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

NOVEMBER 4, 2013

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HEARD BEFORE THE HONORABLE WILLIAM E. SMITH

and

MAGISTRATE JUDGE PATRICIA A. SULLIVAN
(Conference)

ATTENDEES:

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4 NOVEMBER 2013 -- 1:00 P.M.

THE COURT: Good afternoon, everybody. I see some familiar faces, mostly not.

I'm Judge Smith. I'm the Judge who will be handling this matter, and with me on the right is Magistrate Judge Patricia Sullivan.

You've probably met some other folks at the table, but I brought everybody here because I thought it would be good for you to put names with faces. Ryan is our calendar clerk. Probably the person you've been dealing with mostly and will be dealing with, Ryan Jackson. Law Clerk Noah Kaufman. Over here is Tim Baldwin. He is Judge Sullivan's law clerk. And Anne Clayton is the court reporter that you'll see a fair bit of and get transcripts from. And Martha is the calendar clerk for Judge Sullivan. So these are the folks you'll be dealing with a lot in the course of the litigation.

We're having this conference recorded by the stenographer more as a note-taking function. This is the equivalent of a chambers conference, but it will be helpful for us to have it recorded and it might be helpful for some of you so if you'd like that, let us know, let Anne know.

So it might be useful maybe if we get started by

having you go around the room and tell us sort of who you are because we would like to know that and then we'll start in on the agenda that we sent you. And of course, that's a flexible agenda so if there's more you'd like to talk about as we go through each of these points, we're certainly open to it. I have some additional things that have cropped up since we sent that order out to you.

So why don't we -- how are you organized here?

Plaintiffs over here. Why don't we start over here and have you go down. Obviously, I know Jeff. So who do you represent?

MR. PINE: Local counsel for the Plaintiffs,
American Sales and Rochester Drug, along with Patrick
Lynch and Maria Deaton of my firm.

MR. MELTZER: Good afternoon, your Honor.

Joseph Meltzer, counsel for the Plaintiffs, American
Sales.

MR. SOBOL: Tom Sobol with the law firm of Hagens Berman Sobol Shapiro from Cambridge, Massachusetts representing American Sales. And to place that in context as you'll hear the Plaintiffs, there's American Sales and Rochester Drug who are the two direct purchasers in the case or proposed direct purchasers class.

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MS. JOHNSON-PARKER: Good afternoon, your Honor. Kristen Johnson-Parker, also from Hagens Berman Sobol Shapiro, counsel for American Sales and direct purchasers class.

Good afternoon, your Honor. MR. SORENSEN: David Sorensen of the law firm of Berger & Montague in Philadelphia representing Rochester Drug, one of the few direct purchasers class.

MR. KANE: Good afternoon, your Honor. Kane, also with Berger & Montague in Philadelphia on behalf of direct purchasers class and Plaintiff, Rochester Drug.

MR. CLARK: Good afternoon, your Honor. Neill Clark for Rochester Drug Cooperative with the law firm of Faruqi & Faruqi in Pennsylvania on behalf of Rochester Drug and direct purchaser plaintiffs.

MS. ARTHUR: Good afternoon, your Honor. Elizabeth Arthur from Hilliard and Shadowen from Austin, Texas, on behalf of the United Food and Commercial Workers Local 1776 and Participating Employers Health and Welfare Fund. We are also with the end-payor class. And we are one of the proposed class representatives.

MR. RICHARDS: Your Honor, Doug Richards from Cohen Milstein, New York office of Cohen Milstein. We are here for the end-payor class, and my firm represents New York Hotel Trades Council, which is one of the proposed class representatives.

MR. MIGLIORI: Good afternoon, your Honor.

Donald Migliori from Motley Rice here locally in

Providence, Rhode Island on behalf of the City of

Providence and indirect purchasers class.

MR. BUCHMAN: Michael Buchman on behalf of the City of Providence, and I'm with Motley Rice in New York City and part of the end-payor class and one of the proposed class representatives in this case.

MR. MILLER: Good afternoon, your Honor. Marvin Miller from Chicago on behalf of Painters District Council 30 Health and Welfare Fund, end-payors, and I would also be one of the class representatives.

MS. FANNING: Good afternoon, your Honor. Lori Fanning from Chicago, and I also represent Painters

District Council 30 Health and Welfare Fund.

MR. LANDRY: Good afternoon, your Honor. This will be the Defendant's group. I'm William Landry with Blish and Cavanagh here in Providence. I'm representing the Lupin Defendants in the American Sales direct purchaser case.

MS. ARUTYUNOVA: Good afternoon, your Honor. My name is Zarema Arutyunova from Bingham McCutchen in

Washington, D.C. I represent the Lupin Group. 1 Good afternoon, your Honor. 2 MR. ECKLES: Paul Eckles from Skadden, New York office. We represent 3 4 Actavis. 5 MR. SUNSHINE: Good afternoon, your Honor. Steve Sunshine, Skadden D.C. office, representing 6 7 Actavis. You'll pardon me in advance if I mispronounce Actavis as Activais. It's a name shift from Watson, 8 9 which was much easier. 10 MR. KESSIMIAN: Good afternoon, your Honor. Paul Kessimian, local counsel for Actavis. 11 12 MR. GIDLEY: Good afternoon, your Honor. 13 Gidley on behalf of Defendant, Warner Chilcott, with 14 White & Case in their D.C. office. 15 MR. PACE: Good afternoon, your Honor. Jack 16 Pace from White & Case for Warner Chilcott. 17 MR. TARANTINO: Good afternoon, your Honor. 18 John Tarantino, local counsel for Warner Chilcott. 19 colleagues, I know you know Nicole Benjamin; and also 20 Alison Hanstead from White & Case; Christian Jenner of 21 Partridge Snow and Hahn also on behalf of Actavis. 22 Sean Tepe on behalf of Actavis. 23 THE COURT: Great.

MR. LYNCH: I'm with Jeff Pine. Patrick Lynch.

MR. LENISKI: Joe Leniski from Bransetter

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Stranch & Jennings in Nashville, Tennessee on behalf of Teamsters Local 237 Health and Welfare Fund out of New York.

MR. JERZYK: Good afternoon, your Honor.

Matthew Jerzyk for the City of Providence.

MR. PADWA: Jeffrey Padwa for the City of Providence.

MS. FINKELMAN: Good afternoon, your Honor.

Natalie Finkelman for United Food and Commercial

Workers Local 1776 in Philadelphia.

THE COURT: My understanding is that no one is here for the Allied Services Welfare Fund, Electrical Workers 242 and FOP Fort Lauderdale; is that right?

Anyone know anything or why they're not here?

Nobody has any information? Okay.

All right. Well, I think we should jump right in. I appreciate very much the statements that you provided. They've been very helpful to me to read those statements. I know Judge Sullivan found them helpful as well. I thought it might be useful if we had just an oral presentation, a brief oral presentation about the cases if someone's ready to do that. I kind of left it to you to figure out who would take the lead. Have you been volunteered?

MR. SORENSEN: Again, I'm David Sorensen on

behalf of Plaintiffs. Your Honor, as you know, this is an antitrust case. There are different groups of Plaintiffs, that is who I represent and my colleagues represent direct purchasers, that is the first purchasers of the brand of product at issue in this case from the Defendants mostly wholesale, and bring in as a class being a class of all similar purchasers of Loestrin 24 Fe from Warner Chilcott during the class period.

Your Honor, as you know, this case involves brand Internet drugs and the competition that occurs between them and the efforts by Defendants from, in our view, to delay that competition.

THE COURT: Let me just -- if you don't mind,
I'm going to throw out some random questions. So
Rochester Drug is a wholesaler that then sells drugs to
the big chains like CVS and Wal-Mart, Walgreens, that
sort of thing?

MR. SORENSEN: Yes, it resells to retail pharmacies, who have smaller pharmacies in the case of Rochester Drug but, yes, it does resale.

THE COURT: So the wholesalers who are in the class that you propose to present, how many -- I don't know anything about the market. So how many such wholesalers?

MR. SORENSEN: Your Honor, we don't know for sure until we get data from Defendants about their sales. It can range in recent years from in the low 40's to 30 to below 30. Depends on the drug. Over the years, there's been an amount of consolidation in the wholesale industry. In years past, there will be more and some of them purchased by others, others have gone out of business. So it has decreased in size. We won't know the exact number until we get purchase data, sales data from the Defendants and that will show us exactly for that drug how many there are. I would expect it to be in the range I just described.

And these cases have been brought for a number of years, having to do with efforts basically by brand companies to delay generic competition. And I think it's important, very important for the Court to understand the underlying economics and system, regulatory system that is in play here.

Basically, not to belabor it, but in 1984
Congress passed something called the Hatch-Waxman Act.
That Act allowed and incentivized generic companies to challenge brand patents and provide quicker and abbreviated drug application for companies to get their generic bioequivalent sales brand drugs approved on the market. That was passed in 1984. What happened after

that, the efforts of essentially brand companies to then prevent generic companies from doing that. And why did that happen? Well, as the years have gone on, a pattern has developed which is that within now days of generic entry, where generic is now available, essentially all of the brand sales switch from brand to generic. In the years past it happened more slowly. Now it's happened literally within days. That is, all the prescriptions that used to be filled by the brand virtually overnight start being filled by generic.

So the brand company sees that coming and knows that when generic entry starts, they're going to essentially lose all their sales. That happens for a combination of reasons, among them every state in this country have what's called generic substitution laws. That's what allows you when you walk into a pharmacy with a prescription for the pharmacist to essentially give you the generic without having to call your doctor or do anything else. If the generic has been approved by the FDA, the pharmacist can fill your prescription for the brand drug with the generic. Insurers in the country's third-party payors and the entire healthcare system over the last 20 years and beyond that has been geared toward getting generics into the hands of patients faster and faster to save money because

they're all cheaper.

So what started to happen, this is like in the '90's, going back a bit, is that brand companies knowing that when a generic entered the market they're going to lose all their sales started engaging in efforts to stop that. There are a variety of tactics that brand companies used. Among them that is at issue in this case are commonly called reverse payment or pay-for-delay.

What are those? Brands would get notified by a generic that generic has an application pending to bring in the generic version of the brand product.

Brands typically sue generics for patent infringement fast enough, within 45 days, get a 30-month stay. It's basically an automatic 30-month equivalent to an injunction simply by suing. They don't have to prove anything. No injunction hearing. If we sue, you get a stay. It's a tremendous incentive for them to sue regardless of whether their case has any merit. Why? They automatically get two-and-a-half years of delay. They lose their brand immediately or two-and-a-half years of protection.

THE COURT: That has to be triggered by the generic utilizing that option for that last-minute proceeding, essentially declaring the patent to be

invalid which is, if I understand it, considered to be a patent infringement which can be sued upon.

MR. SORENSEN: It provides jurisdiction for a patent infringement. It's tied with a paragraph IV certification, which in the statute means that the generic company is saying that the brand patent is invalid and/or their generic does not infringe it.

THE COURT: So give me some context of dates in this case. The patent was going to expire when?

MR. SORENSEN: The patent I believe was expiring in 2014.

THE COURT: January 2014; is that right?

MR. SORENSEN: Right. Then the FDA approved Warner Chilcott's product in '06. Watson immediately challenged the patent saying we want to bring in our generic; your patents are invalid and/or we don't infringe, which then turned into patent infringement litigation.

THE COURT: Which ultimately settled in 2009?

MR. SORENSEN: The pay-for-delay reverse payment is basically this: The patentholder is suing generic for infringement, alleged infringement. They settle in a way that the patentholder provides compensation to generic which pushes the generic's entry date into the future, potentially all the way to the end of the

patent term. Without that compensation logically the agreeing entry date that the two agreed to would come early in time, more to the present. That's all that's been agreed. But if generic says I'll wait a year, but I won't wait two years unless you give me something, and that something is compensation, financial compensation, then they're called pay-for-delay because the pay from the brand is delaying date of generic entry.

It's also called reverse payment because it's reversing what normally happens in a patent case. In a patent case usually the alleged infringer to settle pays the patentholder if it settles. In this case, it's the patentholder who is paying the alleged infringer. The reverse of what normally happens.

THE COURT: If I understand it correctly, there's also a 180-day exclusive right that the generic possesses so that a different generic cannot come on the market for that 180 days following the expiration of the patent. Is that how that works?

