/Hovenkamp treatise. And in that treatise, we've got some quotes up here on the screen, what's discussed is that antitrust cases in particular are difficult ones. There can be pros and cons on both sides, and there are public interest implications as well. And all of those things counsel toward incenting litigants to bring their cases in a timely fashion because it's not fair to the defendants. The whole idea of repose, if you think there's an issue here to wait, wait and wait and then if it turns out the Court decides there is, now all of a sudden damages have accumulated in a significant way. If you think there's a problem, if you think there's an issue, you should bring it within that relatively generous four-year period. And there's a public interest in that as well because if there is a problem, of course, it's good to have that resolved sooner.

There's no question that these agreements were publicly known, the essential terms were known. The fact of those two business deals done on the same day were known in January of 2009. As I say, these Plaintiffs are very sophisticated parties and counsel.

The next slide here is just kind of an overview of some of the Plaintiffs here and the bars represent Plaintiffs and the number of cases that they're in challenging patent settlements, just recent ones. It's not even a complete list.

So these people know how to bring cases and bring them in a timely fashion, and they didn't do it here. So for that reason, we would submit that these claims are just not timely and that's a basis alone for dismissal.

THE COURT: How would they know whether a settlement is -- of course they wouldn't have known about Actavis in 2009, obviously, but how would they know whether the settlements really are of a nature that they should be challenged? I mean, a press release doesn't give them that kind of information, does it?

MR. MILNE: Well, your Honor, I think the press release as of today, they don't have any -- the only piece of information that they didn't have that goes into the essence of their claim is the fact of the six-month exclusivity. The fact of the two business deals done on the same day together with the two patent settlements was known to them. Nothing's changed in terms of the information base. They knew back in 2009 that that occurred; and that theory of theirs that the two business deals should count as reverse payments as against the one patent settlement, the Loestrin settlement, there's no more information today available than was available in 2009 to support that theory.

And so they had enough information. And while Actavis may not have been decided, these cases were being filed during that window, during that earlier time period so there's no real argument here that, well, we wouldn't have really been focused because Actavis hadn't been decided. These lawyers were out looking for settlements to challenge and cases to bring during that pre-Actavis period as well.

THE COURT: Wouldn't there be at least an argument that it's during that period that the harm is actually occurring and therefore accumulating? You learn -- for example, when the generic comes on the market, you learn how much is going to be charged for the generic, right? You wouldn't know that ahead of time.

MR. MILNE: But your Honor, you would know -- these Plaintiffs know when and they allege that it's as clear as day. It's like the sun setting in the west and rising in the east that when the generic comes in, it comes in at a substantial discount to the brand and it's all very predictable what happens when generic entry occurs. There's no surprise.

And as I say, I keep going back to the issue that their whole theory in these cases is not so much that we were denied our opportunity to enter on the day the generic in fact got its approval from the FDA. They say the world would have been entirely different if there hadn't been a settlement agreement and things would have happened much earlier. They know that theory. They have known that theory for years. It's the theory they're pursuing in all of these cases. And so I would submit it's a little disingenuous to be arguing, oh, well, we couldn't have really known, we wouldn't have known until the generic actually got its approval. Their theory is to the contrary, and they should be held to it when it comes to bringing litigation like this.

Again, they file a lot of these cases. We don't always raise statute of limitations issues in these cases, but here's one where they waited too long.

THE COURT: Have you encountered other cases where these kinds of actions have been filed after the statute of limitations and courts have held that it is the agreement, the entry of the agreement that is the marker for the beginning of the statute to run?

MR. MILNE: Well, the Cipro case, your Honor, that we cite I think falls into that category. To be candid, you know, there are cases going the other way. I'm sure you'll hear about the Nexium case that Judge Young decided. Judge Young, even though he acknowledged the First Circuit is very skeptical about continuing violation theories, you know, didn't allow the limitations period to control.

So there are cases running the other way, but I will point you as well to cases like that recent Sixth Circuit case in which a purchaser was precluded from bringing an action even though it claimed that there were continuing effects.

THE COURT: What's the name of the Sixth Circuit case?

MR. MILNE: It's the Lubrizol case. It's **Z Technologies versus Lubrizol**. I have copies I can hand up.

THE COURT: Sure. Go ahead. Pass them up.

MR. MILNE: So, your Honor, we think the right result here is that because of those policy considerations that Professor Areeda speaks about, plaintiffs in these kinds of cases should be incented to bring those cases early and that's really -- we think Judge Young, frankly, got it wrong on that issue and that the right result here is what we are setting forth here.

THE COURT: So just kind of keeping an eye on the clock, you probably should move to the Actavis cash --

MR. MILNE: Will do, your Honor. I would like to reserve a little bit of time for rebuttal, maybe ten minutes.

THE COURT: Sure.

MR. MILNE: On the payment issue, your Honor, one thing to just set the stage here is that you oftentimes hear about Actavis being a Rule of Reason case. You know, the Court adopted a Rule of Reason standard. And that is true, but the prerequisite to getting into a Rule of Reason analysis is that you have to plead and ultimately prove the existence of a cognizable reverse payment that is large and unjustified. It is that that takes these cases out of the realm of the typical settlement agreement. And the Court was very explicit on that in Actavis and Slide 16 here takes some language out of the Actavis decision where the Court says that companies can settle lawfully by having a license that allows entry to the generic before the expiry of the patent so long as there's not an extrinsic payment to the challenger to stay out, to sit on his hands on the sidelines.

THE COURT: So let me just ask you this. Is it your position that there could never be a settlement to settle one or more patent cases that violates Actavis if it -- I'm not phrasing this correctly.

Are you saying that a non-cash settlement, a structured settlement of this type, no matter what its value or what its value is in comparison to the risks of the litigation, could never be actionable under the Sherman Act?

MR. MILNE: No. No. We're not saying that, your Honor.

THE COURT: Okay. Then what does an agreement have to look like in order for it to meet the large and unjustified standard but not cash?

MR. MILNE: Okay. So I'd like to address that in respect of the different categories of payment that they're claiming here because the arguments are a little bit different.

One thing to start that discussion, your Honor, is that there's this issue of does it need to be money only. There's certainly a good argument for that because in Actavis the Court specifically spoke only about monetary payments and that was against the backdrop where the FTC had been arguing for a much broader definition. But our motion doesn't depend on you concluding that it's got to be money because there's clearly a spectrum. On one end of the spectrum is cash and cash equivalence. And where you have something like that and it's large and unjustified, then I think the Court is saying we go into a Rule of Reason analysis.

But there are other kinds of value, consideration that come about as part of patent settlements that the Court in Actavis was very clear doesn't qualify as a reverse payment.

So for example -- just to take two examples, first the Court explicitly talked about compromising damage claims. The Court used an example of a $100 million damage claim in a patent case settled for $40 million. And the Court said you could view that as an implicit net payment of $60 million, but the Court said we're not going to turn that into a reverse payment. We're not going to take traditional settlement forms like that and convert those into reverse payments. So clearly, it's not all value.

The second example I want to talk about is more relevant to our situation here and that is the early-entry licenses that I had the slide up a few minutes ago where the Court is saying that's lawful. You can have an early-entry license. Those kinds of licenses are also extremely valuable to the generic. Every day earlier, every week earlier, every month earlier entry could be worth millions to a generic firm. And the Court isn't saying, well, that counts as a reverse payment. The Court is explicitly saying that's lawful. And why is that lawful? It's lawful because the value -- in that case it's lawful because the value that the generic company receives out of that license from the early entry comes from the very act of selling the product before patent expiry. There's no extrinsic payment. You just get your money by selling the product. So that's a form of value that clearly is very valuable but doesn't qualify as a reverse payment.

Now, we fervently believe, your Honor, that the six-month exclusive license falls squarely into that category. That license allowed the generic to enter six months early. It was exclusive to be sure during that six-month period, but the generic was allowed to enter. It was valuable. And the only way Watson would make money off of that license is by selling its product early. That's pro-competitive.

Now, the Plaintiffs say it could have been more pro-competitive if they just wouldn't have had it be an exclusive license, if it had been non-exclusive there could have been more competition, but that's not the standard. The standard is do you have an early-entry license and is there an extrinsic payment.

Now, I know that they're arguing other forms of payment, and I want to address that in a second. They're claiming that those are two separate business deals. But they are also claiming that the very existence of that exclusive license is a payment in itself, and we would submit that it can't be. We talk about the Trinko case, the Supreme Court's decision in the Trinko case where the Court said -- the Supreme Court said you can't condemn an arrangement that's otherwise competitive by saying I can think up something that's even more competitive. You know, that kind of Monday morning quarterbacking isn't permitted.

And that's really what we have here on that exclusivity claimed payment.

THE COURT: Well, you're not really answering my question. My question -- you started to answer it when you said the Supreme Court did not limit itself in Actavis to cash payments.

MR. MILNE: Right. Right.

THE COURT: And you seem to believe that implicitly the Supreme Court is envisioning that there could be other kinds of settlements that are non-cash but that are covered by Actavis, that they're non-competitive. I'm trying to understand what is that type of settlement? Give me an example just to give me a frame of reference. I know your argument is that this isn't it. I get that.

MR. MILNE: This doesn't cut it. I understand. And we feel that way very strongly with respect to the exclusive license. But the kind of settlement that might qualify is a settlement of where there is a business transaction done alongside where that business transaction is not for fair value. Maybe we have a slide that articulates where the Court articulates that issue.

In Actavis itself, you know, there was a side business transaction involving a co-promote in the supply agreement and the Court said, you know, we're not going to -- here's the language from Actavis. The Court is saying where a payment that may be going from the brand to the generic reflects the traditional settlement construct such as fair value for services, then that doesn't raise the kinds of concerns that are making us lead some cases into a Rule of Reason inquiry.

