FTC Press Conference on Pay for Delay Case
May 28, 2015
Transcript

Moderator: Ladies and gentlemen, thank you for standing by, and welcome to the Press Conference call. At this time, all participants are in a listen-only mode. Later we will conduct a question-and-answer session. (Operator instructions.) And as a reminder, your conference is being recorded.

You will now hear background noise and silence until your conference begins.

Justin Cole: Good morning, everybody, and welcome to the Federal Trade Commission. I'm Justin Cole, the Director of Public Affairs. At this point, for those of you in the room, if you could just put your devices on silent, we'd appreciate it, and people joining us on the conference line, if they could just ensure their phones are on mute.

Chairman Ramirez will shortly provide opening remarks on our announcement today, and she'll be followed by Debbie Feinstein, the Director of Bureau of Competition, and we will then open the floor to questions in the room and then on the conference line.

With that, I'll pass it over to Chairman Ramirez.

Chairwoman Ramirez: Good morning, everyone. I want to thank you for joining us for today's press conference. I'm very pleased to announce that the Federal Trade Commission has reached a landmark settlement resolving our antitrust suit against Cephalon Incorporated for unlawfully blocking generic drug competition to its blockbuster sleep-disorder drug, Provigil. This settlement will ensure that $1.2 billion will be available to compensate purchasers of Provigil, including drug wholesalers, pharmacies, and insurers who were harmed by this illegal conduct.

The settlement also includes an injunction prohibiting Teva Pharmaceutical Industries from any similar violations in the future. Teva acquired Cephalon in 2012 and is the world's largest generic drug manufacturer. FTC lawyers were scheduled to go to trial in this case in Federal District Court in Philadelphia next Monday. If approved by the court, this settlement will resolve all of the FTC's charges in this pay-for-delay case.

For well over a decade, the FTC has been committed to stopping anticompetitive pay-for-delay agreements in which a branded drug company pays a generic competitor to drop a patent infringement suit. We've estimated that these pay-for-delay drug deals cost American

consumers and taxpayers billions of dollars in inflated prescription drug prices.

In 2013, the agency won a major victory in the Supreme Court in *FTC v. Actavis*, when the court ruled that reverse payment patent settlements are subject to scrutiny under the antitrust laws. I believe this settlement brings us another step closer to stopping these illegal arrangements.

Now, to provide some background, I'd like to take a minute to explain the facts of this case and why the FTC took action. Had we proceeded to trial, we were prepared to prove that Cephalon unlawfully protected its lucrative Provigil monopoly by reaching agreements in late 2005 and early 2006 with four generic drug makers, Teva, Barr, Mylan, and Ranbaxy, to drop their patent challenges, which delayed generic entry for six years.

In exchange for settling, the generic drug makers received compensation from Cephalon worth a combined $300 million. This compensation came in the form of side transactions entered into at the same time as the patent settlement. The side deals involved purchases of active pharmaceutical ingredients, intellectual property licenses, and drug development deals. But overwhelming evidence which the FTC would have presented in court shows that the purpose of those transactions was to induce the generic companies to abandon their patent challenges.

I'd like to sum up by saying that this settlement demonstrates the FTC's ongoing commitment on behalf of consumers to ensure that America's healthcare markets remain competitive, resulting in lower drugs prices and greater innovation for consumers. Let me also emphasize that the monetary payment in this case is important not only because pharmacies and other purchasers who overpaid for Provigil will get money back, monetary relief is also a key tool in deterring companies from committing antitrust violations since it deprives wrongdoers of ill-gotten gains resulting from their illegal conduct. As the settlement clearly underscores, the FTC will not hesitate to use all of the remedies available to us to obtain meaningful relief for affected customers and ensure a level playing field for competitors.

Finally, I'd like to thank the FTC case team and especially Marcus Myer and Brad Albert, as well as Debbie Feinstein, the Director of our Bureau of Competition, for their hard work in bringing this matter to a favorable resolution. I'd like to now turn the floor over to Debbie, so that she can explain the details of the proposed settlement.

Debbie Feinstein — Thank you, Chairwoman. Let me add my thanks to Marcus Myer, Brad Albert, and the entire team who has worked so hard for so many years on these issues. The proposed order has two important features: First, an

injunction that prevents Teva from engaging in a common form of reverse payments agreements, and second, a $1.2 billion payment that will be used to provide redress to purchasers who overpaid as a result of Cephalon's conduct.

First, the injunction is designed to prevent Teva from using supposedly independent business deals as a mechanism to share monopoly profits. The order bars Teva from entering into certain business deals of the type at issue in the Cephalon litigation. Specifically, it cannot enter into a business deal expressly conditioned on a patent litigation settlement that restricts that generic's entry or enter into any business deal within 30 days of such a patent settlement.

The order does not prevent Teva from entering into truly independent business deals. It also preserves Teva's ability to enter into settlement agreements that would normally be unlikely to be anti-competitive. These include straightforward settlements for an entry date before patent expiration or settlements involving payments to avoid future litigation costs. The proposed injunctive relief will apply to all branded and generic US pharmaceutical operations of Teva, the largest generic drug maker in the United States.