MR. SORENSEN: Almost. You're referring to 180 days exclusivity for the first generic that files for patent certification. It's designed to give generics the incentive to challenge patents because that 180 days can be extremely valuable to a generic company.

It provides no other company can receive FDA approval for their generic for six months, which is why this is so valuable. If the brand product sold let's say at a dollar a pill, just for ease of math, the profit margin on a brand product is often very large. It's let's call it 90 percent. Takes ten cents to make the chemical, sells for a dollar. First generic can sell it for 90 cents. The brand is making tremendous profit margin, 90 versus 10. Once that 180 days expires, other generics can get approval. The price quickly drops to ten cents.

THE COURT: My question is where does the 180 days run from? What's that period?

MR. SORENSEN: Various triggers but it can run from the first day of market. Marketed and it runs. Then after six months it expires. There are other provisions at play in the case in terms of how that can be forfeited, how generic companies can lose it, which will also be part of this case but it runs from -- one trigger is when you start to market. The first to file. Later filers typically you don't get that.

One of the features for pay-for-delay agreements that had been discussed in the case law is what's called a bottling or cork in the bottle. It has various descriptions. Basically since no other

generics can get approval until what's called the first-filer exclusivity has been triggered and expires, if the first filer has delayed its entry, if they agree to a reverse payment deal and wait five years to enter, it delays everybody because nobody else can get on the market for five-and-a-half years. That's called cork in the bottle or bottling because it's literally stopping all.

So, your Honor, here the basic allegation is that Watson, the first filer, challenges the patent for Warner Chilcott's product oral contraceptive. They litigate for some time. There are no substantive patent rulings and they settle. We challenge that settlement as an unlawful pay-for-delay reverse payment. It has features in it that's somewhat different than some of this, although common in itself. One of the main features, there are others, is what's called a process of a no-authorized generic. I'll explain it. What is that?

We talked about the 180-day exclusivity but that does not run against the brand company itself, meaning a brand company like Warner Chilcott is as free to launch or sell its brand product as a generic, take off the brand name, price it like a generic. Brand companies typically don't do that until a generic

launches.

So if I'm selling a brand product at a dollar, I just keep doing that and then when a generic launches at 90 cents or 80 cents, many brand companies, and Warner Chilcott has done this, many brand companies say, well, we're going to lose more brand sales anyway to the generic, we might as well make some money, some profit by launching our own generic. It's called an authorized generic, meaning the brand company sells it itself, sometimes through a subsidiary, sometimes they license a company. It's the same product as the brand, in this case literally in all sense of the word take off the brand name and sell it as a generic.

Why is that important? It's important in this case and other cases that are pending in other courts because the authorized generic competes like a generic, so that when Watson, let's say, wants to launch its generic and be the first one and maybe wants to sell it at that 90-cent level at that first six months, the presence of an authorized generic will tend to push that price down. So you have two generics. Remember I said before after six months the price drops rapidly down to cost. It becomes a commodity. The step in that direction is launch of generic. You have two generics competing during the 180 days, and the price

drops and a portion of the sales that would go to the generic are recaptured by the brand, approximately half. This authorized generics have been studied, as a matter of fact this entire industry has been studied a lot. A lot of FTC work, a lot of academic work, at this point a lot of studies. This is an extremely well-studied industry. The dynamics and the examples I'm giving are coming from years of actual data analysis.

So what began to happen is that brand companies who would otherwise launch authorized generics which during that six months would bring prices down helping all purchasers, helping competition, have said to generic companies, you know what, you stay off the market, we'll settle our patent case by you staying off the market for two years, three years, five years, whatever it is. And in return we'll pay you by promising not to launch our authorized generic. We could launch it, we would launch it. It would make money for us, the brand talking, but if you stay off the market with your generic until a date we agree to in the future we won't authorize a generic.

That promise is part of the Warner Chilcott
Watson deal that we challenge. There are other parts
of it. That promise is part of the way the brand paid

the generic to delay marketing its generic. It's transferring, just as if I hand you a hundred dollar bill, it's transferring millions of dollars that everybody knows is being transferred. There's no mystery about this. People can disagree about the exact number, the price effects and so forth. This is all pretty well studied including by the FTC. The brand is transferring money to the generic and in return the generic is agreeing to stay off the market. While that is happening the brand continues selling at that price, stays at a dollar.

Your Honor, this is in the presentation. I'm sure you realize the whole issue of how close we look at reverse payment pay was the subject of a recent Supreme Court opinion.

THE COURT: Right. I read it.

MR. SORENSEN: The FTC versus Actavis case issued in June. Your Honor, a couple of things about that. That case established that cases like this must be governed by the Rule of Reason. The Supreme Court reading it looked at the whole issue of patent settlements and antitrust law, looked at prior precedents and said when we look at patent settlements we analyzed them on the Rule of Reason. There's no blanket immunity to a patent settlement. And they

start applying it to this particular case.

Hatch-Waxman is a pro-statute designed to recognize generics, and it is potentially being undermined by these kinds of arrangements.

Importantly, your Honor, a couple of things.

One, in that case the brand and the generic entered into a deal that allowed the generic to come in five-and-a-half years before patent expiration. It doesn't matter there's no immunity because there's no agreement we're talking about that allowed competition a few days, a few years before patent expiration.

That's not the patent.

What else is going on in the agreement is compensation. In there, it wasn't a straight payment. It wasn't the brand handed the generic money to stay off the market. There were some deals like that kind of in the early years, but even in the Supreme Court they're dealing with what the defendants were alleging was not a payment at all. It was a side deal for other services that the generic was providing but the FTC was alleging that was on a motion to dismiss. So the FTC was alleging these side deals were really a conduit, a way for brand to compensate the generic to stay off the market. If they could prove that, then it was a violation.

This question of how reverse payments work, how

THE COURT: I'm going to kind of cut you off there. I want to stay on track. We have a lot to cover. I want the Defendants to say their peace. I have two questions I want to ask. Is there anything additional that anyone --

MR. RICHARDS: My name is Doug Richards from Cohen and Milstein. I represent end-payors, which is a different class.

So rather than retreading ground that Mr. Sorensen has really covered, I'd like to make a couple of basic points about the substance of the case and then a couple of points about how the class relates to mine.

First thing is, yes, there's a new thing here with some clarity coming out in the Supreme Court decision in Actavis but you should also be aware there's been litigation about these kinds of deals going on 12, 13 years; and on the Plaintiffs side of the table here, both of these sides you have a number of people who have been working together on these cases for a very long time. We know each other very well. We've litigated many of these cases before. We've learned and know one another and work pretty effectively as a team.

pay-for-delay works and what's wrong with it has been one of the hottest, maybe the hottest subject of antitrust scholarship for a long time. In addition to the <u>Actavis</u> case, there's a very good academic paper from Professor Herbert Hovenkamp, Professor Carl Shapiro and Professor Aaron Edlin, the people who on the academic side have been the leading lights of this for a long time called "Activating Actavis," which we recommend to the Court as an academic take on the Supreme Court in <u>Actavis</u> and how it can be applied and how it should be applied to cases going forward.

The key thing I think is really essential and is getting lost as there's a lot of complexities in this case is what's wrong with reverse payments. Just to give a hypothetical, I'm not saying this case, I'm trying to give you a hypothetical of what's fundamentally wrong when you have a brand name drug manufacturing a big blockbuster drug, they may be making say \$2 billion in sales on that drug. When the generic comes to market, often generic would make \$100 million in a year to two, brand name profit will plummet to 200. They don't have to think very hard to go from 2 billion to something like 300 million so they've got a moment that comes where they say why are we hurting each other. We could just divide up the --

instead of competing with each other, we can divide up the market, keep only the brand on the market, prevent competition and have a bigger part if we can just divide up.

That is core of what's really wrong and evil about these cases. What you have is not different from competitors agreeing to divide the market, you get the United States, I get Europe, you get this state, I get that state, or we agree to charge a higher price collectively. What they're doing is instead of competing with one another they're teaming up and keeping the price high in the public and dividing up the additional money they collect as a consequence of doing that. I would submit that's really -- it's called dividing up monopoly rents in antitrust speak. That's fundamentally what's going on in these cases, and you kind of need to see that in order to see past the complexities.

So on the substance that's all I'm saying.

Mr. Sorensen did a very good job of laying out a lot of basics here.

Then you get to the question of the classes.

Mr. Sorensen and basically this side of the table
represents what are referred to as the direct purchaser
class. They're referred to as direct purchasers

Brick that's very controversial that for purposes of federal damages claim under federal antitrust law only the first buyer in the chain, not the people to whom things are later sold. So as I think your Honor pointed out, that class consists of people who resold the drug at a price. And you may find yourself asking, well, how did they go on the other end of sale. The thrust of Illinois Brick was to say that's where we stop the analysis. We're not looking past that. But it was a very controversial decision to which there was a very strong dissent and many, many states disagree with it.

And that's really how you get to the other class that I represent, which is the class for damages purposes pursuing state law claims under the laws of the states that disagree with Illinois Brick in that they say the person who should be able to sue for this is the person who pays the higher price at the end of the chain. That's when you hear us describe what class we represent as an end-payor, that's because we are the people who pay the price at the end of the chain, the ultimate end-payor.

The directs have their rights under federal law, and we're not asserting damage claims under federal law

because we can't. We have our rights under the state laws that disagree with that federal law.

So that's essentially what drives the fact that we have two classes here. They're different classes because there can be divergence of interest in how you present your case so it's generally recognized that they should be separate representation from the directs and indirects.

THE COURT: Let me interrupt you there just for a second, and I think we might talk more about this later on, but you made the distinction that your state law claims are damage claims but your substantive law claims are federal antitrust.

MR. RICHARDS: We can't bring damages claims. So many of the complaints have a federal injunctive claim in them. If you look at damages claims and end-payors --

THE COURT: So I guess the question that leads me to ask we're going to talk about later since you brought it up is does that raise choice of law issues that we need to pay attention to or is that a question for much later, late in the litigation, in the trial, I guess.

MR. RICHARDS: It's a question that will sometimes come up on motions to dismiss. We would

submit that the generally prevailing rule is that people have their claims under the laws of the states where they made their purchase. Sometimes defendants will argue it should be something else. Choice of law sometimes comes up as an issue. Sometimes people will try and argue that because all the conduct of the defendants was focused on the state, that law could be applied nationwide, which is an argument that has some support for it.

In general, in most of these cases what the courts have said, you can bring these claims under the law in all the repealer states generally because they repealed Illinois Brick in one way or another. permit end-payors to sue where federal law doesn't. these are claims they have asserted to the extent they're damages claims under state law where states have disagreed with the federal law of the Supreme Court in <u>Illinois Brick</u>. There's a really important Supreme Court case that people don't get focus, ARC America. Very important case. What ARC America said is federal antitrust law saying that the direct purchaser gets to sue doesn't preempt the state antitrust law. The state antitrust law that wants end-payors to recover are a separate and entirely distinct body of law.

We have our rights to recover whatever damages state law gives us the right to sue for, and they have a right to bring their claim for damages under federal law. It's not an either/or. They're in addition to one another. They're cumulative with one another. The Supreme Court looked at it and addressed it in ARC America.

I don't want to take up too much time. The only other point is who the direct purchasers are. The end-payor class basically consists of two subgroups, which generally are not put into separate subclasses. There are the consumers, the people who actually took the drug and paid the price for it. But typically with drugs when you purchase it at the pharmacy counter, consumer pays part of the purchase price but part of the purchase price at that transaction at the drugstore counter is actually paid by their health insurer.

So in addition to consumers of whom there are millions, you also have what we refer to as third-party payors as part of the class. And the third-party payors are entities that pay part of that price pursuant to health insurance plans in some way at the pharmacy counter. One of those is the City of Providence, which is here as a class representative for all of the end-payors, but the City of Providence pays

part of the purchase price when one of its employees buys a drug at the drugstore counter just like a lot of other health insurers and so on.

When you get to notice in these cases, the general number that's thrown around of how many third-party payors there are that eventually get recovery given notice, I think the most common number is 14,000. Kind of a sense of how many there are. You have an end-payor class consists of millions of consumers and something like 14,000 third-party payors who share in the purchase price at the point of sale.