So obviously, if there's a plausible claim that the payment for services is not for fair value, then you can move forward into a Rule of Reason.

THE COURT: But the word used there is "payment," which I thought your argument was that Actavis was limited to cash payments and I think that's what, you correct me if I'm wrong, I think that's what the Court in Lamictal essentially held, isn't it?

MR. MILNE: Yes.

THE COURT: Judge Walls?

MR. MILNE: And what I will say, your Honor, is we certainly believe that that is a very supportable position, but our motion doesn't depend on that. Our motion doesn't depend on you concluding it can only be cash because we think that the payments that are being alleged here fall so far on the, if you will, fair side of the equation based on what the Plaintiffs have pled here that --

THE COURT: That leads to my next question then. If non-cash settlements can potentially violate the rule in Actavis, and you're conceding that they can, theoretically, I may or may not agree with that. I don't know. I might agree with Judge Walls. I don't know. But let's just say that's the case. How is a plaintiff to understand the issue of fair value, the question of fair value without digging deeper in discovery to figure out what the settlement considerations were?

MR. MILNE: Your Honor, that kind of position, and I'm sure we're going to hear that from the Plaintiffs, that kind of position is basically saying, well, I can take any -- you know, business deals alongside settlements are ubiquitous. They're commonplace across industries. It happens all the time. I think that's one of the reasons why the Supreme Court was careful to say that, you know, we're not trying to turn all of those into potential reverse payment cases.

So under Twombly, the Supreme Court says you have to come forward with something that's plausible, not just a conclusion. You can't come in and say -- repeat the mantra "lack of fair value." You have to allege something that makes it plausible, that the payments are in some sense not plausibly linked to the services provided. And these Plaintiffs in this case haven't come close to even attempting to do that.

With respect to the co-promotion agreement, all they do is recite the --

THE COURT: But how do we know that?

MR. MILNE: Pardon me?

THE COURT: How do we know that? I mean, the Supreme Court is like the gift that keeps on giving. It tells you in Actavis cash is bad but maybe other things are bad too, but we won't tell you what they are. And then they give you Iqbal and Twombly and say you've got to plead plenty to tell us what's bad, but we haven't even told you what could be bad.

MR. MILNE: Your Honor, my belief is the Supreme Court meant --

THE COURT: How are we supposed to figure this out?

MR. MILNE: And I want to be clear on our position, too, your Honor, because I believe that the Supreme Court did mean what it said when it talked about monetary payments. I think you can easily and should follow Judge Walls in the Lamictal case and that makes it a straightforward point for dismissal.

But again, I think we can still win and should still win even if you don't agree with that because with respect to the -- because we're dealing with two separate types of issues here. One is the claimed reverse payment as to the two business deals, the co-promotion and the license and supply agreement. And the Plaintiffs say, well, those qualify as quid pro quo for delay as to Loestrin 24. There are a couple of problems with that. And let's put the chart back up where I have the arrows. It's just easier to talk about.

The first problem is a basic, basic Twombly problem of you have to allege something that makes it plausible that these two business deals were in return for delay on anything but certainly with respect to Loestrin 24 as opposed to say Femcon because there were two patent settlements that day. Why are the arrows running this way? How do we know that? That's a legal conclusion -- you know, that's a conclusion. That's like saying there was a conspiracy and stopping there. You have to allege something more than that, and they haven't done that. So that's issue number one, problem number one.

And as it relates to fair value when you look at what they've alleged, all they allege is the payment side of the ledger. They have the contracts here. They had these contracts to draft their amended complaints. If there was more, if they could have beefed it up, they presumably would have done that.

With respect to the co-promotion agreement, all they say is there are a bunch of royalty obligations that Warner Chilcott took on in relation to the co-promotion activities. They don't say anything about the services to which they were linked, and that's the essence of fair value, but there's nothing in the complaint on that. There are no facts, not even really legal conclusions. We did a word search. I don't even think they utter "fair value" or "lack of fair value" in the complaint. So that is a major problem.

And with the Generess agreement, all they say is, well, Watson ended up marketing Generess and made money off of it, but it doesn't say anything about whether the royalties running back the other way from the generic to the brand were somehow not adequate to qualify as fair value. That's a fundamental Twombly failure.

THE COURT: Well, maybe it is, or maybe it's just that we don't really know what the yardstick is that should be used to assess fair value and that their position is, I don't know, that we can't really say with any certainty how out of proportion the settlement was to the value gained or the risk avoided until we get into discovery. But we know the value of this arrangement or these arrangements is huge. And that should be enough to get by Iqbal and Twombly.

MR. MILNE: Your Honor, I would respectfully disagree with that type of interpretation because if that's all you need to do, because we're talking about big companies doing these settlements all the time, not just in Pharma but in other industries as well. So if all you had to do was say there were tens of millions of dollars involved and that was enough to get you into a big discovery battle, you know, the whole clanking machinery I think as the First Circuit talked about of big antitrust litigation, it's hard to imagine the range of settlements that could fall underneath that that could be subject to antitrust challenge.

I think what the Court was doing in Actavis was trying to strike a balance and trying to convey, I would grant not in the most straightforward way, but in multiple places it said we're not worried about traditional kinds of settlements. It's very traditional to have business deals being done alongside a settlement. It happens all the time. And what the Court is saying is the thing that distinguishes it is if you've got a strong case of it's not for fair value. And you have to plead something. You can't just plead the conclusion. You have to have some basis for being able to say to meet your Rule 11 standard or whatever it may be that this isn't enough. And here we have the doubly critical thing that they're basically pointing the two arrows toward the one agreement. That's something that was not at issue in the Actavis case. There was only one patent settlement on the other side. Again, now that they've seen the agreements, especially, they say they need discovery, they did get some discovery before these complaints were filed, and without any explanation they're pointing the two arrows at the one settlement and nothing at the other. Where does that come from?

THE COURT: What would be the valid -- we're kind of running out of time here but what would be the valid settlement considerations from your point of view that you would compare the value of the business arrangements, the alleged payments?

MR. MILNE: I think at a bare minimum, your Honor, the Plaintiffs would have to say there's something about -- you know, I don't want to write their complaint for them but that there's something about what's the compensation provided on this service agreement that's out of line with industry. Some benchmark, industry standards, other public deals that the company has done. You know, those are the types of things -- and here again, they've had the agreement and so if there was something in it that was unreasonable, one of the things in Actavis that was talked about in the Actavis -- the FTC's complaint in Actavis was that the co-promotion agreement couldn't be terminated. Here, that's not so. They certainly don't allege that and I think the contract doesn't support that.

So there are objective things that they could have and they should have, if they thought they were available, pled and they just haven't done that.

I know I'm running out of time and I want to leave some time for my colleague to speak.

The same sorts of problems exist for the claims that are being asserted against the Lupin agreement. And there basically you have two patent settlements as well, a business arrangement done on the same day. And they're pointing the two arrows this time from one of the patent settlements toward Loestrin 24 and to the business deal toward the Loestrin 24. Again, where does that come from? Why the Loestrin 24 and why not -- this is just the Lupin --

THE COURT: Let me try something out on you.

You can tell me if I'm off base or whatever. But isn't the real value here is that the patentee, Warner, gets to continue to have its monopoly with respect to this drug for a period of years until the early entry period begins and the generic comes on the market? And that's worth tens or hundreds of millions of dollars to Warner, right? So it makes sense if Warner is trying to protect its patent and all the value that goes with it for those four years or so that it has left to run that it would pay a lot of money to the generic to stay out of the market until that point in time and then they get six months exclusivity to enter the market. They'll make a lot of money off of that.

Is it legitimate to assess the value of the so-called reverse payment against the risk of losing the patent?

MR. MILNE: Your Honor, I want to address that in a couple of ways, if I could. First, to your question of how important is the value that the brand is achieving through the agreed entry date, the future entry date that's compensated, if that was the be-all-and-end-all, then the Supreme Court would not have said that a compromise of a patent case involving a license to enter before the patent expires is lawful because that -- it's the same situation. The brand is going to earn its patent-protected profits up to the point that the parties have agreed.

So if you say, oh, well, it would have made millions and hundreds of millions during that period, that should qualify as somehow value received and we have to balance that against the value to the generic of entering early, that's not at all what the Supreme Court talked about. It said those kinds of settlements are lawful.

What the Court is worried about is extrinsic payments to induce a generic to stay off in some way. But the Court is saying that -- in the fair value part of its opinion, the Court is saying if you have a deal that's done alongside and it's for fair value, then you can't view that as a kind of extrinsic payment. You know, we would all agree a bag of cash as my colleagues always say, you know, a bag of cash just handed over to the generic and you agree on later entry date, that may be problematic. But so the Plaintiffs say, well, there was cash payments involved on the co-promote side. Okay? The side -- the business agreement. And they say that's cash, that should qualify as a reverse payment. And the Supreme Court is saying not necessarily. If it's for fair value for those services, it doesn't qualify, and it can't be viewed as the kind of payment to stay off. And then it's just a compromise of patent litigation and the fact that the generic is -- the brand is going to make money while the generic is waiting doesn't count against you in the analysis. But there is a way that the value of the patent does matter and that goes to the question of whether the payment is large because one of -- and this is a slightly different concept in Actavis. You know, one of the fundamental concerns here is, you know, paying a generic in effect to prop up a weak patent that you don't have confidence in. And so if you have a certain amount of time left on your patent and you make -- let's just pick numbers out of the air. Say the patent was worth -- you had ten years worth of sales and it would have netted you $10 million during that period and you enter into a settlement that protects that period. If you pay $8 million in return for protecting that, then that implies you may not have been confident in your patent, you know, 8 million out of a potential 10 million of value. But if you pay $1 million to settle against the value of that patent, then it implies you have a high degree of confidence.