Second, as the chairwoman just outlined, the proposed order requires Cephalon to pay $1.2 billion into a settlement fund that will be used to provide redress to purchasers who overpaid for Provigil as a result of Cephalon's illegal conduct. Any private settlements that preceded the establishment of the fund can be credited against the fund. The settlement fund will also be used to satisfy settlements or damage awards for other parties, such as states or federal purchasers that have claims against Cephalon.

The FTC will not be a claims administrator, however. Consumers will receive any refunds through the class action settlement not directly from the FTC. Any unclaimed funds will go to the US Treasury.

In sum, we believe that the proposed relief is strong, fair, and appropriate given the consumer harm that the FTC charge resulted from the anticompetitive conduct at issue here and that the FTC staff was prepared to prove at trial. Thank you.

Justin Cole — Thank you. So, at this time we'll open it to questions from media in the room. If you could just identify yourself and your media organization, we'd appreciate it. Thank you.

W — Yes?

M [Indiscernible] with the *Wall Street Journal*. I get the injunctive relief part, but the settlement fund, could you just explain the mechanism of how this adds to these payouts? It sounds like for people who have legal claims in court that they settled, Teva is basically committing this fund to pay the claims that it would agree to in court. I'm just not sure exactly the mechanism of how that works or what the commitment adds to what they would have had to do in court.

Chairwoman Ramirez The main objective from the commission's perspective is to ensure that Cephalon does not keep ill-gotten gains. It achieved six years of additional monopoly profit by virtue of these anticompetitive settlement arrangements, so our aim is to ensure that Cephalon doesn't keep those. And so this money will be deposited into a settlement fund, and existing settlements will be offset from the $1.2 billion. But in addition to existing settlements, we've ensured that there's going to be ample amount for any future settlements, and if there's any remaining amount, that money will go to the US Treasury.

M What's the timeframe for that if there was leftover money?

Chairwoman Ramirez It's up to the total of ten years because litigation in these matters are very complicated and it can take some time for those who were affected by the anticompetitive conduct to bring claims. So, we want to ensure there's a sufficient time for that process to unfold, and then at that point, any funds that do remain will go to the US Treasury.

W [Indiscernible] from GCR. How does this settlement compare to what the Commission was expecting to obtain through disgorgement and other remedies if it had gone to trial?

Chairwoman Ramirez Well, at trial, we would have sought to establish a disgorgement amount, and that certainly would have been the subject of testimony by our experts. I will say that amount is a settlement figure, so it is less than we might have obtained at trial, but of course, litigation is always uncertain, not to mention that it takes time for eventual appeals to unfold and conclude. So, our aim in reaching a settlement was to ensure that affected purchasers would receive immediate relief and then also that we obtained very strong relief that will take effect immediately.

Dave Dave McLaughlin at *Bloomberg*. I was wondering if this settlement is basically a template for future cases that you foresee payments of this size going forward, and then if you could just comment a little on what you think the impact on the industry is from the settlement going forward.

Chairwoman Ramirez Sure. Look, in case there was any doubt, I think this settlement shows that the FTC is absolutely committed to putting a stop to these types of illegal

pay-for-delay deals, and not only are we going to seek to put a stop to them, we are also going to go after any ill-gotten gains that may have been obtained during the course of any illegal conduct, so that's first and foremost.

And again, I believe it's going to send a signal. My hope is that this will cause companies who might have been thinking about entering into these types of deals will think twice. I think the Actavis decision by the Supreme Court back in 2013 sent a strong message, and that was certainly an important victory for the Federal Trade Commission. And this is just yet another step in our battle against these illegal deals.

If no one else has any questions, then I guess we'll conclude. Thank you very much for—

Justin Cole: So, if there are no further questions in the room, we have some on the conference call, so we'll open it up for them and pass over to you.

Moderator: Thank you. We have a question from Diane Bartz from Reuters. Please go ahead.

Diane: Similar to the gentleman at the *Wall Street Journal*, I was wondering if you could give me a breakdown of how much has been promised or reached in these independent civil agreements and how much additional redress that the FTC has got.

Chairwoman Ramirez: Diane, as I'm sure you're aware, there was an announcement that the settlement by direct purchasers, a class action that was resolved approximately a month ago, and the public information is that settlement was in the amount of $512 million. There is also another settlement that was arrived at, but the sum is confidential, so I can't tell you that figure. Those are the two existing settlements that we are aware of.

Diane: Okay, go ahead.

Chairwoman Ramirez: So, as you can see, the $1.2 billion disgorgement figure that we've achieved provides ample additional funds for any further redress. But let me also just emphasize so that there's no confusion, our settlement is not set a ceiling for any recovery. We believe that that amount will be enough, but it does not set a ceiling.

Diane: Okay, another quick question I have is I'm wondering about Provigil and its use by the military. Was that part of the impetus for you guys to focus on this particular drug?