THE COURT: That's all very helpful. Let me ask two questions of you folks, then we'll shift over to the other side of the table. One is I'm curious why this case is brought in late 2013 if the patent cases were settled in 2009? And what are the statutes of limitations associated with these kinds of claims?

MR. SOBOL: Good afternoon, your Honor. Tom Sobol. I'll take those two questions backwards.

So the federal claim under the Clayton Act is a four-year statute of limitations. The application of the four-year statute of limitations has some exceptions to it. The two notable ones are what's called the basic accrual rule. I don't know if I said that correctly, accrual rule, means the claim of a

direct purchaser does not accrue until the time the purchaser has actually brought the drug so you would know what it is your damages might be.

There's also a second exception to the statute of limitations rule on the federal side called the continuing violation rule, meaning that while you may have a conspiracy to restrain trade that gets attached at one point in time in the past, if there were acts that occurred pursuant to the conspiracy thereafter, then the statute of limitations -- just doing justice to any end-payor group. Each state has their own statute of limitations that are applicable to the state law claims. Those statutes run anywhere between two-and six-year statutes depending on the state and tend to have similar exceptions to them.

In a case like this, one of the reasons that there's a period of time that exists between when one knows of the barren existence of the agreement as opposed to when the case actually gets filed are driven essentially by three things. The first thing will be what do you really know about the settlement agreement. As we know, the mere fact of a settlement of a piece of litigation does not mean the settlement was illegal or unlawful. You need to learn whether or not there was a reverse payment, the kind of reverse payment that

exists, the size. And that can take some time, number one.

The second thing that lurks underneath a lot of what we talked about so far is the whole causation issue.

The third is a violation of law. And you prove a violation of the law, then the Plaintiffs could also prove when the generic could have gotten to market if the illegal activity had not occurred. So that itself has two branches. One branch is when would the generic otherwise have received regulatory approval, had gotten its candidate approved if there hadn't been unlawful activity. Second, there's a manufacturing branch when the generic companies have been in a position to manufacture large quantities of the drug in order to be able to launch. Although there might be a mere existence of a violation, you might not have any injury accrue until a period of time after that because you have to be able to prove when it is that the unlawful activity occurred.

Also in part the third consideration is that this is a complex industry. And so while you have, with myself being the only exception, some pretty sophisticated Plaintiff lawyers who have been doing this kind of thing for a while, I'll except myself from

that group, the reality of trying to understand what has happened before you can bring the case to satisfy Rule 11 is not straightforward. You can't read something from the FTC and think it's unlawful. You've got to do a study.

THE COURT: My other question and I'll be asking you folks to comment on it, too, you disagree about it in your preliminary filing is where the patent case has been settled, what is the necessity of litigating the patent in the antitrust case to determine its validity? I found Justice Breyer's discussion of that to be a little Pollyanna-ish, maybe.

MR. SOBOL: If I were an Article III judge I might be able to call a Supreme Court judge's opinion Pollyanna-ish. I won't go that far.

First, you've identified exactly what the Court majority said in the <u>Actavis</u> decision, that as a straightforward matter in terms of proving the core piece of a violation, if I understand that decision correctly, if you've got a big payment and you can't explain it through some other way to get an excuse for it, it's only cause celeb. It's got to be delaying the generic's entry. Therefore, if the decision is read that way, you wouldn't need to technically have the patent to prove the core piece of the violation. In

our thinking, which is not monolithic, there are two roles of the patent case in any event for the case. The first is to set the context of the settlement agreement. In other words, can a jury really understand why a payment might be happening one way or another without at least having some understanding about the patent system, what the patents were all about, what the litigation was all about, and what the positions were of the parties. Can they really understand the settlement outside that context? And the thinking of many us, though I haven't taken a poll, is that they can. You've got to set the context of it.

Second, and probably more concretely, is the notion that to prove causation one approach of the Plaintiffs might be to say if there hadn't been a reverse payment in the case but the parties still wanted to settle, what would the settlement have looked like without a payment?

So you have two litigants who have a lawsuit. The only thing they have to therefore bargain since the branded company is taking off the table, all right, I'm not going to bribe you, take a later date, the only thing they have in front of them is to now negotiate an entry date for generic that is reflective of the merits or lack of merits of the underlying patent

disagreement. And in that context we think, we, not a monolithic, right, we think it relevant that the patent merits will help the jury understand to be able to pick, yeah, if there hadn't been the payoff, then, you know, the branded company basically didn't have a leg to stand on because of this, that or the other thing in terms of the underlying patent litigation like the clinical studies that were used to support it were bogus or the crackpot scientist who was trying to get the patent was misrepresenting the science about this, that and the other thing, right, and they are therefore in a position to handicap, if you will, where the settlement otherwise might have occurred if it hadn't involved a payoff.

So it's setting context for the settlement, number one, and also technically on a causation theory if our causation theory is a different form of agreement here's what it will be.

MR. RICHARDS: Judge Smith, if I could add a quick point, again sort of a higher level of extraction to what Mr. Sobol has said, the only point I would emphasize is a simpler point. The Supreme Court enactment made this very clear, you don't have to decide whether a patent was valid or invalid. That's not the exercise of determining --

THE COURT: The Defendants may disagree with that.

MR. RICHARDS: On that question, the Court's opinion is very, very clear. What it says is from a standpoint of determining whether there's a violation, the chance or likelihood, the possibility, the risk that the patent has -- the possibility that the patent might be invalidated is enough to, coupled with one of these payments, to declare the payment unlawful. I would submit that is very, very clear.

THE COURT: Let's move to the Defendants' side.

MR. SUNSHINE: I'll take the first crack at it.

Steve Sunshine for Actavis.

Just as I'm sure your Honor is aware, about a month ago Actavis completed its acquisition of Warner Chilcott. No relation to this lawsuit but now under common parentage.

As you point out, this is a case about an after-the-fact antitrust challenge to a patent settlement. This is a case about two private parties that were engaged in very serious and intense patent litigation who were able to resolve their differences and now are being challenged after the fact by a series of private Plaintiffs who have said we should have litigated a different outcome, we should have better

protected the public interest.

We clearly have some problems with that. I think we've already flushed out a few areas where we and the Plaintiffs don't see eye-to-eye on the Actavis decision and its implications. But just to talk generally I'll first talk a bit about the Hatch-Waxman framework to put some context in and the balance created by Hatch-Waxman, and then I'll talk a bit about the Actavis decision itself, what the Court said, what the Court didn't say, some of the different signals that the Court has and where that leads us here in this case and other cases like this.

This is not the only challenge going on to settlement post-Actavis, but let me first talk about Hatch-Waxman because there is another side to Hatch-Waxman, and I think it's fair to say that Hatch-Waxman is a balance. It's a policy construct that Congress created more than 30 years ago, and it's a balance between trying to spur innovation and reward branded companies for innovating while at the same time to allow generics to enter the market and become available.

One of the things that generics get out of
Hatch-Waxman is that generics do not have to do
clinical trials. The branded company does. We think

about this as a patent case and inventing new molecules but even more about what brand companies do is clinical They have to go through the FDA process, Phase 1, Phase 2, Phase 3, where the product has to be deemed safe; it has to be effective. It has to be run through large clinical trials. What Hatch-Waxman does is allow the generic company to piggyback on those clinical trials. Congress is trying to achieve a balance. That statute now is more than 30 years ago. It's been amended on many occasions to tweak it, to adjust it. Ι think by all accounts stepping back Hatch-Waxman is considered to be a success. How do we know that? Statistic that I've seen is more than 80 percent of prescriptions filled today are generic prescriptions. So generics have been successful.

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My client is I think the second largest generic company in the United States, has a long history of developing new generics, of challenging patents, of shaving years off the projected patent life but also bringing these products to market. My client is in the business of selling drugs, not in the business of patent litigation.

Now, Hatch-Waxman, I think your Honor hit the nail on the head, it creates a constructive act of infringement so an act of infringement is merely

sending in the so-called paragraph IV notice. The generic doesn't have to make sales in the market and risk all the usual liabilities that tend to patent infringement. In exchange for that, there's all these different pieces, and I think you heard from Plaintiffs' side there's a 30-month stay. The reason why a 30-month stay was put in was not to randomly disadvantage generics as they tried to bring products to market. It was to create this balance where the branded company would have an opportunity to prepare its case and the branded company in the meantime could be continuing to develop its product, et cetera. So there is this whole balance piece of Hatch-Waxman.

In this context the <u>Actavis</u> Supreme Court decision comes into play. That case was decided just three months ago. Before the settlements your Honor pointed out, Actavis was in settlement that we're talking about. That settlement was almost five years ago. There was nary a word from any private plaintiff or certainly any Governmental investigation of any type until the <u>Actavis</u> decision was put before the Supreme Court. And so the question -- since the <u>Actavis</u> decision has been handed down by the Court, by our count there's at least 12 cases pending on the question of under what circumstances can reverse payments be

found to be unlawful.

I think there is a great lack of clarity in the Supreme Court's decision. I think we can say a few things about the Court's decision. One is we know it's a Rule of Reason analysis. And that means that the way to test the effects of this product, the effects of the agreement are to balance against the restrictions that they cause to competition, net it out and see if there's an actual harm in the competition. There's no presumptions. That part of the case was the FTC's theory. They were asking for presumptive violation or a so-called quick look and the Court rejected it.

So what the Court did, and perhaps not to characterize too much what Justice Breyer did, but it was almost a cavalier we'll leave it to the lower courts to figure out. In fact, he said that expressly, figure out how to piece these analyses together and how to make it work.

He did offer some guidance, and there are five sets of considerations identified in the opinion.

Those sets of considerations are advisory about how to get the elements of a Rule of Reason analysis done.

And in no case in any of those elements is there irrebuttable presumption provided by the existence of a large and so-called unjustified payment. I think the

Court talks about -- for instance, uses words like a large payment may be a strong indicator, a large payment may provide some balance or some color as to what the patent merits are. But from a Defendant's perspective we would respond, we would answer each piece of those with our own sense of evidence ultimately with the fact that the Plaintiffs have to prove an actual payment, they have to prove that it was large, that it was unjustified, that it actually delayed entry. We heard Mr. Sobol talk about how you prove entry was actually delayed.

The other thing that is very important in any Rule of Reason case is there has to be an adverse effect on the decision. The way we do that is we redefine the market. We look at how much power does the Defendant have in the relevant market. The product we're talking about is a woman's health product, an oral contraceptive that has a competitive market. There are many oral contraceptive markets available for sale. And one of the points that the Defendants will argue is that Warner Chilcott had no and has no market power in oral contraceptives.

So if we kind of go back to then where does this case leave us now, we have Plaintiffs arguing that this is they call it a pay-for-delay, they talk about

exclusion payments, they make a defined term exclusion payment, they talk about paying off the competitors, but let's really cut through the rhetoric and look at what's core of where the allegations of payment are made, because nowhere in the complaint would you see Warner Chilcott handing a bag of cash over to Watson or to Lupin. And all of the allegations of payments are all referenced to other agreements that the parties made and trying to impute value in those agreements that don't relate to the actual agreements themselves.

So what do I mean? For example, there is a product that is called Femring, which is a product that's a hormone replacement therapy for menopausal The agreement that actually exists between the women. parties is that Watson, which has its own line of women's health products, details the sales force, takes over that product and actually sells that product in the marketplace. I think the facts are that Watson made something on the order of 40,000 details. means 40,000 calls on physicians to say, Let me tell you about this product, let me tell you the good of the product. And in exchange for that Watson got 50 percent, there's base fee and there's a more complicated fee but basically Watson gets a percentage of those sales.

So what you have is a stand-alone agreement. And Defendants will argue and I'm sure Plaintiffs will disagree that it's an at-market deal for the promotion of this product. But what we have is Watson's clearly providing services, detailing, it's promoting. Its financial compensation for that deal depends on the success or failure. If it's good at selling the products, it's making more money. If it does a bad job, it makes less money. So I don't think there can be any dispute that that arrangement is not a sham. It's not just a thinly-covered disguise.