And that's what the Court talks about when it says that the size of the payment may be a proxy for confidence or lack of confidence in the patent.

So that's another issue here because the Plaintiffs don't give us that. There's no allegation in the complaint at all that would say these payments in relation to the value of the patent qualify as large, and that's really the concern.

THE COURT: I need to cut you off so that the Lupin folks can have something to say before the Plaintiffs respond.

MR. MILNE: Okay. We'll otherwise stand on our briefs, your Honor.

THE COURT: Okay. Thank you.

MR. BLAD: Thank you, your Honor.

May it please the Court, Leiv Blad for Lupin. I actually won't take too much of the Court's time.

I want to focus on two things, your Honor. One is the agreements that are at issue, and then, second, some answers to some of the questions that you posed earlier.

The Plaintiffs do not allege that the Loestrin settlement agreement between Warner Chilcott and Lupin contains a reverse payment. They say the two side deals contain the large and unjustified reverse payments. Now, the question is whether whatever is in those side agreements constitutes a large and unjustified payment. But even before we get there,

there's a problem in the linkage between those agreements and the Loestrin settlement agreement.

One of the agreements at issue is the Femcon agreement, your Honor. And that was a settlement agreement of patent infringement litigation between Warner Chilcott and Lupin. There is no allegation in the complaint that the patent infringement allegations in that case were sham allegations. There's no fact pled in the complaint even suggesting that the Femcon settlement wasn't tailored to the underlying risk in that litigation.

In paragraph 107, the Plaintiffs refer to the Femcon license agreement as payment for the Loestrin patent litigation but there's -- they don't say anything in that paragraph about that agreement being a term of the settlement of the Femcon patent infringement litigation. So there's nothing in the complaint that would -- no fact pled in the complaint that would lead to a conclusion that the settlement of the Femcon litigation was a sham. Therefore, whatever is in that agreement can't be a large and unjustified payment in the Loestrin litigation.

Now, the complaint contains a lawyer's argument that the Femcon settlement was payment for the Loestrin 24 settlement. But there's no fact pled in the agreement to support that. There's no statement from Lupin alleged in the complaint. There's no document alleged in the complaint in which that's set forward. All it is, is a lawyer's argument that the two are linked.

The second agreement at issue is the Asacol agreement. And again the Plaintiffs assert, this time in paragraph 108, that the Asacol agreement was payment for the Loestrin 24 settlement. But paragraph 108, all paragraph 108 does is it restates the terms of the Asacol agreement. There's no fact pled in that paragraph or anywhere else in the complaint that the Asacol agreement was a sham. There's no statement from Lupin alleged in the complaint linking the Asacol agreement to the Loestrin agreement. There's no document pled in the complaint. Again, all there is, is a lawyer's argument that the Asacol agreement was a reverse payment for the Loestrin 24 settlement. But even if you assume that the Femcon and the Asacol agreements were quid pro quos for the Loestrin 24 settlement, there's no facts pled in the complaint whatsoever that those alleged payments are large or unjustified.

And I want to be specific. There's no comparison of the cost and profit to Lupin in those agreements. There's also no recognition that in both agreements there are contingencies that could terminate the agreement before performance. In both the Femcon and the Asacol agreements, there are provisions that if Lupin's margin is below a certain threshold, Lupin can terminate that agreement. That's in the Femcon agreement. That's paragraph 7.1.5. In the Asacol agreement, that's paragraph 7.1.4.

In the Asacol agreement in paragraph 2.3, Lupin -- Warner Chilcott can terminate the agreement if an at-risk generic comes on the market.

So in other words, at the time those agreements were signed, not only were they not large or justified payments, but there was no guarantee there would even be performance under those agreements.

So at the time of the agreements, there was no way to value those agreements the way the Plaintiffs say that we can do now so that they constitute a large or unjustified payment.

Now, the Plaintiffs tried to get around this problem in three ways. In paragraph 109, they argue that the agreements provided, quote, substantial value to Lupin. I hope so, your Honor. I hope every agreement that Lupin enters into provides substantial benefit to Lupin. Why would you enter into an agreement if it was not going to provide a substantial benefit to the contracting parties? Otherwise, if you get no benefit from it, there's no reason to enter into an agreement. The salient issue is not whether there was substantial benefit to Lupin. The question was whether those agreements contain large and unjustified payments for delayed entry in the sale of Loestrin. And there is not a single fact pled in the complaint to support that allegation.

In paragraph 109, the Plaintiffs also allege that the parties, Warner Chilcott and Lupin, would not have entered into the agreements without the terms that they say constitute large and unjustified payments, but that's just another way of saying the agreements provided substantial benefits to the contracting parties. If the terms provided a benefit to the parties, of course they would have entered into the agreement and without provisions that provide them substantial benefit they would not have entered into the agreement.

So paragraph 109 essentially posits a tautology. They're large or unjustified payments because they provided substantial benefits without which the parties would not have entered into the agreements.

Finally, in paragraph 109, the complaint alleges that the parties couldn't have obtained these benefits if the Loestrin litigation went to a judge or jury.

In other words, there are terms in these agreements that would not have been available as a judgment if the case went to a judge or jury for judgment or verdict.

And to that we say, So what. There are all kinds of agreements in patent settlement litigations where the parties settle on terms that are not limited to specific allegations in the patent infringement litigation. It happens all the time especially in a field like this. This is a complex and complicated field where risk has to be allocated all the time, every day. These parties are entering into agreements all the time. If the only thing that gets them into a long, expensive antitrust case is that a settlement agreement contains a provision on terms that are not at issue in the allegations in the underlying patent infringement litigation, there are all kinds of agreements in this field that are going to be subject to antitrust violation. That can't be what Actavis was positing.

So what we have here, your Honor, is a case in which there isn't a fact pled justifying a conclusion that the Femcon and the Asacol agreements were large and unjustified reverse payments. Instead, all we have is a lawyer's argument that they are linked and that the Femcon and Asacol agreements constitute large and unjustified payments. Our position is that Actavis tried to avoid this very outcome. The point in Actavis was we're not going to let antitrust plaintiffs challenge every patent settlement agreement but where there is a large and unjustified payment on the face of the document under Iqbal and Twombly, then you can assert that large and unjustified payment as a reason why there's an antitrust violation under Actavis. If you do not fit into that narrow confines, our position is that Actavis posits a very narrow claim for plaintiffs in these types of cases, you can't get into Federal Court because otherwise the business judgement of parties to settlement agreements could never be exercised without them fearing a challenge by an antitrust plaintiff in a case like this.

THE COURT: But how do you measure the large and unjustified?

MR. BLAD: It has to be a provision where from the face of the document it is clear that that payment is unrelated, untethered to the underlying risk in the patent infringement litigation.

THE COURT: If the risk of the patent

infringement litigation is that you're going to lose the patent protection, you lose the monopoly, that could be a huge risk, right?

MR. BLAD: That could be a huge risk.

THE COURT: Right. So if that's the way you measure it, that would justify a huge payment to the infringer, the generic, right?

MR. BLAD: Well, our position --

THE COURT: Let me just finish my hypothetical. So the answer to that is obviously, yes. But if the patent is a lousy patent, if it's an invalid patent, then doesn't that seem wrong because if that's the measuring stick, the risk versus as compared to the payment made to avoid that risk on a patent that should be invalidated, that would seem to be the wrong measuring stick. Do you follow my question?

MR. BLAD: I do. Your Honor, again what I would say is combining Iqbal and Twombly and Actavis there must be a large and unjustified payment on the face of the agreements that justifies the case. Now, what would be a payment that would be large and unjustified? In Actavis, it was a payment of between 19 and $30 million a year for nine years. Here there is nothing even closely approximating that. The two agreements at issue, the Femcon agreement was settlement of a patent litigation. There's nothing in the complaint about how that would provide a -- the dollar value to Lupin. There's nothing in the complaint about that.

In the Asacol agreement, there's similarly nothing in that agreement about the value that would have provided to Lupin. There's a generalized statement that it would have been substantial value, but there's nothing in there about the dollar value to Lupin.

There's also nothing in there in that complaint about the fact that under both agreements there may not have been any payments. There was business risk here for Lupin in entering these agreements. In that situation, Lupin's business judgment has to be respected. And under Actavis and Twombly and Iqbal, the patent settlement shouldn't be challenged. That's our bottom line point, your Honor. If every single patent settlement agreement is subject to challenge because a plaintiff's lawyer thinks that the value to the parties was somehow inconsistent with what they believed to be the antitrust principles at play, then the business judgment of the contracting parties will never be respected and that can't be what Actavis set out as a standard.

THE COURT: Okay. Thank you. So let's give the

Plaintiffs a chance.

Just so I can keep some kind of time here that makes sense, you wanted to divide your argument into three parts, right?

MR. SOBOL: Yes, your Honor.

THE COURT: In fairness, I've given them an hour and 15 minutes. I'll give you the same subject to the court reporter.

We may take a break at some time just to give the court reporter a break.

MR. RICHARDS: One is we have different claims and some of these issues only pertain to my case so I'll need some of his time or some time at the end.

THE COURT: Everybody will get what they need, I hope.

MR. SOBOL: I kept some notes and I'm making sure that I'm yielding Mr. Richards at least the amount of time that the Lupin guy was provided, so Mr. Richards has no worries in that regard.

If I may approach, your Honor, I've got some slides, too, here.

While our slide presentation is being put up on the screen, your Honor, I'm going to dig in while that's being done.