Now, we'll have a debate over what's the proper fair market valuation of that, and our position will be that that was at fair market value. But that's what I mean when there's talk about pay-for-delay. We should be very clear that all of the payments that are alleged by Plaintiffs are coming indirectly through other agreements. So that's true for Femcon, that's true for the two products that went to Lupin as an authorized generic, Asacol -- I think it's Femcon in that case. And it's also true for the generic product that Watson is now selling on the market.

So these are agreements, each case these additional agreements are actually bringing a new product to market.

So the product that Watson got, Generess, is actually competing with Warner Chilcott's Loestrin. These are two very similar oral contraceptives. So this product not only are we talking about trying to get disguise consideration but is also introducing a few products in the market that is competing that customers have to choose which one to buy.

I went into too much detail and I apologize for that, but I'm only talking about can they even prove a payment. We haven't even gotten to is it really large --

THE COURT: I don't want to cut you off in terms of what you want to talk about in terms of Defendants' position, but it might be a good segue into sort of the next topic on the agenda, which is -- actually a couple of the next topics. Do we have everybody here? I guess that's the first question I have. Are there going to be other cases joined to this? Are there going to be other parties? And one thing that we had a question about is whether there are going to be any so-called opt-out Plaintiffs join in this action. Does anybody have any comment about that?

MR. TARANTINO: Before you go there, there's another aspect of the Defendants' case Jack wants to address.

THE COURT: I did kind of cut you off a little bit.

MR. PACE: Thank you, your Honor. Jack Pace for Warner Chilcott.

I'll touch on the opt-out question briefly and Plaintiff or anyone who is aware of the issues can cover it. Often in these cases there are opt-out Plaintiffs, large purchasers who prefer to proceed alone. As Mr. Richards noted earlier on, some of the Plaintiffs lawyers have worked with each other for many years. Some of us on the defense side feel the same way vis-a-vis the Plaintiffs lawyers. A typical pattern is in some of the cases, more recently just a few months or less into a case some of the retail chains filed separate complaints, often the same as the class complaints but sometimes with little variations.

So if this case follows that pattern, I guess we wouldn't be surprised to see any direct purchaser, for example, opt-out complaints in the very near future and that could affect things like scheduling and other synchronization.

THE COURT: When you're referring to those Plaintiffs would be large retailers, we were thinking the possibility of like a large hospital, for example, or does that happen?

MR. SOBOL: If I may. So there are times when on the end-payor's side, the indirect payor's side, there are some large healthcare institutions that have filed their own cases, too. Aetna, Keiser are examples where that has happened. It's relatively rare but it has happened.

On the direct purchasers side, as Mr. Pace points out -- appreciate your having brought up the opt-out issue -- depending upon how the case goes, while sometimes you might find some more attractions, too, we don't know, typically by the time we get to this point here we at least have a sense of who the class lawyers are. We have a pretty good group sense. We can't guarantee that this is the direct grouping, that's the indirect side.

On the indirect side they have a pretty comfortable feeling that Aetna or Keiser are probably not going to come in at this stage. We probably need a little more water go over the dam before we see somebody come on our side.

MR. SORENSEN: On the opt-out side, there are cases, typically Rite-Aid, Walgreens, CVS, large chains, when they bring suit they typically bring suit under assignment from wholesalers, that is they purchase their drugs from wholesalers and they get

assignment from their purchasers. Say if CVS buys a thousand units from a wholesaler, they get an assignment agreement between them and their wholesaler for purposes of brining antitrust cases. Those thousand units are assigned to CVS so they can step into the shoes of the purchaser for purposes of antitrust law.

That's typically how those cases are framed. When they do bring suit, I'm not speaking for them in this case, often when they bring suit they will present themselves to the court as saying we are not here to delay the case. They'll kind of jump in whenever they jump in and try to, in effect, not have that filing delay.

But obviously I'm not speaking for them.

They're not here in this room. That has happened with varying degrees of success by the way. It can create issues. I'm not pretending it doesn't, but that's sometimes how they frame themselves.

THE COURT: In your experience, it usually happens within a couple of months of this conference?

MR. SORENSEN: Yes. Sometimes it's happened -there's a bit of a variation there but typically in
that time frame.

MR. MILLER: If I might, I'm Marvin Miller.

That may be true with regard to the directs. On the indirect side, I think as a footnote to what Mr. Sobol said, the Aetnas and Keisers, some of the other large third-party payors typically come in way down the road near the end of the case. They won't be filing generally their own case within our case.

MR. PACE: One other data point, your Honor. In a recent case against Pfizer regarding Effexor, frankly, after a team scheduling conference like this, that caused within a matter of days a number of opt-outs who filed their complaints. We all went home from the initial status conference in that case in the District of New Jersey to find a number of opt-out Plaintiffs had filed just triggered by the publicity surrounding the initial case conference.

THE COURT: Okay. You were --

MR. PACE: I'll note two simple points. The first one relates to some allegations that are really against Warner Chilcott alone, and mentioning it now really goes to something that I suspect we'll touch on briefly in the need for the case to shape and develop a little bit through the consolidated amended complaints and other things before we have a perfect sense of some matters that will be very important for us all to deal with. But the one issue that didn't come up in some of

the discussion so far is that as to Warner Chilcott in particular, there are a number of allegations depending on the complaint that deal with what's sometimes called in the forum of a Section 2 Sherman Act monopolization claim.

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One way or another all the complaints at least contain factual allegations regarding product hopping by Warner Chilcott or incremental improvement in the Loestrin product. The allegation that is essentially challenging the launch of a new version of Loestrin of Warner Chilcott referred to as the Lo Loestrin, the form dose of Loestrin, which according to the complaints really had no effect or came in two forms. Number one, it was something that generic competitors were forced to keep up with so the Plaintiffs characterize delay generic competition, launch of the new form of product that generics would want to take advantage of substitution to compete with. Then also very simply the complaints against some of the specific claims, some of the factual allegations allege essentially the new products, the lower dose form wasn't sufficiently innovative to avoid the antitrust That's a claim that is in a footnote to Plaintiffs' statement of the case. The Plaintiffs seem to hint that that might change in the final

consolidated complaint. That may get moved from Sherman Act Section 2 category to part of a Section 1 theory, and I guess we'll wait and see what the consolidated Amended Complaint raises but that's something we mention at the outset because that sounds like it's still going to be part of this case.

And I'll note it's not just the Defendants here that characterize that claim as novel. There haven't been many product hopping cases out there. Two of the three pharmaceutical product hopping cases were dismissed on the pleadings. One of the cases pending right now against our client, Warner Chilcott, the judge in the Eastern District of Pennsylvania invited Defendants to file summary judgment briefs. There are other claims unique to Warner Chilcott have to have discovery, you can talk about that on discovery.

The last thing I'll note as to settlement claims, to emphasize this is important, maybe this is a segue to get into scheduling, it is important these claims do have an impact on the type of discovery, if any, are required later on down the road.

Again, as Mr. Sunshine put well, it's Rule of Reason inquiry that the Supreme Court described, lower courts are just now going through the process of beginning to try to understand which types of

settlement agreements are ones that should survive a motion to dismiss and get into discovery and which ones may not.

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In the beginning of this status conference, we made a lot hypotheticals about settlement agreements, cases that may be -- I think the word was evil settlement agreements, they may have involved blockbuster drugs or large, naked cash payments. as will become clear in the briefing on the motion to dismiss if it goes as we expect, there was no naked cash payment in this case. It's not one of those And even as to the no-authorized generic deal, again, some courts are grappling with to determine if cases should even go into discovery at all. compensation for generic took the form of really the revenue from increased competition, this is the Judge Posner decision we cited in the Asahi Glass and that certainly can't be reverse payment, that is essentially what we're dealing with. These are patent shortening settlements. But I'll stop there and save the rest for discussion of the schedule.

THE COURT: Okay. Let's use that as sort of a jumping off point to the question of kind of first phase of scheduling the consolidated complaint and answer for motions to dismiss.

Do I take it there's a consensus agreement that a consolidated complaint should be filed in the MDL action, at least one, or should there be two?

MR. SOBOL: So at least on Plaintiffs' side, I don't anticipate any disagreement by the Defendants, all the cases can be consolidated for pretrial purposes. There would be two consolidated complaints. One for the end-payor class, one for the direct purchaser class. That's necessary for a variety of reasons to have those two. Although there are obviously some significant similarity of facts and significant similarities in terms of law, there's also some significant differences, too, so we'd have two separate consolidated complaints, one for the indirect and one for the directs.

There's some timing -- I think at least the Plaintiffs' proposals were a little bit different, but I think after a little bit of discussion December 6th for the filing of the two consolidated complaints would be in order. And then I think I'll stop talking for a moment before we turn to the issue of the timing and the briefing of motions to dismiss.

MR. BUCHMAN: Michael Buchman for the indirect purchaser.

I would agree with what Mr. Sobol said, but I

would add that I believe based on our discussion with the Defendant that although December 6th, 2013, would be a good date for Plaintiffs to file their separate complaints, the direct purchasers would file their separate complaint, we would file our own separate complaint as is typically done in these types of cases.

THE COURT: I take it you all agree.

MR. SUNSHINE: We agree. It's very complicated. It's easier to work off of one set. These are cases that at a minimum being highly shaped we can only do that when there's some commonality with what the Plaintiffs have actually alleged.

THE COURT: There's an interesting decision written by Judge Sutton in the Sixth Circuit, which I'll confess I haven't fully read which doesn't seem to be all that lengthy but I guess I just became aware of it and I imagine most of you have read it, which talks about the difference between terminology used. There was a master complaint versus cases consolidated for administrative purposes. Do any of you have any views about that?

MR. SOBOL: We do, your Honor. So unlike a mass tort kind of situation, if you will, the tradition has been this period that when the parties file a consolidated complaint, those Plaintiffs, those class

representatives are filing the case in a docket number in the jurisdiction. Accordingly, I'll speak only for the direct purchasers, but I anticipate the answer is the same for indirect purchasers, when we file our consolidated complaint, the two named Plaintiffs will have filed a case in this Court and expect to go to trial in this Court, therefore not be a lexicon issue, meaning that there's no

who-is-going-to-try-which-case-where.

So even though, for instance, Rochester Drug originally filed a case elsewhere, because it's going to be a named Plaintiff in a docket number that was originally filed here, we're going forward in a trial in this Court and we get rid of any lexicon issues. Do you all agree with that?

MR. BUCHMAN: Mike Buchman, again, for the end-payor Plaintiffs.

With regard to the City of Providence case, which was filed in this district, that would be true.

Mr. Sobol's statement is correct.

With regard to other Plaintiffs' claims, cases that were filed outside the district, they would get MDL'd back to their transfer court to the conclusion of pretrial like discovery. So we would imagine those cases going back to those other districts.

THE COURT: So you differ on that point, then, I take it, right?

MR. SOBOL: We differ in the sense that we have structured things so we're not differing about an issue of law because we have structured things that are both Plaintiffs are filing here, we don't have the issue that the indirects have decided to choose.

THE COURT: Right. I mean, you're deciding basically to waive, if that's the correct word, any lexicon issue filing. You folks are saying, the City of Providence obviously is in this district. You folks are saying your non-Rhode Island cases, you want to invoke lexicon and not waive it. I don't know if "waiver" is the right term but that's what you're saying.

MR. BUCHMAN: That's correct, your Honor.

THE COURT: But that's an issue we can obviously deal with down the road. My understanding is that a lot of times we get to that point the MDL district judge simply gets designated in a district of wherever and solves your lexicon problem, right?

You're nodding. You don't want to say it out loud. All right.

And from the Defendants' point of view, anything you want to say about that issue?

MR. SUNSHINE: Not from me, your Honor.

MR. PACE: No, your Honor.

THE COURT: December 6th, then.

What comes next? Are we expecting motions to dismiss or Answers or what?

MR. PACE: Jack Pace for the Warner Chilcott Defendants.

Based on the complaints we've seen so far prior to consolidation and amendment, we have every expectation we would be moving to dismiss. I put it that way because there are some things that need to be decided, things that need to be synchronized, I guess, among the various complaints before we have a perfect sense of what we're dealing with. I mentioned the incremental improvement type claim before and we already saw an indication in the statement of the case that that may change. Maybe diminished issues, maybe be dropped all together, may be part of some overall scheme Section 1 Sherman Act. We're not sure.

December 6th the Defendants see how that claim is put. That may have an impact on the various arguments we've made.

Similarly, mentioned in the very same footnote is patent fraud and sham litigation claims about Warner Chilcott alone, and those appear I think in the

original of 12, nine of the 12 said something about the patent claims being meritless. Three of them characterize the patent suits a sham in some way. So that will need to be synchronized a little bit in the consolidated amended complaints before we really see what our arguments will be in particular.

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I will note very briefly there are a few differences among the various complaints that need to Three of 12 have Sherman Act Section 2 be sorted out. We'll see if those survive. Three of the 12 claims. improper orange book listing, the patent was improperly listed in the orange book. We don't know if that will survive the consolidation. One has made a state law monopolization theory. So we'll see. I think it was We'll see if that makes it in there. Teamsters. Just the state law claims generally are something that have a great impact on the motion to dismiss process. are sometimes in other cases motions to dismiss by score card or grid in the sense that there are so many state law claims that you often have to keep track in that wav.

Here in the early count there are 90, twenty-two state law protection claims and unjust enrichment claims under the laws of all 50 states. We'll have to see how that all gets synchronized in the process

before we know what we're looking at issue by issue.

That's what our expectation was in a motion to dismiss.

Defendants during the meet-and-confer session last Thursday proposed that the Defendants would have 60 days after seeing those new complaints to file our motion to dismiss. That would bring us to February 6th, I believe, then the Plaintiffs would have 45 days to respond to that which would get us to March 24th and we would then get 30 days to file reply briefs, which would get us to April 23rd. That was the proposal we made to Plaintiffs during our meet-and-confer session last week, your Honor.

MR. SOBOL: If I may.

THE COURT: Sure.

MR. SOBOL: First, I think that Mr. Pace has done an excellent job cataloging my word that I had for synchronizing.

I will say this. In dealing with a scheduling issue, we really are trying to juggle two things. What is going to be a schedule in a motion to dismiss? Implicit in that is are we otherwise sitting around doing nothing. If we're otherwise sitting around doing nothing, then that obviously changes the Plaintiffs' perspective as to how we move ahead with the motion to dismiss schedule because we can -- frankly, the

Plaintiffs don't care if the motions to dismiss are decided in 2014 or the day before trial as long it's not critical to the trial.

So my answer, therefore, is going to entail both what we really think is going to be involved in the motion to dismiss but also whether or not we're sitting around doing nothing in the meantime or not, which I think is the more critical issue.

It's clear that there's going to be a reverse payment claim in all the cases. It's clear the parties understand the standard there is the Rule of Reason. While we're not the best lawyers, we can at least plead the existence of a reverse payment agreement that is large that has no justification that is larger than the avoiding costs of litigation. We can plead causation, the existence of damages and, therefore, we think core start of the case is going to survive a 12(b)(6) no matter whether we give the Defendants two weeks, two months or how ever long to deal with it.

There are other aspects of the case, different kinds of claims that might be brought. If they involve fraud in the patent office, they're going to involve the same underlying facts regarding the mischief that was involved in getting these patents in the first place. That provides the context of first payment

allegation anyway. And the issue regarding the sham litigation that's brought on the basis of those fraudulent patents, if that's what's pled, it's not going to raise significant different facts.

It's correct to note that some the complaints also have a claim that Warner Chilcott is essentially the master of the Tweet, that they move the goalposts around left and right on the generics as you go forward marching forward trying to get a generic on the market. That involves some different issues. But even there the Plaintiffs and Defendants all agree the test is a Rule of Reason test, is the purported innovation which is real and a Tweet to defeat generic competition have greater -- is it more pro-competitive than anti-competitive? So that's going to survive a 12(b)(6) as well as it did in the case that Mr. Pace identified.

Now, having said all that, if we are going to be doing nothing in the meantime, then we think the schedule should be moved much more quickly. However, we think that we don't need to be doing anything, nothing in the meantime, and there's two very specific things that can be done in the meantime which if they're occurring I would leave it to the Court's discretion or whatever argument Mr. Buchman or

Mr. Richards on the end-payors' side in terms of how they want to push the Defendants' response.

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We think regardless the case should be moved forward on the reverse payments agreement. There are two things that should be produced. First, all of the patent litigation documents. We need the documents that passed between the litigants in the patent litigation because most of that stuff is not on ECF in terms of whether there were depositions or documents. If it is on ECF, half the time it's under seal so we can't read it or deal with it. And it's information that while defense counsel are going to bemoan this at length, we are of the view that if it's documents that passed between the parties in some recent Amylin litigation and the parties are here, it should be the kind of thing that should get produced. That gives us something to be doing in the meantime while we're waiting for weeks for the Defendants to draft the 12(b)(6) papers.

The second part would be documents passed between the parties leading up to the time to what they consider the reverse payment agreement. So what were the communications back and forth with respect to that. As an example, even the settlement documentation itself we only have redacted copies of, and we should be able

parties, which by definition is not governed by any attorney-client privilege, will be produced.

If those two things in our view are happening,

to have unredacted copies of the agreement materials

and all other communications that passed between the

from the direct purchasers point of view, we still think that the motions to dismiss should come in at some point earlier but we recognize we're doing those things. And we have a holiday season. Why would we be pounding our chests with timing of issues, a week here or a week there? That's our overall view of things.

THE COURT: I think I suppose the other thing that needs to go on is the process for selection of lead counsel, which is next on the agenda. Maybe you all have reached some agreements on that. I don't know. But that's something else that will be taking place.

MR. SOBOL: There are two other things that are on your schedule that are things that can be done in the meantime. One is how we identify lead counsel, and then the second is how we address electronic information.

As to the lead counsel issue --

THE COURT: Let's hold off on that. We'll get to that in a moment. I do have a couple of questions

about the -- it seems to me without knowing much at all about this whole business, that once these consolidated complaints are filed, we're going to have various counts to be put in a few different boxes. But the main count I understand is the reverse payment allegation, from that all the way down to what you've identified as 50-state consumer protection counts.

So at one level some of this is going to self-select out. The pleadings in the consolidated complaint are going to be made narrower and fewer things to deal with.

One thing, though, that I'm not really sure I understand is how can you prevail on a motion to dismiss on the reverse payment allegations without getting into, pretty far into the weeds on the economics of these drugs. How is a judge supposed to be able to tell whether this is an exorbitant payment or one that just reflects the cost of litigation and the risks without having a lot of economic information, what the market is, what the profit margins are and value of the patent and on and on and on? So how do I do that? Can you take a shot at trying to explain. I don't want us wasting time.

MR. SUNSHINE: I understand your Honor's question.

THE COURT: If I could just interrupt you. I'm sorry to do that. I don't like interrupting people.

Maybe you have some experience from these other post-Actavis cases. I think you said there are six or so, I forget the number, cases knocking around district court.

MR. SUNSHINE: I think that there's 12 of those cases post-Actavis, a couple of which have been through a motion to dismiss stage. Taking those two cases, part of the cases were denied. One, if this case was narrowly limited to just the so-called reverse payment part of it, I think the question would be a pretty standard question under Twombly and Iqbal whether there's plausibility here of the settlement but the allegation as made makes sense.

Right now the complaint said hundreds of millions of dollars passed. And we can give you some actual sales numbers of products that could be judicially recognized. I recognize that may not be an easy burden for us, but I think -- I will say I think that Mr. Sobol and his colleagues should put pen to paper. We should see what they come up with and then we'd be in a much better position to answer you directly.

The second part is we can all move pretty

quickly. The Plaintiffs picked December 6th they want to do the consolidated complaint. Our clients, Mr. Pace's client, Lupin, they're not organized by these departments. So we're talking about doing discovery multiple times and going fast. Let's move these quickly from the Watson perspective is five years old, Plaintiffs having just found out about this issue. So let's shepherd that case as quickly as we can. Let's do discovery quickly. It's a big case. There's a lot of parties involved.

MR. PACE: I will note two things. With respect to settlement agreement claims, this is being thought about, considered by certain courts as noted right now and it's been briefed in a number of courts. In the Lipitor case the judge issued a ruling paring away a large portion of the case and setting the settlement claims for separate briefing. So we'll standby for that. But these are arguments that can be made based on the pleadings and submitting even copies of the settlement agreements themselves to the extent that is something that clarifies, directly contradicts, frankly, the allegations in the complaint.

I mentioned the <u>Asahi Glass</u> example just as an illustration, though it applies not only potentially to the no-authorized generic agreement but also the

allegation of the world-wide life one may find when one looks at the settlement agreement don't exactly square with the agreement itself. Nonetheless, if that's the argument, the argument is there's compensation there to the generic is just the revenue from early entry, that's something, respectfully, Defendants think can be ruled on the motion to dismiss.

As to other parts of the case, the non-settlement agreement parts, what survives a motion to dismiss really will have an impact on the type of discovery we get into, whether the incremental innovation claims survive will determine whether and to what extent the parties really get into documents about the development of the Lo Loestrin product and whether it was sufficiently innovative compared to the prior version.

Whether the sham litigation and patent fraud claims are even in the new complaint, let alone survive a motion to dismiss, will determine whether and to what extent the parties need to get into any type of discovery on the invention itself and the prosecution of the patent. Those decisions themselves will determine the number of custodians we have and we would hope not to have to go back to custodians multiple times. The number of interrogatories, the scope of

third-party discovery, all of which would be extensive or not depending on different contours of the case.

As the consolidated complaints shape the case, the motions to dismiss shape the case and the rulings on the motion to dismiss shape the case. For all those reasons in our initial meet-and-confer with the Plaintiffs, the Defendants proposed a schedule that provided the things we discussed so far, filing of new complaints, briefing on motions to dismiss, we understood there are agreements of payments of interim counsel, then we'll see what we have in terms of the efficient conduct of discovery.

THE COURT: So obviously there's disagreement on what goes on during the period that the motions to dismiss are being filed.

MR. RICHARDS: Your Honor, I'm concerned -there's a point I think is very important. You're
hearing quite correctly there's a lot of consolidation
and judgment calls being made in putting the
consolidated complaint together about what to include
and what not to include. Especially at the end-payor
side of the case, it's nearly impossible to make those
decisions without lead counsel having been appointed.
So the notion that we start a clock on that at the
December 6th date without lead counsel appointed --

THE COURT: Let's talk about that. My decision is we're going to have a process for that and you tell me what you think is a reasonable amount of time. I mean, I guess what you need to know from me is what kind of application process I'm thinking of, what kind of factors I'm interested in.

MR. RICHARDS: I guess more fundamentally I'm saying it's hard to agree on the December 6th date because we don't know when counsel is going to be appointed, then we need time to draft a complaint. The clock needs to begin to run to work out a schedule to know who's on the case.

 $$\operatorname{MR}.$ SOBOL: I'll let the indirects finish and jump in.

MR. BUCHMAN: Michael Buchman, again, for end-payor Plaintiffs.

We have submitted a motion for appointment of co-lead counsel and proposed four firms, and the proposal is based upon an agreement among all counsel that are on file for the end-payor Plaintiffs. There was an order this morning that was entered electronically, a text order denying the motion as moot and we intended to address that issue with the Court if the Court would be willing to discuss that.

THE COURT: I denied it as moot because I said

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in my order we would talk about it here, then you could make your motions after. So I just saw it as jumping the gun a little bit. Tell me -- you wanted to --

MR. SOBOL: Speaking for only the direct purchaser class, we had proposed that the four firms who were representing two proposed Plaintiffs be designated as co-lead counsel or an executive committee, and we also proposed that the Lynch firm be liaison counsel. The reason we've done that is the following: The four firms work well together. There is an enormous amount of work that needs to be done in the case. As you can see, we're able to share roles in terms of who is able to do what, that kind of thing. It's efficient, too, and time-tested in the sense that the group of institutional clients that we represent through the class are accustomed to the notion that there's going to be a battery of firms.

We also have to dig into our pockets quite a bit in a case like this, as you can imagine, so it's a way to make sure that the firms that are funding this case also have some voice in terms of direction and that kind of thing.

The long and the short of it is that unlike some other situations where there are battles between the two Plaintiff lawyers for a petition or a need to

perhaps have the Court discipline the Plaintiffs Bar in terms of making us be more efficient if we had like 20 firms and we represented some big consumer class, here we represent a group of institutions. The four firms work together well. We would be efficient, and so that's the way we would prefer to go forward.