May it please the Court, I'd like to start, your

Honor, with three background items which I think will help frame -- in an effort to best educate you and your staff about these issues, try to take a step back about _Actavis_. The three issues will be, first, what's the general construct in that decision; and then second, how does the timeline in this case play out in relationship to that construct; and then third, drill into why we think that the payments are properly pled and tick through each of those payments.

So first, one of the -- the starting observation in the whole _Actavis_ world is this: When a brand company sues a generic company for infringement on the basis of a technical but not real active infringement, by that I mean an ANDA has been filed but nothing more, the product is not in the marketplace, no economic injury has happened to the brand company at that point in time, the lawsuit only involves the merits of the patent. And the brand's position is I have a valid patent, you infringe it, you should not be allowed to enter the market until the expiry of that patent. The generic's position is almost invariably: The patent is invalid. It shouldn't be enforceable. I don't infringe. I should be allowed to enter the market today.

Now, because of that, the settlement of that lawsuit standing by itself cannot involve consideration, cash, some other form of financial incentive that passes from the brand company to the generic or vice versa because there is no damage claim in the case.

Now, having made that fundamental observation that the Supreme Court makes in Actavis then, go to Slide 3, the basic resolution of most Hatch-Waxman cases that are not going to implicate any question about whether they're anti-competitive or not are those of the many, many settlements that are out there in which the two companies simply agree upon an entry date and nothing more. If those two parties agree upon an entry date and nothing more, that entry date is going to reflect the comparative perceptions of the parties with respect to the risks of their losing their position in the patent infringement case.

And the Supreme Court was quite clear that if that is all that happens in the case, then there's nothing unlawful about it because there is going to be presumably a bargaining by both sides as to when the generic may enter. The generic wants to enter as early as it can; the brand company wants it to be as late as it can. And if that's it, that's fine.

Now, the Supreme Court recognized that sometimes

-- next slide -- sometimes those two parties now meeting with one another in addition to having an arm's-length agreement on the entry date, they may decide that they want to have other business arrangements.

Now, sometimes those business arrangements are going to be if what the Supreme Court indicated, and I'm going to drill into this much more later in a few moments, but let's just live with it for a moment. If those business arrangements are for fair value, meaning that what is being given by one company is relatively the same as the other companies for fair value, in other words, there's nothing more than fair value, again I'll return to that expression in a moment, well then that's okay because there's no something beyond fair value that would be affecting the earlier part of the negotiation about what the entry date would be. And that's fine.

Now, a third thing crops in, Slide 5, which is this. In this negotiation, it's fair and appropriate for the brand company to say, well, if we're settling this lawsuit today rather than going forward with this infringement case for the next two or three years, whatever, then I won't have to pay my lawyers for the next two or three years and pay expenses to litigate that case. I will be saving some money. So rather than -- as an inducement for us just to be done with this case, as an inducement for us to settle this case, the brand company will pay to the generic company the fair value of what it is that the brand company believes it's saving by way of litigation expenses and costs, one or two million dollars, maybe some expenses, that kind of thing, that would also be all right so says the Supreme Court.

Now, finally, going to Slide 6, and this is where the issue then crops up. What if in that agreement there's some other financial inducement that goes from the brand company to the generic?

For instance, as we'll talk about here, obviously, what if there's some promise about not competing on an authorized generic? What if there's some agreement to try to keep other generics out of the market and some leverage provided there? What if there's some cash? Although we don't see cash. It's too naked and obvious for antitrust violation. These deals get masked more. What if the side deals weren't for fair value. Again, I'll drill into what that means.

If there is, so the Supreme Court says, some financial inducement that moves from the brand company to the generic company that is not explained by the litigation costs or fair value for the side deals, well then that raises the big question. If you're giving this extra consideration, this extra financial inducement, what's it for? And the inference that the Supreme Court indicates, Slide 7, is that it must be that that original agreed date is going to be earlier -- excuse me, it's going to be later. The agreed entry date of the generic will be later than had otherwise would have been arranged if there was no financial inducement.

In other words, the brand company is giving the generic something. What's the generic got left to give? The only thing it has left to give in that deal is yielding to the monopoly being perpetuated for many years to go. That's the overall framework.

Now, there are some things we need to piece apart there and there's some attributes of our complaint that I need to discuss, but that's ultimately what the Supreme Court is doing.

In other words, in answering the question what's a large and unjustified payment, it has these three features. The first feature is that it is not explained for fair litigation cost avoidance; it is not explained for the fair value of the side deals, and its's not explained by anything else in the transaction so we're going to infer that it has to have something to do with the entry date. That's the first part.

The second thing is often if the thing that's passing from the brand company to the generic company is not something that could have been accomplished in the litigation itself, well then that raises a big, red flag.

It's like, well, wait a second. This isn't a part of the lawsuit. You're doing something outside of the lawsuit that's going to raise the spectre that it's going to -- that you have to get something back from the generic that you wouldn't get in the lawsuit, which is a later entry date.

The third thing that we sometimes see in the cases, it's not a requirement for a large and unjustified payment but the Supreme Court makes this observation, is that if what the generic company is getting in this deal is actually more value than it would get if it just won the litigation, in other words, if the generic company had gone forward and pressed forward and won the litigation and then you look at what its financial return would be if it won the litigation and you compare that to what it was getting in the settlement, if it gets in the settlement something more than it would have won, then that really raises a question as to whether or not there's an anti-competitive feature to the deal.

In this lawsuit, as I will explain, all three of those features, a financial inducement to delay, that something that's not in the lawsuit and which is going to end up putting in the pockets of Watson something more than it would get if they even won the litigation makes it that this case goes forward on this 12(b)(6) motion.

Now, the second thing I want to do was put this then in the time frame of this case so you can see therefore what we're talking about here.

One moment, please.

(Pause.)

MR. MILNE: Can you position that so we can see it? We haven't had a chance to see it.

MR. SOBOL: If Mr. Milne perhaps --

THE COURT: It might be good if you just came over and sat here in the jury box, you can see it. And anyone that wants to --

MR. SOBOL: So my fancy graphics here, your Honor, which I also think comply with the expense guidelines in this case, show first that the agreements that were entered into here were entered into in

January of 2009.

Now, at that point in time, the patent at issue was set to expire in July of 2014. Under the transaction that gave rise here, Warner Chilcott caused Watson to agree to delay its entry, so we allege, until 2014. If I may, so what we allege therefore is that for the consideration, the extra things I'm about to describe, rather than entering and agreeing to enter in January 2014, Watson would have entered some very significant period of time before then. Our complaint alleges that that time would have been September of 2009. Parenthetically, less than four --

THE COURT: Turn that microphone toward you when you're standing there.

MR. SOBOL: Thank you, your Honor.

It would have entered the market, Watson would have entered the market in September of 2009. That's not a randomly picked date because it turns out that that's the date that the FDA actually issued final ANDA approval to Watson to launch its drug.

So we have a pretty significant event here and a pretty rare situation where a generic company holding a valid final FDA approval for ANDA in September of 2009, solely by reason of its contracts with Warner Chilcott decides not to launch that product for over four years, thereabouts.

Parenthetically, by the way, September 2009 is less than four years from the time that the complaints were filed.

Now, there should be one more observation about the timeline before I then move to the payments.

Recall, your Honor, that these two parties when they were litigating as adversaries and competitors, the brand's position to Watson was that you're not entitled to any exclusivity at any point in time because when you launch Warner Chilcott says to Watson, when you launch your product, I, Warner Chilcott, will be able to launch an authorized generic at the same time under my NDA. So whenever you may win your litigation or whenever you may launch, you won't be entitled to exclusivity at the time that you launch because I at least get to launch an authorized generic.

Watson says to Warner Chilcott, well, I don't think you're entitled to your monopoly even today because you've got a crummy patent. In fact, we think it's a pretty rank patent and we've seen what we've alleged in the case, and we don't think you should have, you, Warner Chilcott, should have any exclusivity today.

The paradox of a lawsuit, of a settlement of a lawsuit under the way that these Defendants did this is that their settlement accomplishes the exact opposite of the litigation position. Because what happens instead is now Warner Chilcott gets years of exclusivity and Watson says to it, okay, you can have your four years of exclusivity and charge what you want and make as many hundreds of millions of dollars as you'd like. And then Warner Chilcott says, No problem because when you go to market we'll give you the exclusivity that you wanted. We won't launch our authorized generic and so you'll get all the money for generics during some period of time, number one; and number two, you're also going to be able to charge somewhat higher prices because you won't have any competition by any generic companies at that time. So it really reverses both things.

Now, in this case --

THE COURT: And just so I understand, and you correct me if I'm wrong, what is the barrier to other generics entering? Is it the process set up by Hatch-Waxman?

MR. SOBOL: It's the process set up by Hatch-Waxman, yes. It's also the pendency of the lawsuits. So I guess I should describe it this way. In order for a generic to enter the market, it has to file an ANDA; it has to certify against the patents. If the brand company in response to that brings a lawsuit, that stops the FDA from being able to approve that ANDA for at least two-and-a-half years, 30 months. So that's one thing that stops them.

The next thing that stops them is if they settle that lawsuit, which is what happened here, before that stay goes away, right, then the brand company can effectuate a further delay of those later generics, which is what we pled happened here. There's also --

THE COURT: But how? That's the part I don't understand. I understand the two-and-a-half year stay, but how does the second piece --

MR. SOBOL: Sure. I'll roll it out like this.

So I have to first start with the first generic so that you get a sense about what's going to be going on. Okay?

When the first ANDA filer files its ANDA and if it's substantially complete, then it's entitled to first-to-file status meaning when, as, and if it launches its product, it gets to be on the market for six months by itself and nobody else can enter in the meantime.