I would also say, by the way, if you exercise your discretion, which judges sometimes do, no, no, I don't care you guys get along, I'm going to do it my way, we don't need to still be reorganized. We're still going to work together probably anyway unless you order us not to, and we're still going to have a complaint done on December 6th even if you don't appoint a co-lead for another year because that's the way we work together on the case. And I wonder whether we should except Mr. Lynch himself from -- maybe an exception, a waiver of the local rule, we're fine with Mr. Pine as well.

MR. MELTZER: Joseph Meltzer, direct purchaser class.

We jumped the gun as well and filed a motion last week. It was my mistake. It was a little unclear. We were trying to put something on file to the extent it would be appropriate to talk about it today.

THE COURT: I have sort of two things about this that I'm interested in discussing. One is that I'm a fan of competition in this whole business, trying to manage attorneys fees and what the ultimate fee application is going to be. A number of years ago I wrote an opinion in a case called <u>Cabletron</u>, which was a Securities transaction in the State of New Hampshire, which explained a lot of reasons about how a judge goes about assessing what a reasonable fee is. In fact, I think your firm or one of your firms, Milberg Weiss firm was in that.

MR. SOBOL: No one now.

MR. RICHARDS: I was at one time a partner of Milberg Weiss, but we've been gone for several years for reasons you're probably aware.

THE COURT: So if everyone works together in the way that you're describing, sort of the question I have is how do I go about applying the element of competition, if you will, injecting that into the process? That's number one. And number two, maybe it's the answer to question number one, I'm interested in aggressive management of your fees in the way that you work. So I'm interested in once we figure out who lead counsel is going to be or if it's all of you working together, one thing I think we're going to be

talking about is a process for managing the work and our review of the work that's going on. So we need to kind of figure out how to do that because, you know, as judges meet about these things and talk about these things, that's something that's a consensus that's an effective tool that is often used.

MR. RICHARDS: Your Honor, there was a lot of debate within the judiciary and appropriate criteria between lead counsel and competition between lead counsel in the form of a task force in the First Circuit.

THE COURT: I read it. Read <u>Cabletron</u>.

MR. RICHARDS: I think the basic conclusions that are in that report are consistent with what's embodied in Rule 23, which is criteria of the selection of class counsel and the competition among class counsel that should be relevant, knowledgeable of applicable law, capability of running the case, the kind of things that make the difference between having a successful outcome of the class and an unsuccessful outcome of the class. Keep in mind in these cases no one collects any fees until the Court approves them at the end of the case. It's not as though they completely get away from the court. They're never awarded fees in the first place until the court grants

them at the end of the case. You always have the right and ability and demand to approve those fees before anyone collects any of them. And I think the conclusion that was reached in the report, which I think is consistent with the content of Rule 23, is that's the kind of competition this case needs. With that the underlying concept we made our motion for end-payor class to have counsel appointed, I think if you look at the credentials of the four firms we proposed are all qualified, very high in the criteria under Rule 23, and I would submit those are the criteria the Court ought to apply.

THE COURT: I think what would be helpful to you, though, even if I agree with everything you said is for you to have some guidance from us as to the kinds of things that we would be unwilling to agree to that you might charge. For example, if you're going to bring four associates to a deposition, I'm not going to approve four associates at a deposition. If you're going to fly a private jet to take a deposition in Cleveland, well, I'm going to approve business class air fare, not a private jet. Those kinds of things. I think we're all a lot better off if those kinds of parameters are understood ahead of time than if it all comes in in a big bill at the end.

MR. RICHARDS: And I'm sure none of us would 1 2 disagree with that. It's fairly routine practice but 3 not always regulation of the court for lead counsel to 4 distribute something to all the lawyers representing 5 the end-payors' class early in the case laying out 6 exactly what kinds of things you're putting your firm 7 You don't want people who have a tertiary 8 involvement in the case running up bills either. 9 are floating around within the private parties that 10 does this the lists and criteria we circulate anyway. 11 If your Honor wants to be involved in a definition of those, we can give you a proposal. We can take one of 12 13 those and propose it and your Honor can consider to 14 change something in there and add something or add a 15 limitation or not there. It's not as though this 16 process goes around without any of that. It's 17 something we police within our own group.

THE COURT: Okay. Anybody else want to comment on that?

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All right. I'm not sure how we're going to move forward on it, because I didn't envision that you were going to be coming in as a completely unified two groups here so I have to think about what to do with that.

MR. SOBOL: Maybe I should make a magnanimous

suggestion, your Honor. Why don't each of the directs and indirects make a proposal. If you think it's satisfactory, has the safeguards you think are appropriate or not --

THE COURT: You mean individually make a proposal as lead counsel?

MR. SOBOL: They should make a proposal how ever they make a proposal. I have a hunch where we're going to end up because I've already indicated to you what our position is. Right? As an example, I think our proposal is insufficient in describing some of the things we think we're more efficient as a group. We need to address that concern you had. Our submission did not deal with what the criteria are of the expense discipline that we're going to exhibit, nor was our submission adequate in terms of showing to you the discipline that we'll show in terms of staffing certain kinds of activities.

So with having heard you, I will at least, speaking for myself, I haven't spoken to these guys yet, but I think what we would do is make a proposal addressing your concerns and it will either make the grade or it won't make the grade.

Again, to repeat something going back to another subject, from our perspective this is a different track

because we can still track dealing with motions to dismiss and discovery and the like while you're doing this other thing in any event.

THE COURT: All right. That seems like a reasonable suggestion. Maybe that's what all of you should do.

MR. RICHARDS: Again, for the end-payors, your Honor, it's a little more difficult to proceed without having this resolved because as I mentioned before, we have millions of consumers in the class, 14,000 third-party payors, any firm can file a new case any time they want to. We've got people filing these cases we've never heard of, don't know anything about --

THE COURT: Isn't the easy way for you to do this is to jointly appoint lead counsel through the filing of the consolidated complaint subject to --

MR. RICHARDS: It's not unlikely then, but I can't predict what would happen, but it's not unlikely there may be people with cases on file and maybe disagree with what we plan to do with the many decisions defense counsel have identified. We don't know who the lead is.

THE COURT: I'm not sure I'm following that.

MR. RICHARDS: In putting a consolidated complaint together, we have a great many decisions to

make about what to include and what not to include.

With so many cases, so many lawyers, so many Plaintiffs for whom someone can sue, you will very often find disagreement among the various people about what form that should take so how do we get to one complaint.

It's very, very, very difficult.

MR. MIGLIORI: If I may, your Honor, Don Migliori for Motley Rice.

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One of the things we've done is form an interim committee that's been agreed on on the indirect side. Everybody that's got a complaint in this Court is in agreement with a proposal. If the Court wants to allow for competition for this protective other firm or interest that wants to come in, it can be handled in the context of allowing us to go forward as an interim committee subject to the date of December 6th as the date to see if anyone had gotten involved, then have any kind of competition or opportunity for somebody with a different interest to get involved but to keep ourselves organized, when we're talking instead of a few indirect purchasers, thousands of indirect purchasers, let's go forward with an indirect group subject to Court ability to increase, decrease that control and then on the 6th we reassess and then go forward.

As a group, efficiencies are here, understanding of the law in the various states is with this group, and we're not speaking for anybody or I should say that there's nobody before this Court that's speaking as part of this group. So it's all inclusive at this stage on an interim basis, and it alleviates some of the concerns the Court has.

THE COURT: Picking up on Mr. Sobol's suggestions, if I understand what he's suggesting, why wouldn't it make sense for you folks to do essentially the same thing he's proposing for the direct purchaser group?

MR. RICHARDS: It would be great if we could and we can on behalf of, I think, on behalf of the people who already proposed a leadership group. We can come up, I'm sure, with a single consolidated group for that group. The only real difference between the direct group and end-payor group is they have a fairly small and focused number of Plaintiffs in these cases where as we, any lawyer who wants to come in with a new case can come in, one of the millions of consumer Plaintiffs or the 14,000 third-party payor Plaintiffs.

THE COURT: The practical reality is you have a running start. You're experienced in the field.

You're going to be following this suggestion. You get

appointed as the interim lead group and then you go 2 through the process of giving me some kind of detailed 3 proposal along the same lines as what the direct 4 purchasers are going to provide. We take a look at 5 We may have other ideas. Somebody else wants to come along in the meantime and get into the mix with 6 you, then fine. I mean, that's fine. I think you 7 8 probably have the advantage over them, but maybe we'll 9 all get surprised. We'll just deal with that as it 10 happens.

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MR. RICHARDS: We can do it on that basis. Ι have no doubt as a group what the Court proposed can look at that on its own behalf.

THE COURT: I imagine that there are some pretty good orders floating around in these other cases where judges have tried to do sort of the things I'm talking about, right?

MR. SOBOL: Yes, your Honor.

MR. MIGLIORI: We'll make yours state of the art.

> THE COURT: Right.

MR. PACE: Your Honor, may I make one -- I think the Defendants' only concern in this whole process is to the extent that it impacts the filing of consolidated amended complaints. I thought I heard

directs and indirects saying something slightly different along the way, that the direct purchasers noting that even if this issue isn't resolved by the time we reached the date we're talking about earlier, December 6th, they might file their complaint and that might not necessarily be the case for indirect purchasers.

MR. MILLER: That's a misunderstanding.

MR. PACE: All we want to avoid, of course, if there are other Plaintiffs joining and other complaints getting filed after this case, they'll start some sort of staggered process. If that's been resolved, that's our concern.

MR. MIGLIORI: We're on the same page.

MR. SOBOL: If I may, your Honor, turn back to the motion to dismiss because you had asked a question if there are any post-Actavis decisions that would help you decide this. In the <u>Lipitor</u> case, which is pending in front of Judge Sheridan in Trenton, New Jersey, Judge Sheridan issued a decision denying a motion to dismiss post-Actavis, ruling that there is no cash requirement under Actavis. And he's allowed the Plaintiffs to file an Amended Complaint and go forward to clean things up from some other things he dismissed which are not relevant to the Actavis.

Second, the <u>Nexium</u> case that is pending in Boston in front of Judge William Young, he too denied a motion to dismiss, issued a written opinion post-<u>Actavis</u> indicating there's no cash requirement. He also, his opinion deals with the specific issue of a no-authorized generic provision and how a no-authorized generic provision may be the kind of payment that's unlawful under <u>Actavis</u>. So those are the two post-<u>Actavis</u> decisions that are out there.

The <u>Asahi</u> case by Judge Posner I believe is a pre-<u>Actavis</u> case. I think you'll see an awful lot of pre-<u>Actavis</u> law there that's been rejected so it's not relevant.

Finally, Mr. Pace did note that sometimes there's an attachment of the actual agreements in the motion to dismiss stage. We'd actually like to see what happens here not what happened in another case, Effexor, which is that the defendants refused to give us the unredacted agreements. We went forward with a complaint. A motion to dismiss was filed. And in the motion to dismiss we saw the unredacted complaint. Excuse me, agreements. So here, again, that's another one of the reasons we say that let's walk and chew gum, have some modest discovery that occurs. Motion to dismiss is not going to be dealt with December 6th

stage.

MR. SUNSHINE: To add to the last comments, we think the <u>Lipitor</u> and <u>Nexium</u> motions to dismiss are actually cases right on point because both of those decisions the Court shaped parts of the case, parts of the case were dismissed and parts of the case were kept, and that's precisely the set of issues we're facing with some of the allegations, frankly, internally consistent with one another. If we have one complaint, we could have a set of responses back; and just as happened in <u>Lipitor</u> and <u>Nexium</u>, your Honor can shape the case and make it efficient going forward.

THE COURT: I don't want to argue. I appreciate that and I don't want to get into a back and forth sort of arguing a motion to dismiss here. We will deal with that.

I do want to close the loop on the counsel selection issue. What I think the upshot of this discussion we had is we'll get an order out that on an interim basis appoints the committee for each of the groups with the outside of that order being the filing of a consolidated complaint. And that order will contemplate that in the meantime while you're developing a consolidated complaint, you will submit, I suppose, proposals on behalf of each of your respective

firms about what you think parameters of going forward should be, ideas you have for cost containment and then we will take a look at that, and working off of that make some decisions about whether we want to continue with the appointment of a committee with certain parameters attached or do we want to do something different. So sort of stage this out.