So in the normal kind of a situation -- I'm going to talk about how this differs a little bit, but in the normal kind of situation all the other generic companies therefore back up in line and are bottlenecked until that first-filer's exclusivity either lapses or gets forfeited or something else like that. Okay?

What commonly happens and what sort of happened here is that the first filer before it has to launch settles its case and agrees to a date much longer out.

Now, all those other generic companies are like, well, now we have to sit around and wait for that guy, the first filer to launch.

THE COURT: So that's the piece I was missing, the ability to stave off the other generics and to have the six months exclusivity continues with or is bound by the settlement that the generic reaches with the brand; is that right? So if a generic as in this case says, okay, we'll wait three or four years, then we'll take our six months, the others still have to wait behind that?

MR. SOBOL: The answer to that is yes. Technically, they're not bound obviously by the settlement. They're bound by when the first generic launches or forfeits its exclusivity. That's typically what happens. So that they are technically -- because the FDA won't give them final FDA approval. That kind of thing happens all the time. So it's bottlenecking. It's one of the things -- so I'm going to turn back to that in just a moment.

So there are the following kinds of consideration that we think change the balance here and, therefore, quite clearly rise to large and unjustified payments.

The first is that Warner Chilcott agreed that when Watson does enter the market Warner Chilcott will not launch an authorized generic.

Now, our complaint pleads that we think that that's worth tens or hundreds of millions of dollars. The basic math in this situation is relatively simple, though.

As our complaint alleges, when an authorized generic does launch and they would here otherwise, that's what we plead, the authorized generic and the first-to-file share the market 50/50. If there's no authorized generic, then that means that Watson gets to have all the generic units during that six months.

So one consequence, first, is that they just double what they're going to get during the first six months.

The second thing that happens is because there's only one generic on the market for that first six months rather than two, Watson can charge a higher generic price because it has no generic competition. Also we plead those things, we plead some numbers.

One could bother to do some basic math, but the allegations of the complaint are adequate in alleging that it's worth tens or hundreds of millions of dollars. Certainly if you look at this product at that time, the branded sales are roughly at about $350 million. We think that the complaint quite clearly and there's more than sufficient detail at this stage indicates that that no AG promise by Warner Chilcott to Watson was worth tens or hundreds of millions of dollars, and I'm going to leave it like that. There are further calculations, frankly, that I've done, that we've done, but they're not in the complaint and they're not relevant. I'm not going to complicate the proceedings.

Now, the second piece of what happened here is that Watson originally -- is that there's an agreement to -- there is what I will call an exclusivity by collusion rather than exclusivity by law.

What do I mean by that? Normally, a first-to-file under law is entitled to six months of exclusivity when they launch, meaning exclusivity from other ANDA, other generic ANDAs. Okay? And the law provides that. However, under the law that was applicable to this ANDA, in order to keep that first-to-file status, the generic has to obtain tentative approval or final approval within 30 months of filing the ANDA. We plead that. That was a matter of law. It's not contested by anybody.

As a result, here Watson did not get tentative or final approval within 30 months of filing its ANDA. It filed its ANDA in April of 2006. So it needed to get tentative or final approval on its ANDA by October of 2008, and it did not.

So there was a clear possibility that Watson might actually lose its exclusivity. In the deal that was struck between Warner Chilcott and Watson, Warner Chilcott promised Watson that don't worry about your exclusivity, the possibility that you may have lost your first-to-file exclusivity. Why? Because we are promising you that we will not license anybody else -- when we undertake any settlement, we will not license anybody else to come into the market during your first six months.

So what we say is that was also a highly valuable promise with real value because otherwise Watson would be entering the market with other generics around and would lose much more of market share, not have 100 percent to even 50 percent if there was an authorized generic, but maybe more like a third or 20 percent of the market and at markedly less prices if it hadn't been that promise from Warner Chilcott to Watson.

Now, there are also two side deals. And much was made about whether or not there were adequate allegations with respect to them or not. They are the Femring agreement first. Now, what I'll say about this are two things and just to be able to have a little bit of clarity or not clarity to this Actavis situation. I promised you that I was going to go back to what's fair value for services or goods. And I suppose that there are two different ways that the Supreme Court might have meant that. Way one is that they meant that it has to be some amount of money over and above fair profit from a deal. The other way that the Supreme Court might have meant it is it's some amount of money over and above the actual cost of the services and goods to the provider. In other words, it's ambiguous I suggest in Actavis as to whether or not by "fair value" they mean they are willing to accept there to be a profit margin or not.

Now, I will suggest to you, to your Honor, that I think the best economic and policy argument is that the Supreme Court meant or must have meant that by "fair value" they mean only paying the fair value of the cost of the goods and services and not any additional profit.

Why do I suggest that? Well, because the profit might be the incentive to then do something else. In other words, here, as an example, there might be profit in the Femring deal, and I'd suggest there will be in a moment; or in the Generess deals that Watson otherwise wouldn't be getting, that it couldn't get in the lawsuit that might make lining its pockets more than it even would have if it had won the lawsuit and therefore there's some reason to that as to why it is I think that legal position should be the proper interpretation.

But putting that aside, on this motion what I think that you can conclude is this: That we certainly have pled that both of those two side deals were components of an overall payment arrangement; they provided some sort of value to Watson that it would not otherwise have, and that it certainly should be left to a matter of discovery whether or not those two additional side deals are contributing over and above the other tens or hundreds of millions of dollars that was going to Watson anyway.

Why do I say discovery? Well, as an example, under the Generess Fe deal, Watson maxes out on its cost of goods sold at 15 percent and its license fee to Warner Chilcott is 15 percent in net sales. So that leaves roughly another 70 percent of the money that it makes on that drug after its other overhead expenses for it to make an awful lot of money. And that certainly raises a question as to whether or not a lot of the money that Watson is making on that deal is not fair value, whatever term that one uses, whatever conclusion one has as a matter of law there.

Similarly, the Femring deal, which provides for a share of 50 percent of the net sales over a benchmark, the benchmark is $10 million a year, we don't know if Warner Chilcott was making a lot more than $10 million or a lot less than $10 million a year before and therefore whether or not this is some fair contribution or not dividing them. So I do think that it would be appropriate to leave that up to discovery.

THE COURT: Okay. You don't want to pause there so your colleagues can --

MR. SOBOL: Yes.

THE COURT: Why don't we take a short break. We'll be off the record for a moment.

(Discussion off the record.)

(Recess.)

THE COURT: All right. Go ahead.

MR. RICHARDS: Good afternoon, again, your Honor. Doug Richards from Cohen Milstein.

I think a useful way to frame this would be to look at page 8 of the Defendant's slides where Mr. Milne listed four key issues. And what I'd like to do is just say a few words about the second and third of those issues. I'll put off everything I have to say about the statute of limitations and monopoly power, if anything, until after the Directs have had their say on those subjects.

The Court asked very pointedly what does an agreement have to look like to be actionable if it's not cash. That was an entirely perfect and right question to ask. We address that question in our brief and we anchor our answer to that question in our brief to the pertinent language in Actavis so I would refer you to the brief. But to be very short and simple, our position in reading Actavis, which we explain, is that there are two elements that have to be established in order for the burden to shift to the Defendants to justify what we're complaining about. One is there has to be substantial value to the generic. That's because it has to be a payment to the generic. The concern is that they're getting delay. The delay in the generic coming to market, is there some kind of value going in exchange for that.

So the standard, and this is there in the language of Actavis, is there substantial value going to the generic. Substantial value is different from fair value in terms of justification. So just substantial value. That's element one.

Element two is the generic couldn't have obtained that benefit through litigation. If those two standards are satisfied, and we plead them very specifically in our complaint in those terms and in our brief we explain why under Actavis those are the right two things that need to be shown, the key point that I think has been missed so far is that then the burden shifts because behind Actavis you have to understand that what the Supreme Court is saying is the Rule of Reason applies. And to understand what's happening here, you have to think about the antitrust Rule of Reason. The way the antitrust Rule of Reason works is you show potential suspicion of something and then it becomes the defendant's burden to justify it.

So when we get to large and unjustified, I would submit there's a fundamental error going on in a lot of what's been said to the Court today because it is not our burden to plead that it is large or that it is not justified. Large and unjustified, large by reason of fair value, all of that is issues of justification under the Rule of Reason. And the Court may recall in February of this year an opinion that your Honor issued in the Steward Health Care case where the Court pointed out: Courts have generally recognized that the existence of a business justification is not properly determined on a motion to dismiss, citing the Creative Copier case.

And then later in the opinion -- and this is interpreting the Rule of Reason that the Court was doing this so it's really directly on point. You cite Creative Copier and I quote from it saying: "The presence of a business justification is not appropriately raised at the motion to dismiss stage. The plaintiff is not required to allege the negative of every possible justification the defendants might offer for their conduct."

Our view of Actavis under the Rule of Reason that the Court adopts is that there are those two elements we have to establish and then the burden shifts to the Defendants to show fair value, which is a justification, or pro-competitive benefits, which is one of the main thrusts of their brief, which again would be a justification.

Under your Honor's own opinion in Steward Health, we don't have to plead in avoidance of those rebuttals. The Supreme Court case on that point is Gomez versus Toledo. A plaintiff is not required to plead in avoidance of defenses. From the standpoint of just Rule 12(b)(6) and pleading, that is not our burden.

So consistently, I think if you look at our complaint and look at our brief, you'll see we plead in the same words the same things that we take out of Actavis that we think establish our initial burden shifting the burden to the Defendants; and all of this stuff that they're saying we haven't sufficiently pled, you know, an absence of fair value, an absence of business justification is all trying to require us to plead in avoidance of what's their burden to show under the Rule of Reason.