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And also just to complete the thought on that, one thing that I think I'm inclined to do is that whatever the outcome of that process is, I think we will likely put into place, and Judge Sullivan and I will talk about how to do this, kind of an ongoing monitoring process of the fees so that we're not dealing with this two years from now. I think that would be effective. It worked really well in a recent death penalty litigation that we had, we monitored fees in that way. As you probably know, fees in death penalty cases can get very, very expensive, too. That worked very, very well, the process we worked on together. We'll probably do something like that, monthly status conferences with Judge Sullivan, monthly reports, something like that. That kind of closes the loop on counsel selection for now.

Let's talk about this proposal Mr. Sobol has made several times about getting some exchange of

materials going while the motion to dismiss is moving forward. What about the patent litigation documents?

MR. BUCHMAN: Your Honor, if I may before you turn to Defendants, I'd like to add a couple of points to what Mr. Sobol said, there are more practical points to bring to the Court's attention. First of all, these documents that were supplied in the underlying patent litigation have already been pulled. They're electronically stored, and there would be absolutely no burden to Defendant other than pushing some buttons and burning them on CDs and turning them over to us with the understanding that even though there's no confidentiality order in place right now they would only be reviewed on an attorneys-eyes-only basis.

THE COURT: Thank you.

MR. PACE: Your Honor, to begin on the patent litigation materials, two points of clarification maybe. It's not quite as simple as pressing a button and handing over those documents. There's a very, very practical issue and a court procedural issue at least, these are document that, to be sure, were cases our clients were involved in, different patent lawyers handled those cases. These are not things that we necessarily even all have complete access to. Some work would be necessary to collect those documents in

the first place, organize them. They weren't necessarily produced in the same way that someone sometimes produces a large antitrust case, a single database. So there is some work and review that would need to be done before the documents are turned over.

More fundamentally, there's not even necessarily permission by the parties sitting in the courtroom to turn those documents over necessarily. Those documents Mr. Buchman suggested were produced in that case subject to protective orders and often with very specific controls for who could see the documents inhouse and outside. So until protective orders are in existence, the Defendants don't have the ability to turn over those documents.

THE COURT: He's not suggesting they be turned over tomorrow. I think he's simply saying that they're happy to enter a protective order that restricts the documents to attorneys-eyes-only in order to facilitate the process. That's what I understood him to be saying.

MR. PACE: I understand. I believe -- this is something we can certainly talk about in more detail but this is something that I think there would still need to be a proposal. There isn't a restriction in the underlying patent cases that would be violating

that, even turning over to outside counsel only. came up in a recent case involving Plaintiff counsel here where the protective order in that scenario involved getting permission from the court even if it was going to be produced an on outside counsel basis. That was in part because some of the materials involved Defendants and other parties who were third parties to subsequent antitrust cases. Maybe that was some of the reasons why there were those heightened protections. So there was a process to go to the patent court to get that permission. If that's what's required, like the other case that's something we were going to keep the Court updated certainly but that's a process so it's not quite as simple as turning over the documents even an on outside counsel basis right away.

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THE COURT: What about the settlement documents?

MR. PACE: The settlement documents strike us as something maybe not necessarily raising the same type of concerns. Again, subject to an agreement for confidentiality and caucusing with the other

Defendants, I think it's something we could talk about.

THE COURT: It seems to me you've got to give up the settlement documents. In this litigation, you're not going to get away with unredacted settlement documents, I don't think.

MR. PACE: Your Honor, I'll agree. I'll note the point Mr. Sobol made about the prior case affects our case. That was a different situation. The Court ruled early on there would be no discovery pending the motion to dismiss whatsoever. Then when the motions to dismiss were filed, I believe those agreement were attached so it happened anyway. I think here we're sort of looking at something different.

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THE COURT: I'm in favor, without prejudging the merits of the motion to dismiss at all, I am in favor generally speaking with the suggestion of the Plaintiffs' group that we begin the process of exchange and try to get that facilitated as much as possible while the period of the consolidated complaint is getting drafted and you're working on your motion to I think it's important to remember that it's dismiss. your clients that ultimately control whatever they did in the context of the patent litigation, protective orders and the parties were adverse, it's not the patent attorneys that decide whether those things need to remain in place. It's your clients. Your clients are in charge. But I understand there's some logistics to it.

What I would suggest is that we set a deadline for you to go back and figure these things out with

your clients and counsel and then you have a conference on it and see if you can't work out a time for this exchange of materials to take place. I'm thinking, you know, give you a couple of weeks to get that done and you all have your conference. If you can't get it done in that conference, then Judge Sullivan can intervene at that point to find out what the problems are.

MR. SORENSEN: I want to make sure that there's an element of understanding of what both sides are talking about. Sobol was talking about not only settlement agreements but the documents exchanged between the Defendants leading up to the agreements that are not subject to any privilege. By definition, they were exchanged. I didn't hear the Defendants when they were talking about distributing the settlement agreements --

THE COURT: I want to just stick with the settlement documents at the moment. All exchange of information leading up to the settlement, that's a big request. That's going to get into some deeper issues of discovery. Not to say it's not doable, but that leads us down the path of electronic discovery. I'd like to start with the low end group here and see what we can get done in a couple of weeks, have you confer on that and get that information exchanged. We do have

Thanksgiving coming up. We're talking about you've got to get a consolidated complaint drafted, so let's see what we get done in a couple of weeks then have you confer. Let's see where you are at least with respect to the patent litigation documents, the settlement documents, then that's probably a good segue to talk about the larger issue of discovery.

What are we looking at here? Let's just assume for a minute that the motion to dismiss is denied --

MR. MILLER: You didn't disclose the date when they're going to file their motion to dismiss.

THE COURT: I'm working with the dates you gave me.

MR. MILLER: That was a proposal that the

Defendant gave to us, so I'm not sure we agreed to it.

I didn't think we agreed to go after February to file
the motion to dismiss.

THE COURT: I misunderstood. I thought you all were in agreement on that.

MR. MELTZER: I think Mr. Sobol pointed out before part of our hesitation to agree to that 60-day schedule is to whether we were going to do anything. If we were going to move forward with discovery, exchange patent documents and some of the settlement agreements, I think we're okay with that. I think Tom

pointed out earlier he didn't want to quibble with a week or two weeks at least from the direct purchasers side. We're okay with that schedule. We wanted to do some discovery in the individual --

MR. SORENSEN: That's our position.

MR. BUCHMAN: We agree with that, the indirect.

THE COURT: We're okay on this schedule with the process I just outlined about getting the exchange of information. It may go beyond what I said. We'll talk about that now. Let's talk about discovery and what we're looking at.

MR. SOBOL: If I may, so they fall -- the discovery buckets if you will, fall in the following categories. There'll obviously be the to-and-fro that precedes the settlement agreements is a liability issue. There will be the need to get produced from the Defendants documents regarding -- or documents and data regarding projections of the consequences of generic entry and similar information, economic information that goes to how it is that generic entry brings down the price and quantities of the drug in this situation. Those are essentially the issues. There will be issues regarding the performance of the agreements following entering into them.

As I indicated, one of the issues under the

statute of limitations issue, for example, is whether or not there are continuing violations. So what things do they perform on the agreement after that? There is the issue of causation. So there, again, there'll be discovery regarding the generic applications that were filed and whether or not and how are we going to prove whether and, if so, when the generic applications would have been approved by the FDA that typically involved getting correspondence between the would be generic and the FDA among other things. There may be on the main factoring side of causation the thrust case of discovery regarding any questions there are regarding developing launch of quantities of products to go forward.

And on class certification, there is the discovery issue of the electronic transaction data. So each of the Defendants will have information regarding what they sold, when they sold it and at what price and to whom they sold it. That's needed on the direct purchasers side and the indirect purchasers side for class certification.

Before I turn -- and that information, by the way, also there's some modeling of damages, of course. I'm sure the Defendants will want -- I should also say that in terms of the number of depositions that get

taken typically, there are usually some 30(b)(6) depositions that are categorical on these issues against each of the Defendants. Once we're able to identify the people who were the actual negotiators, then you're able to identify who you're going to depose

in terms of the negotiators' work.

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THE COURT: Spell that out for me, what you mean by categorical 30(b)(6)?

MR. SOBOL: For instance, one kind of 30(b)(6) we have is a 30(b)(6) on economic issues. So provide the person most knowledgeable regarding your projections of consequence of generic entry in this situation. As to generic companies there might be a 30(b)(6) provide the person most knowledgeable regarding communication with the FDA and your ability or not to get FDA approval. There have been 30(b)(6)s on -- both of them are talking to me at the same time -- on for instance, you know, do you have somebody who has the person most knowledgeable regarding the value of the consideration you got for the settlement That's what I mean by categorical 30(b)(6)sagreement. on those kinds of topics. Sometimes we found it cuts through things and gets right to the chase. You tell us who knows the most about the critical issues in the case. Let's take his or her deposition and find out if

they really knew something or find out the real person who does. That's what I meant by that.

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Our direct, the proposal was that fact discovery would go through the next calendar year with class certification during the next calendar year. expert discovery typically falls into the following Because there are some patent issues here, categories. there will be the need to have a couple of experts that are going to deal with patent issues. If there are clinical issues that we have, we'll have a clinician. If there's a general issue of a patent, we'll have a skilled patent attorney. There's typically an expert or two that deal with causation issues, a regulatory approval expert, a manufacturing expert. There will be an economic expert that deals with market power questions, for instance, and maybe the same with a different economic expert model the damages. Those are some of the broad categories without limiting ourselves.

Obviously, I'm trying to give you a sense that the Plaintiffs are likely to have a half a dozen or maybe ten or so experts covering some fairly wide and diverse and arguably complex issues but hopefully we can make simple issues. That goes for a period of time. The Defendants come forward with their experts.

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We file rebuttal reports. There are depositions that happen in connection with all of that.

Is there anything that you guys were whispering in my ear that I forgot?

Third-party discovery sometimes but I'm not sure we're going to have that issue. Sometimes we have third-party discovery if, for instance, some of the would-be generics are not a Defendant.

If we say there's a case where a generic or two would have entered the market that's not a Defendant in the case, it's not clear to me how much of that or not we're really going to have in this particular situation. So I think that's the broad brush of it.

THE COURT: Your proposal is fact discovery closing approximately a year from now and then expert reports moving on from there, end of November, defense experts January?

MR. SOBOL: There's a direct and indirect purchaser proposal. I don't have the docket number of the direct purchaser proposal.

(Mr. Sobel confers.)

THE COURT: What I have is the indirect. I don't have direct.

MR. SOBOL: It's fair to say the direct proposal is a couple of months later than the indirect's

proposal. We thought that was a more realistic proposal. There's no science to this.

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I will say this in terms of a schedule. Whether it's 10 months from now or 12 moths from now because of fact discovery, I'm also saying this with some bit of trepidation, from my perspective it's the designated trial date that is going to move people to get things done or not. Experience shows that having that as a target means whether or not people are working on weekends or not working on weekends, whether or not they're efficiently doing things or doing things in a And I know the trial dates can sometimes move, but from my perspective, and I know this is the antithesis of what Mr. Pace and former eloquent gang of lawyers can say on their side of this, by having a trial date it's going to be the most efficient way to keep the lawyers fees down, the most efficient way to keep everything else down and move the case.

THE COURT: I don't disagree with that in principal, but I think we'd be really Pollyanna-ish if we set a firm trial date today.

MR. SOBOL: Justice Breyer and I have something in common.

THE COURT: We can leave that for a little bit.

This proposal seems pretty aggressive.

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MR. MELTZER: I have a clean copy served on the Defendants. We didn't file it. We met late last week. It should say direct issue.

THE COURT: What's the Defendants ten-thousand-foot discovery schedule?

MR. SUNSHINE: What I just heard was a massive amount of discovery from Defendants virtually covering every aspect of our business. And if we're talking about patent prosecution dating going back to the '90's, files from 2006 and then all the way up to present, and I think Plaintiffs were also talking just about the discovery they want from us, market definition will be an issue here. There will be a fair amount of third-party discovery that we'll need just on that issue alone. As Defendants we haven't put forward a counter-schedule and we thought that was premature given the agenda for this conference. We're happy to give you a response and give you the discovery. The ten-thousand-foot level is an awful lot to accomplish in a short period of time.