THE COURT: So there must be some yardstick otherwise every settlement of a patent litigation would survive a 12(b)(6) antitrust case.

MR. RICHARDS: Yes. There's content to this yardstick. It has to be something of substantial value that's being given to the generic in conjunction with the very deal. I keep hearing from the Defendants, Oh, you know, this happens all the time; we always do these totally unrelated things at the same time. Well, no. I mean, in business activities people don't just always do totally unrelated things at the identical time. They do them when they're related to each other. And the problem is that when you have a substantial value going to the generic at the same time as a deal is being made that restricts competition or delays generic entry, the Court is saying red flag, and doubly red flag when it's something they couldn't even have achieved in the litigation.

THE COURT: But if it's either large or substantial or something that they couldn't get through litigation, then what you're saying is as long as it's vague, you survive 12(b)(6), you can bring an antitrust claim.

MR. RICHARDS: No. What I would submit is what the Defendants are trying to do is create safe harbors. They're trying to get the Court to adopt a rule of law that will provide a template for how they can get the compensation that they want to get to people to delay generic entry. That's what this is all about, all the kinds of arguments to try and come up with some kind of safe harbor. There shouldn't be a safe harbor. That's what the Supreme Court said. If there's substantial value going from the brand to the generic at the same time as the deal and it's not even something they could have gotten in the case, why do they have to do it? You have to ask yourself if it's totally unrelated, why do they even have to do it. And Judge Young rightly said -- I can't remember the exact words, but in his opinion he says something that's totally unrelated is subject to condemnation by the courts. That unrelatedness is critical. And that's why in Actavis the Court says something you couldn't even have gotten in the case.

THE COURT: That's reading a lot of micromanagement by the courts of the business relationship between the generics and the brand. And even if that were the rule, why wouldn't the parties then say, okay, fine, if they can't be on the same day, we'll just do these deals six months apart. That's what frustrates me about this whole business, and I'd like to ask you about this.

MR. RICHARDS: If they don't happen at the same time, you have a trust problem trying to cut them as a deal. It's not an accident that these totally unrelated things happen at the same time. They happen at the same time because they're all part of one deal.

THE COURT: Let me ask you a different question because you seem to -- you're reading a lot into Actavis and arguably reading a lot out of it. And what I'd like you to address, this is probably the time to address it, this is what Judge Walls is talking about in his opinion is the Supreme Court knows how to write an opinion that talks about consideration and value, and they know how to write an opinion that talks about cash. And they wrote an opinion that talked about cash.

Now, we could speculate about why they did that but that was -- I think we could all agree that's the facts of Actavis. That was the case they had before them.

MR. RICHARDS: They used the word "cash" a couple of times because the case they had before them was cash. But as I think the Court has pointed out in Nexium and as Judge Sheridan agreed in Lipitor, the rationale of the opinion doesn't logically stop at cash. It's complete formalism to suggest if I give someone $10 million in value in some clever side deal but without paying them cash, all the rule books should go out the window then.

THE COURT: Why did they write it the way they did? Judge Walls says it reeks, it reeks with --

MR. RICHARDS: They used the word "cash" because that's what they had in front of them, but I would submit there's nothing in the reasoning of the Court's opinion that would support a limitation to cash. And that's what Judge Young found; that's what Judge Sheridan found.

But your Honor, I don't want to take up too much time. I promised to be brief. That is my view about items two and three.

THE COURT: Thank you. It's interesting. I appreciate it.

Okay. Who's next?

MS. JOHNSON: That would be me, your Honor. Kristen Johnson from Hagens Berman Sobol Shapiro, who will be briefly, I promise, addressing the statute of limitations argument.

THE COURT: Okay.

MS. JOHNSON: The Clayton Act provides that a private plaintiff can recover treble damages for antitrust actions that are commenced within four years after the cause of action accrues. So that's the framework we start from.

Plaintiffs have identified three separate and independent reasons that we don't have a statute of limitations problem here.

Now, Mr. Milne this morning I'm afraid may have conflated the basic accrual rule -- say that three times fast -- with the continuing violation piece. So let's go back to basics for a minute.

According to Zenith Radio, which is the Supreme Court: Cause of action for future damages will accrue only on the date those damages are suffered. Thereafter, plaintiff can sue to recover any time within four years from the date they were inflicted.

So what does that mean here? Here, the Direct Purchaser Class Plaintiffs antitrust complaint was filed on May 14th, 2013. The Indirects' complaint, first complaint was filed a little bit earlier than that.

The Direct Purchasers in their complaint are only seeking over-charge damages that accrued on or after September 1st, 2009. So where do we get that date? That is the date when the FDA gave final approval to Watson's generic.

Now, it has something interesting in this case, your Honor, for those lawyers who work on many similar cases. In this case, we have the FDA giving final approval to a generic and that generic, Watson, staying off the market after it receives final approval. In other cases, including the Nexium case you've heard so much about, there's a question about when the generic would have been approved. We don't have that here. We know. And therefore, the Direct Purchasers are only seeking damages from the date on which they accrued, meaning the date on which they first paid a super-competitive price for branded Loestrin 24 when they would have otherwise, but for the agreement and the performance of the agreement, paid for a less expensive generic product.

Now, Mr. Milne said during argument that what the Court should focus on is the, quote, discrete event. Presumably he means the signing of the agreement and that it is the discrete event that matters for statute of limitations purposes. Multiple courts have rejected that. If you look at the Relafen decision, which is a District of Massachusetts decision, there the discrete event at issue was the filing of an allegedly sham lawsuit.

The Relafen court pointed out that while purchasers might some day be injured because the FDA stay would prevent generic competitors from entering the market, that depends on whether the FDA itself would even approve such competitors. That was unknown at the time the lawsuit was filed. So the Relafen court rejected this discrete event hypothesis as have three other generic delay reverse payment courts. That would include the Nexium, K-Dur and Skelaxin decisions.

Now, turning to the continuing violation rule, a Direct Purchaser may recover --

THE COURT: Have you had a chance to read the Sixth Circuit opinion that counsel handed up?

MS. JOHNSON: I have, your Honor. I have that right here. That's the Z Tech case, a recent decision from the Sixth Circuit. That case is a merger case. It is not a monopolization case. And why does that matter? Because the Z Tech court itself noted that the continuing violation rule applies to monopolization cases which would include the case here before your Honor. The Court stated in Z Tech, quote: "While the Supreme Court has never directly limited the scope of the continuing violation doctrine, it appears to have employed the doctrine only in conspiracy and monopolization cases, not involving mergers and acquisitions. Therefore, the Z Tech court concludes that in that merger case the continuing violation rule is not applicable."

One other recent decision I'd like to bring to the Court's attention, the Defendants, though they did not cite it today, in their briefing cited to the District Court decision in **Oliver v. SD3C, LLC**.

Since the Defendant's reply brief has gone in, the Ninth Circuit has issued a decision on the appeal from that. In that case, the Ninth Circuit noted that the unabated inertial consequences that Mr. Milne referred to earlier is the exception and not the rule, and that the unabated inertial consequences concept only applies when the wrongful conduct is irrevocable, immutable, permanent and final.

Here, the Ninth Circuit says in its decision: The defendants could have ceased charging a price-fixed price at any time.

That brings me, your Honor, to a recognition that at the time that the agreement was filed, Plaintiffs hadn't been harmed yet, not just because the generic product didn't have final approval so we hadn't paid over-charges, but because the Defendants hadn't actually performed on the promises that were included in the agreement, which is to say that in order for that agreement to cause injury to the Plaintiffs, Warner Chilcott would have to actually not launch an authorized generic; Watson would have to not launch its own generic product until July 2009. Payments flowed in both directions there. Warner Chilcott would have had to continue making payments under the Generess and Femring agreements as far as I can tell through at least 2011, if not ongoing. That's something to be decided in discovery.

But in any event, it is the continuing performance of those duties that leads to the injury the Plaintiffs complain of today.

And finally, there's a slide I noticed in the Defendants' deck. I don't remember whether they referred to it today or not, but suggests and cites some case law that the Court may look to documents that are cited in the complaint even if they're not attached to the complaint. And so I would note for the record that there's no mention in our complaint of the much touted January 2009 press release the Defendants point to as presumably, they argue, disclosing the information that would have been known. The Defendants give us lawyers on the Plaintiffs' side an awful lot of credit for being smart enough to know when there's something fishy going on; but if you look at the actual January 2009 press release at issue in this case, all that it discloses is Watson's agreements not to launch until January 2014, some unknown payment that they use the word "pay" to Watson based on the sales of Femring, and an oblique reference to a license for an unnamed oral contraceptive product in late-stage development.

So let's look at what the press release did not disclose. It did not disclose Warner Chilcott's promise not to launch an authorized generic. It did not disclose the 180-day created exclusivity as to other ANDA competitors. It did not disclose the large Femring payments to Watson. It used the word "pay." It said there would be a payment. It didn't say how much. It didn't give the percentage of those amounts. And finally, it didn't disclose that there was an exclusive right to market and sell Warner Chilcott's Generess Fe product on which Watson has earned tens of millions of dollars since its launch in May of 2011.

So that's all three rules, your Honor, basic accrual, continuing violation and fraudulent concealment. Thank you.

THE COURT: Okay. Thank you.

MR. RICHARDS: Your Honor, if I could have two to three minutes.

THE COURT: Sure. Go ahead.