THE COURT: What do you see as the number of experts you anticipate?

MR. SUNSHINE: In these kind of cases, your Honor, our experience has been there are multiple experts. They could be in the five to ten range. 0ne of the reasons why we stress so much to your Honor about deciding the motion to dismiss is the number of issues that can trip in the case which directly affects the number of experts. To give one example, if the new product hopping is in the case or out of the case put in all kinds of issues, FDA approval, is a product providing benefit. As clearly the reverse payment case, then we would have an economist on liability, an economist on damages, an industry expert. So that five to ten number is pretty typical. If the case is bigger and more complicated, we've seen more than that number from each side.

MR. PACE: Your Honor, I'd just like to note for the record -- Jake Pace, again.

The notes with respect to some discovery that we think will come up and maybe some things that we can do early if we're going to get started, as Mr. Sobol put it keep busy in the meantime, we will be propounding as necessary discovery on the Plaintiffs certainly. We're a firm believer discovery is a two-way street, and we'll probably be using that slogan here and there. There are certain things I think are probably easy for the Plaintiffs to produce very quickly that I think would allow us to assess the case early on. It may simply be one, but at least one of the direct purchaser

Plaintiffs is proceeding with the claim based on not necessarily its own purchases but an assignment of another's rights. I think in the American Sales, I was just looking through the American Sales complaint, the earlier version paragraph 20 talks about how American Sales proceeds based on assignment of claims based on purchase from McKesson, the wholesaler. In other words, McKesson in this situation is a direct purchaser, not American Sales. There is an assignment agreement presumably that assigns the claims from McKesson to American Sales. We think that would be one contract that could be produced fairly easy as part of an initial exchange. To the extent any direct purchaser provided an assignment, that is something I think we would want.

Similarly, there are purchase data that may exist in ready form from the perspective of the Plaintiff or reimbursement data that may exist on the part of third-party payors and the indirect purchasers. That certainly we'll pursue at the appropriate time. If it turns out that's something that is push-button ready, that can be part of the equal exchange perhaps.

Lastly, on third-party discovery, I think we would know -- I agree Mr. Sunshine mentioned there would be market definition questions, reasons why we

would be taking discovery of third-party competitors. Oral contraceptives is a highly competitive marketplace. I think there will be issues looking at how some competitors of Defendants viewed the marketplace and adjusted their sales strategy. That would go to the market definition issue. Discovery on third-party competitors would be relevant in analysis of a but-for world and the complaints kind of simplistically say that but for certain conduct generics would have come to market very early and would have taken over the market, generic side of the market completely. It's a hypothetical world that damages would be based on here. You need not look at what other oral contraceptives within or on the market, what else was going on in the real word to see what sales would be. That's a reason why we would anticipate third-party discovery.

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We would also anticipate significant discovery from wholesalers. Cardinal Health, McKesson and Bergen purchase over 90 percent of direct purchases of any drug. And then to the extent that there are Plaintiffs and cases like this, they proceed often, not always, on assignment.

So with large scale purchasers like that who are members of a potential class being proposed here, we

would seek discovery from those wholesalers as well.

They may go to a number of issues in this case, damages in particular, but also impact are the direct purchasers better off in the but-for world that they're supposing than they actually were in the real world.

That's something you would want discovery at every step in the distribution chain to see did somebody pass on the markup or pass on the over-charge.

I mention that because it's something that might take time. It wouldn't be surprising to anyone in this room wholesale sometimes in certain states not in this court's jurisdiction sometimes object to third-party discovery just like competitors who are not here. It's a process that will take time and need to be completed before the Defendants could fully respond to class certification motions that we anticipate down the line should we get there.

MR. SORENSEN: Your Honor, if I may briefly.
THE COURT: Sure.

MR. SORENSEN: Some of the areas of potential discovery that you're discussing with respect to absent class members in particular, if it is pursued by subpoena there also may be motion practice with respect to protective orders that both -- Mr. Pace mentions large wholesalers, McKesson, Cardinal Health and Bergen

are the three largest wholesalers in the United States. In the last 15 years we've dealt with this extensively in connection with these cases. They each have their own outside counsel or law firms that they are represented by and those counsel will have in past cases filed their own motion for protective order. Sometimes we have also filed as class counsel. We are talking about absent class member discovery, which is typically tightly controlled by district courts.

I just wanted to mention that because depending on the scope and exactly what it is the Defendants start to seek, it wouldn't surprise me at all if there were that kind of motion practice that would have to be figured out before actual discovery occurs.

And also in terms of relevant market, market power is an issue. From our perspective, it's not nearly as complicated an issue as defense present it to be given the fact that for the most part brand generic drugs, brand sales and price are largely unaffected by the product until their own generic comes in. So you have a product selling at a dollar with a hundred units of sales, that pretty much stays that way or even goes up regardless of what other products are out there under a generic itself. FDA approved, that's what triggers the change so not the general discussion of

out-market that occurs in other antitrust cases has very limited application to these kinds of cases and that can be another potential area of disagreement, which can then also lead to various motions for a protective order and so forth. So I just wanted to flag those.

THE COURT: What I'd like to do at this point is I'd like to get you into a typical kind of Rule 26 meet-and-confer process where you start talking about what it is that you think you're going to need and try to reach agreements as to what you think you can begin to exchange at this point, even though we're in the midst of a motion to dismiss process.

There's a process, you've been through this before with each other I take it. So there's probably a lot you know that I don't about material that can begin to get exchanged, identification of some of these folks as 30(b)(6) folks. I'd like to get that going now.

I would prefer not to set a full schedule of discovery of the case at this point, because I'd like to see that motion to dismiss process kind of work its way through. But I would like to see you get that discovery, informal discovery process going and maybe even some of the more formal discovery, perhaps

beginning with your first sets of interrogatories, kind of formalize it after you have some of this meet-and-confer so we can get that process started. Even though we don't have a formal case management order in place with hard deadlines in it, there's no reason you can't start getting down that road. That's what I'd like to see happen. Put off the harder issues for when we get through the motion to dismiss process, we know what the shape of the complaint is and then we'll get the order in place at that time and really get rolling with discovery.

Does that make sense to all of you?

MR. SUNSHINE: It does, your Honor.

THE COURT: Any reason why you can't start that process?

MR. SOBOL: No, your Honor. I assume that would also include your Agenda Item Number 10, the e-discovery.

THE COURT: That was actually next on my list.

Let's take a five-minute recess.

(Short recess.)

THE COURT: I wanted to at least give you a chance to catch your flights so we can kind of accelerate through the last items. I think we've covered everything I felt like we needed to cover with

respect to scheduling is fine. We'll pick that up at a future conference.

One thing that I want to have you just know is I intend to use some kind of a monthly status report/conference with you folks once we get into the groove and that would -- my vision of that, subject to discussing it, maybe change it later is the principal lawyers would be here in person but other folks could participate by phone or listen in by phone. It may be ultimately we can get to a point where we could do this by video conference or by telephone. We'll see. I'm open to how that works out.

Another thing I want to get you thinking about is with respect to e-discovery. I don't think we have to go into any depth on that today. It's clear to me this is probably going to involve a lot of e-discovery. The one idea I'm toying with is asking you to designate a 30(b)(6) witness for e-discovery and having Magistrate Judge Sullivan and maybe myself attend that deposition so we get a really early and clear handle on what the e-discovery issues are.

So I think it's likely that we're going to want you to do that, to appoint a technical person since you're a 30(b)(6) guy or gal on these issues and we're going to have a judge there. Okay? So that's

something you should be thinking about.

We talked enough I think about class certification in terms of where it fits into the scheduling, talked a lot about the class or classes so I think we can put off any in-depth discussion about that to a later point.

I think we touched on summary judgment enough for today. We talked briefly about choice of law issues. I don't think we need to go into any more depth on that.

I think I want to talk to you about the website. We're working on that. I don't think it's up to an external yet, but we've got it on an internal template. It will be up shortly. Everything will be on that website, including orders, transcripts, so forth.

I do want to hear about the settlement process and in terms of what your vision is, who will be the mediator, mediators, what you wanted or expect or interested in from the court side. So who wants to start on that.

MR. SOBOL: So in our experience there is mediation. Most of these cases get settled; they don't get tried. There's a bunch of issues that everybody has typically happens at a point much later on during the course of the litigation, certainly after the

12(b)(6) motions are decided and well into things.

Sometimes we select a mediator from outside the Court.

If that's the predilection of the Court that's running the case, that's acceptable to the Court, there are some mediators out there that have handled cases like this in the past so they are familiar with some of the issues and don't have to get an education on things.

Other times we use people who are brand new as well.

Sometimes we do the settlement without any mediators at all because there is -- I mean, these are at least at some level business disputes, if you will, and the lawyers have the ability to communicate with one another.

So absent really sort of fairly clear guidance from the Court in terms of the Court wishes to do something differently, typically there's when we're touching base once a month, whatever the Court randomly says are you talking or not, is this the time or not and then when, as and if it is ripe, something happens. I don't mean to be too loose about it because it's not really. The case gets resolved, the case goes away or the case gets settled or perhaps gets tried. That's really the way we handle them.

From our perspective, if the Court has a strong desire to do something differently, and that sometimes

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happens, we are content to move things along and touch base on it periodically during status conferences when we can then find out if it makes sense to do it.

THE COURT: You all agree with that?

MR. BUCHMAN: We would agree with that in general and we would add one additional point, that there should be at some point a court-ordered mediation And we believe, our perspective is that that should occur after the close of discovery and after class certification briefing has been completed because at that point the parties have a complete picture in front of them and can have a meaningful dialogue.

We would agree with what Mr. Sobol said, if we can have those discussions earlier, that's fine. would be wonderful, but there should be one court-ordered day of mediation after discovery and class certification.

MR. SUNSHINE: We generally agree with what both of our colleagues from the Plaintiffs' side have said. These cases have settled both through the private process and court-supervised process. Clearly parties seem to have closed the gap on our expectations around this case. But a lot of that may be summary judgment I think we'll also have a bit of a type issues. challenge in the fact that the <u>Actavis</u> decision

provides such uncertainty as to what the law is. We had a number of cases pending as we mentioned earlier. So clarity on the development of the law will help shape the parties' expectations.

Having said that, I think we're open for discussion on a resolution. It's probably premature.

THE COURT: So nobody has any fixed idea about who can be or cannot be involved in the mediation? You're all open on that? I specifically want to know whether you -- and I'm not saying this is going to happen, I just want to know, do you expect that the judges who are involved in this case stay the heck out of everything related to mediation, it would be some outsider who does it, or are you open-minded to the idea we utilize the judges perhaps for that purpose?

MR. SOBOL: I should say it more clearly. We've had cases where the Article III judge mediated the settlement in chambers. We've had cases where the Article III judge designates a magistrate judge and settles the case that way. We've had cases where the Article III judge or the magistrate judge formally appoints an outside mediator and that mediator speaks to the court. We've had situations with private mediators and the private mediator does not speak to the Court, and we've had situations --

THE COURT: You're open to all of those things.

That's all I want to get from you at this point.

Okay. So we'll have more conversations about that in the future.

THE COURT: All right. Is there anything else that --

MR. SORENSEN: Housekeeping, pro hac motions.

My understanding is we were going to file them and we were advised to wait for this conference.

THE COURT: Right. You need to get those pro hac motions filed. Ryan can speak to that.

(Discussion held.)

THE COURT: As far as local counsel goes, it seems like you folks have local counsel and the liaison counsel for your group. I guess for you folks, you've got it, too. And I think each of the Defendants have local counsel. We're going to leave things the way they are. I put a waiver of the local counsel rule because I didn't want everybody running out hiring a separate firm for local counsel. It looks to me like everyone is situated where you are for local counsel.

Is there anything else that anybody thinks we ought to talk about today before everybody runs to the airport?

MR. PADWA: I think there should be an order

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asking everybody to eat dinner here in Providence.
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              THE COURT: All right. We'll be talking, I'm
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       sure.
               (Conference concluded at 4:00 p.m.)
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<u>CERTIFICATION</u>

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

----Anne M. Clayton, RPR

November 26, 2013

Date