MR. RICHARDS: Again, this is in our brief, but it's responsive to what's been said. In our view there are three rules apart from fraudulent concealment. There's the basic accrual rule, which your Honor alluded to when you said, well, how can you have a claim when there's not been an injury yet. And the fundamental point there is how can you sue if you don't have an injury. Do you want to say to people, oh, you should have brought a lawsuit when you didn't have any reason yet to think that there was an injury? You couldn't find anything in the marketplace that suggests there would have been generic entry. You should have pled injury when you couldn't have conjured it in your imagination. Totally unfair. The premise of the basic accrual rule is when should you have sued. Okay?

And if somebody were to come in and allege -- and sometimes it's argued that this happened, someone comes in and alleges injury when there's no conceivable basis, these Defendants argue that it's totally speculative and should be dismissed under Twombly. That's the way they would respond to that.

So on the one hand they're saying, well, they should have done it earlier. And then if you do it, they say you can't do that yet. This is just, you know, betwixt and between. Until there's a basis for claiming an injury, someone shouldn't be required to be able to sue. So under the basic accrual rule, we win.

Now, fortunately for the Directs that's a more complete victory for them because they have a four-year statute of limitations for everything. Some of the statutes of limitations under pertinent states are shorter so we need the additional rules but there are two other rules that save us. The continuing wrong doctrine. Ms. Parker has done a good job explaining the permutations of the continuing wrong doctrine. One thing she left out though is we cite the Supreme Court decision in Klehr, K-L-E-H-R, which makes clear that in consumer cases the federal courts take the view that when it's a consumer with ongoing purchases, when that's what the case is about, every next purchase is a continuing rule. It's a different rule from a commercial transaction that's just finished where there aren't ongoing sales. That's what Klehr says.

And the cases that the Defendants have come and cited to you today are cases on the other side of that divide. They cite the Berkson case. That involved the purchase of a pineapple plantation. There was no continuing sale there at all. So that case has nothing to do with what you deal with here where you have ongoing sales after the fact. Z Technology, too. They were talking about whether it applies to a price increase following a merger of acquisition. Totally inapposite facts having nothing to do with the kind of case you have here where there's conduct and then continuing sales at the high price. The law is under those circumstances it's a continuing violation, you get to go back for the full period of limitations whether it's four or three years.

And the last point I'll make is there's another doctrine, the speculative damages doctrine. It also comes out of the Zenith case. It's different. What it says is -- it kind of ties into the basic accrual rule in a case like this one. What it says is even when you have injuries that began before the four-year period, which we don't even have here, even if we did, if the later injuries are speculative because you don't know what you're going to purchase, you're still saved.

So that's another doctrine that saves us. It's different from the basic accrual rule but it's important to our case because some of our statute of limitations are shorter. Thank you.

THE COURT: Thanks very much.

Okay. Who's next?

MS. JOHNSON: Your Honor, I happen to have a copy of the Oliver case here that I mentioned.

THE COURT: I think you sent it, didn't you, in the letter? Was that not Oliver?

MS. JOHNSON: I'm not sure that we've cited it formally on the record, your Honor.

THE COURT: Okay. You can pass it up if you'd like.

MS. JOHNSON: Thank you.

THE COURT: Was there one more from the

Plaintiffs' side? No?

MR. SOBOL: We're done.

THE COURT: Okay. Mr. Milne.

MR. MILNE: Thank you, your Honor.

We're just trying to work our slides here, but I will begin.

Your Honor, just focusing on the statute of limitations issues since those were discussed last, I would make a few observations. You did not hear from the Plaintiffs that they -- the response to the core issue that I raised, that is that in these cases their claim is not that the injury would commence right at the time in the real world that the FDA approved the generic's application but in the world without the agreement that they posit that things could have happened sooner. And that is why, that is why they should be required to come in and make their challenge in a timely fashion. This isn't a situation where they just waited a little while. They waited until well outside the limitations period. They had four years. And the idea that the press release that was public and was disseminated on widely-read in legal circles publications didn't give them enough information I think really doesn't pass the red face test, your Honor.

Their theory here is that these -- the essence of their theory is that these two agreements entered alongside the settlement of the Loestrin litigation qualify as reverse payments. The press release revealed that there were those two side agreements, that they were announced on the same day and that they contained various types of payments including cash payments. That's the essence of what they're arguing here.

THE COURT: Why isn't that just a notice of a future harm, essentially?

MR. MILNE: Your Honor, because of the point I made at the outset, that their claim is that the harm commenced the moment the generic promised not to introduce its product until the agreed entry date.

THE COURT: Let's say you have a contract, any kind of a contract. You have a contract, an ongoing contract with someone to perform some services for you. They're managing your property, let's say. Okay? And they send you a letter that says, Even though we have this contract to manage your property for you, we're giving you notice today that six months from now we're going to stop complying with our obligations under the contract. And then you wait -- let's say the statute of limitations is three years. You wait -- you go beyond the period of time that would run from the date of the notice. You wait for three years or one day before three years from the date they actually stopped working. You're saying that you missed the statute of limitations because you knew that six months from the date of the notice they were going to stop working for you. But for that first six months there's no harm. They're still doing the work they're obligated to do, right? That's basically your argument, right?

MR. MILNE: I think there's a little bit of a difference in our argument, your Honor, and I'm glad you asked the question because the Plaintiffs' view of this world as they articulate in all of these cases is that absent the settlement agreement that is publicly known, they know that it has been entered and they know that it contains this promise, that absent that, things would have been different. In other words, it's not some -- it's not like, you know, the FDA approval date is a date certain that we all know when the agreement was entered into. That is something that may shift, and they're saying that in these cases always they're saying that if the parties just hadn't done that agreement -- and you kind of heard this from Mr. Sobol, that if the parties just hadn't done this agreement, things would have been different. There would have been a different scenario for entry. Maybe the generic would have hurried up on its responses to inquiries from the FDA and gotten that approval a little bit earlier if they had more incentive is the argument they make. Or maybe they would have continued litigating and the generic would have gotten a positive result and found an avenue into the market sooner.

And so it's not really like you have a date certain where you can say, okay, injury clicks in after this event. So it really is a different situation and because they're on notice, you know, and knowing the circumstances of these kinds of cases, they really ought to have brought their case within the four-year window.

And on this issue of continuing violation, I would just commend your Honor to read the cases because there really is a difference between what's claimed here where you have discrete agreements where the only allegation is, well, you performed. The generic didn't immediately enter the marketplace and the brand kept selling its brand, and they carried out the terms of these business agreements compared to a price-fixing conspiracy where the ongoing sales that get talked about in cases like Klehr's are situations where you have a much more active collusion and wrongdoing that's claimed in the cases. The <u>Zenith</u> case is a case where the Court talks about continuing violations relating to a big patent pool where there was an active boycott going on among Canadian patentholders, and it was a very, very different situation.

So I think when you look at those cases you will see a stark difference. And the <u>Doherty</u> case from the First Circuit is also interesting because, you know, you heard about, well, continuing sales, continuing activity pursuant to the wrongdoing. There you had the continuing receipt of allegedly inflated salaries. So there was the wrongdoing and then these policemen kept collecting the inflated salaries and a very similar argument to what you're hearing here. Well, it kind of flows from the originally challenged thing, contract agreement or even merger transaction in <u>Z Tech</u>.

THE COURT: I get it. You won't have any time for the rest.

MR. MILNE: Sorry, your Honor.

And obviously, I want to talk about the reverse payment issues.

I would -- you raised the question about Judge Walls' conclusion in the <u>Lamictal</u> case that the Supreme Court focused on money. And I would go back to that and say you're absolutely right, Judge. It wasn't once or twice. It was repeatedly through that opinion, and we totally agree with Judge Walls that that opinion reeks of money. And it's important to keep in mind that the FTC was arguing to the Supreme Court in that case that for a broader standard for what would qualify as a reverse payment, very much akin to what these Plaintiffs are putting forth today that it should be any kind of substantial value or anything that was valuable that couldn't have been obtained in the litigation, but the Court knows how to adopt that kind of standard. And if it wanted to, it could have in <u>Actavis</u> itself because <u>Actavis</u> involved alleged side agreements that couldn't have been obtained in litigation. And so rather -- they say, well, <u>Actavis</u> involved cash. <u>Actavis</u> involved alleged side agreements, and the Court didn't adopt the standard that said, well, because those side agreements could not have been obtained in the underlying litigation therefore that's why we should view them as a reverse payment.

When the Court talked about the side deals, what the Court focused on, was very careful to do was to point out the language that we put up on the screen about how recognizing really that business transactions that happen alongside patent settlements all the time so that if there is a traditional kind of settlement that involves fair value for services, we're not going to treat that as a reverse payment. It doesn't raise the kinds of competitive concerns.

Now, Mr. Richards talked about the burdens here. In a Rule of Reason case, the Plaintiff has the burden of pleading and ultimately proving a substantial anti-competitive effect. And with respect to this claim of side agreement, what the Supreme Court has said in this language that I put back up on the screen here is that we don't have that same concern about substantial anti-competitive effect when a side business transaction is for fair value. So it's squarely their burden, their burden to plead facts that make it plausible that these agreements, these business transactions were not for fair value. And they haven't done that here, your Honor. They haven't even really tried. They are trying to live under the standard that all they have to do is show that it's valuable in some sense to the generic; but as my colleagues said, and as Judge Walls recognized in the Lamictal decision and Judge Posner as well in the Asahi case that we cite, is that nobody would ever enter into an agreement if there wasn't substantial consideration running both ways. That's the essence of an enforceable contract. You have to have value running both ways. So that can't be the test. The Court was trying to strike a balance, and it was saying --

THE COURT: I think they're saying not just substantial value -- well, maybe they're saying substantial value alone does it, but they may be saying substantial value plus a result that couldn't be obtained in litigation. Those two things, that is something more --

MR. MILNE: It's a little bit more.

THE COURT: -- than just a deal.

MR. MILNE: And I talked about part of that a second ago because that test, that's the test that the FTC put forward. And you don't see that adopted by the Supreme Court in Actavis. The test that substantial value together with you couldn't have obtained it in the litigation. And I would submit that Actavis itself suggests that the situation in Actavis suggests otherwise because, as I say, there were side agreements at issue in Actavis that couldn't have been obtained in litigation and yet the Court didn't say, okay, that's how we define a payment. They kept saying "money."

And also, when you look at the kinds of agreements that the Court said were lawful, you take the early entry license, you said if you compromise on an entry date, that's lawful; we're not going to consider that a reverse payment. Compromising on a date somewhere between the two extremes of immediate entry once you win the patent litigation and waiting until the patent expires, that's also something that can't be achieved in litigation.

THE COURT: All right. I understand your point. There's just a difference here of opinion as to what the burden is with respect to pleading and whether -- you know, their argument is that they don't have to plead around your justifications, and you think that they've got to do more than just allege something that is so conclusory as to say it's large and they couldn't get it out of a litigation.

MR. MILNE: I would say that's right. And I think we have support for our view, number one, in the fact that the FTC -- that the Court pointedly did not accept the FTC's definition of what qualified as a payment and you don't see that reflected in the Actavis opinion at all. You hear it talk about money, money, money. And this language that I have up on the screen here where when we're talking about burden the Court is saying: Where a reverse payment reflects traditional considerations such as fair value for services, there is not the same concern of a patentee using its monopoly profits to avoid the risk of invalidation.

THE COURT: But how do you tell that at the pleading stage? That's really, I think --

MR. MILNE: And it comes back to Twombly. It comes back to Iqbal. They have to allege some plausible facts to make it other than a legal conclusion or a conclusory allegation that says this side business transaction is somehow not sweetheart in some significant way. They have to do that. They can't just come in and utter the phrase "not for fair value," or say there was money paid to the generic. It could have been a completely fair value deal. And I think what the Court is trying to do, the Supreme Court, is trying to say we don't want to bring all these kinds of transactions under the rubric of a potential antitrust challenge and so there has to be a screen and that's one of the screens.

I would like to spend a second on the exclusive license because that's another thing that was discussed. And one issue that came up in the colloquy with Mr. Sobol is this bottleneck idea. And the fact that the generic, Watson, took longer than 30 months to get its FDA approval in the real world eliminates the idea of a bottleneck because other generics were perfectly free to continue to litigate their patent cases; and if they would have won, there was nothing about an exclusivity period that would have barred any other generic from coming in to market in this situation.

And the other thing about this so-called no AG provision is I think you need to be cognizant of the context here. This agreement was negotiated in 2008 and finalized in 2009. And at that time, your Honor, there was legislation pending in Congress that would have made the introduction of an authorized generic by a branded company unlawful. Congressional legislators -- and we have a couple of slides on this.

Bryan, let's go back one or two.

So back starting in 2005, legislators, including Representative Waxman of Hatch-Waxman fame, were writing letters saying we don't like authorized generics. We don't like brand companies coming into the market with their own generic when the first ANDA generic comes in. We think that's a bad thing under the Hatch-Waxman Act. Now, the branded companies disagreed with that, but that was the environment that we were in.

FTC officials were echoing that concern at this time, and the next slide shows that. 2005, 2006, FTC Commissioner Leibowitz is making the same kinds of statements and that culminated in legislation coming into Congress, and this is the key provision from it, which this legislation was introduced in multiple Congresses including in 2009 that would have made a branded company a holder of a new drug application. It made it unlawful for them to manufacture, sell, distribute or market an authorized generic.

So at the time that Warner Chilcott made this promise not to introduce an authorized generic by giving that six months of exclusivity, how can you plausibly call that any kind of meaningful payment when the situation that it was facing was -- you know, it was promising not to do something that FTC officials, pending legislation and Congress and legislators were saying you shouldn't do anyway. And I think with that I will stop, your Honor, unless you have any other questions.

THE COURT: No. I think I've got it.

Mr. Sobol?

MR. SOBOL: Briefly, your Honor, first regarding that last point, the claim that the FTC has taken the position that authorized generic provisions are anti-competitive and that what's going on here is somehow incorrect, if you can go to Slide 36 of our slides, please. I think what you'll find is that the exact opposite position has been taken by the FTC. The FTC considers it a complete misrepresentation of its position that it hasn't said anything other than that no AG provisions are anti-competitive. It has filed an amicus brief in the Effexor case by making it clear that another generic company had wrongly claimed that the FTC took the position in Actavis that an exclusive license can never be a reverse payment. I'm sorry. In the Lamictal case. No, that was in the Effexor case, actually.

The FTC has also made it clear that whether a particular exclusive license amounts to a reverse payment must be evaluated on its facts. In other words, the FTC is saying that this exclusive license agreement is hogwash. You need to look at the actual dynamics of what's going on in a particular case. And the FTC consistently states as follows: That the FTC has consistently characterized no AG commitments to first-filers as payments, as payments regardless of whether the commitment took the form of an exclusive license.

That's actually the position of the FTC. I think, your Honor, that --

THE COURT: I think his point is that that wasn't the position of the FTC in 2008 or at least there was legislation pending in Congress.

MR. SOBOL: Actually, they cite to some things that occurred back in 2005 during which Pharma, we have materials about this that I think are before you somewhere in our materials in our opposition, Pharma actually took the position in the mid-2000's, your Honor, that authorized generics are valid, good competition, that they reduce prices to consumers. And Pharma also took the position that generic companies that were trying to fight the possibility of authorized generics coming into the market, Pharma took the position that the generic companies were actually trying to cause an anti-competitive result.

For a short period of time during the 2000's, there was a question in the mid-2000s as to whether or not the long-term consequences of authorized generics might reduce some incentives of generics to undertake activities by way of trying to enter the market early. And that was completely debunked repeatedly by Pharma, by the FTC, by academia well before these agreements were entered into.

Now, it may be that at some trial Warner Chilcott wants to come in and say, well, we didn't mean to be doing something bad, ladies and gentlemen, because we actually thought there was some valid purpose to this. But it's got nothing to do with what we're doing here today in terms of a 12(b)(6).

I'll conclude on this note, your Honor. You started this proceeding I think correctly, because we've all wondered about it, with Chief Justice's comment, "Good luck to the District Court judges that are going to have to grapple with these issues." But implicit in that is that that's what's going to end up having to happen. In other words, what's going to have to happen in this case and in many other cases, given the fact that there is the possibility for rampant collusion between brand companies and generic companies in our society to keep drug prices up, yet there's a desire also to be fair to the brand companies and generic companies in terms of what they might have by way of their rational business justifications if they have them that we're going to have to dig into the weeds in these cases. But that's exactly what Actavis tells us.

In this case, our complaint does not need to rely upon some burden-shifting issue. We have painstakingly gone through how tens or hundreds of millions of dollars passed from Warner Chilcott to Watson through a no-authorized generic deal, through granting some faux exclusivity for six months that

Watson had no entitlement to, and to two co-promotion agreements or marketing agreements which are exactly the kind of agreements that were at issue in Actavis where there are payments, cash payments on one of them that go from Warner Chilcott to Watson. And that's exactly what existed in Actavis.

THE COURT: Okay. Well, I agree with you that courts are going to have to grapple with this and it's going to result in some, as seems to happen, District Court opinions all over the lot and ultimately the Circuits are going to have to weigh in and maybe the Supreme Court will have to clarify it.

We're getting near the end. Does anybody have something urgent they need to say?

MR. MILNE: Your Honor, may I have ten seconds? We're the movants. We usually get to have a quick last word.

THE COURT: All right. You were standing up. Did you have something?

MR. SORENSEN: No.

THE COURT: Just keep it very brief. I really don't want you to repeat what's already been said.

MR. MILNE: No. I just want to make clear that with respect to the FTC and its positions of things that Mr. Sobol was reading out. The FTC has certainly changed its tune so more recently it has taken a position hostile. But at the time that these agreements were entered into, the situation was as I indicated, legislation pending, statements of the sort -- I mean there are quotes right there.

So our only point is context does matter. Even the FTC language --

THE COURT: I understand that. And maybe at some point all of that will really become relevant; but at the motion to dismiss stage, I'm not sure that I can delve in too deeply of what was in the mind of the parties making this deal in the mid-2000's in terms of what was going on in Congress at the time. That's not in the complaint. I've got to look at what's in the complaint.

MR. MILNE: Well, your Honor, I think the reason we point it out is I think it goes to the plausibility of the idea that an exclusive license like this would qualify as a reverse payment. It's not the first argument we make because I think the essence of the argument is that the value coming from an exclusive license only is derived by selling the product before the patent expires. We talked about that.

But in addition here, going to plausibility is the idea that how is it plausible that this could be viewed as a reverse payment in the context of that time frame where this kind of backdrop existed. It might be more plausible if you fast-forward and assume two companies doing a settlement with that type of term three, four years later. That might be a different scenario in terms of that element of plausibility.

The first argument would be the same in both cases, and that's what Judge Walls found. Judge Walls was dealing with this exact same type of six-month exclusivity window in the Lamictal decision, and he dismissed the case on the pleadings. We think your Honor should do the same. Thanks.

THE COURT: All right. Well, thank you very much. There's a lot to chew on here. So we'll be in recess, and I'll begin that.

MR. SOBOL: Thank you, your Honor.

MS. JOHNSON: Thank you.

(Court concluded at 4:50 p.m.)

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

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

/s/ Anne M. Clayton

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Anne M. Clayton, RPR

July 7, 2014

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Date