Chairwoman Ramirez We were focused on what we believe to be anticompetitive conduct, and we brought a lawsuit once we learned and investigated the facts and then proceeded with the enforcement action. Our aim is to achieve and ensure that all affected purchasers can obtain meaningful relief.

Diane Thank you.

Moderator Thank you. And we also have a question from the line of Matthew Herper from *Forbes*. Please go ahead. Mr. Herper, your line is open. We'll move to the line of Mary Serebrov from *Bio World*. Please go ahead.

Mary Hello. Since these kind of settlement involve both a brand company and generic companies, so far the FTC has only gone after the brand companies. Are you looking at in the future also going after generic companies that participate in these pay-for-delay settlements?

Chairwoman Ramirez In this particular case, we did only sue Cephalon, and that was a decision that was made by the commission. We brought this suit back in 2008. Our aim was to seek and obtain an immediate or a quick and prompt resolution so that there could be generic entry, so we did make a decision not to sue the generics. It was an attempt to streamline the litigation in the hopes of obtaining quick and prompt resolution of the lawsuit.

As it turned out, however, the lawsuit did end up getting delayed, and here we are. The trial was about to begin only in June of 2015. But in others, we have sued generics. That was just simply a decision that was made in this particular context.

Mary One other question, what factors go into your determination as to how large the settlement should be in cases like this?

Chairwoman Ramirez Well, it all depends on the facts of the case. As part of the case that we intended to present, we did have an estimate of what we believed would have been ill-gotten gains. But again, the amount of the settlement, it is a settlement figure, so it is one that we believe again will guarantee that affected purchasers will have meaningful relief, but it is a compromised figure, as happens in all settlements.

Mary Thank you.

Moderator (Operator instructions.) We're going to go to the line of Jonathon Shacat from *FDA News*. Please go ahead.

Jonathon Do you have an estimate of how much Cephalon earned through the ill-gotten gains?

Chairwoman Ramirez We were prepared to present an estimate during the course of trial, and there would have been undoubtedly challenges to that figure. At the end of the day, the $1.2 billion that constitutes our settlement figure is one that we believe is adequate and appropriate under the circumstances of this case, particularly when you also look at the very strong injunctive relief that we were able to obtain. It binds not only Cephalon itself, but also the entire US operations of its parent, Teva Pharmaceuticals.

Jonathon How much money was earned through the ill-gotten gains?

Chairwoman Ramirez Again, we would have presented a figure had we gone to trial, but the amount that we settled on is one that we think is an appropriate figure for resolution of this type of case.

Moderator And our next question is from Barney Jopson from *Financial Times*. Please go ahead.

Barney Yes, hello, I have a couple of technical questions. The first is has Teva actually admitted wrongdoing here, or is this one of those no-admission settlements?

Chairwoman Ramirez There has been no admission of wrongdoing. We certainly believe that we had overwhelming evidence to establish our case, but we did decide to settle. We think it's a good outcome. Had we proceeded to trial, it could have taken some time for the conclusion of the trial itself and any appeals. Instead, we've got relief that will take place immediately upon the court's approval.

Barney Okay, and then the second one was by when does Teva have to pay this $1.2 billion?

Chairwoman Ramirez We can provide you that information. I don't have it at the ready. Keep in mind this is a settlement that still needs to be approved by the court, so those papers are being submitted today, but we can certainly provide you that information at a later time.

Barney Okay, thanks.

Moderator Our next question is from the line of Matthew Herper from *Forbes*. Please go ahead.

Matthew Hopefully this works this time. Can you hear me?

Chairwoman Ramirez Yes.

Matthew — Okay. First, is this the largest pay-to-delay settlement you've had? And then my broader question is this happened so long ago, and Cephalon was bought. Most of the executives there, I mean, a lot of them would have gotten payouts or have left. The company obviously profited and then sold itself. Is there any potential for going after actual people involved in doing this as opposed to companies in trying to create disincentives if pay-for-delay deals are so bad?

Chairwoman Ramirez — When we first initiated the lawsuit, again, the aim was to foster the entry of generic competition. Unfortunately, because of delays in the litigation process, that proved not to be feasible, so we were then put in a position of having to seek other appropriate relief, and that's why we went and made a point of seeking disgorgement.

This is the largest settlement in FTC history for this type of case. It's $1.2 billion. That's a big sum, and I think that will send a very strong signal to any company that is contemplating entering into any type of deal that is anticompetitive. I think the FTC has been absolutely committed to this effort to put a stop to these types of deals. At the same time, there's no question that pharmaceutical companies have gotten incredibly creative in the way that they try to get around the antitrust laws, so we're going to continue our fight. And I believe that both the Supreme Court ruling in the Actavis case years ago and this particular action sends a very strong signal to everybody in this marketplace.

Moderator — And we'll move to the line of Melissa Lipman with Law360. Please go ahead.

Melissa — Hello. I was just wondering when this would be before put before the judge for approval. Will you still be in court on Monday to present this to Judge Goldberg?

Chairwoman Ramirez — The papers were filed already, and there will be no court appearance on Monday in light of the settlement. Then the court will of course review the proposed settlement and then take action at that time.

Melissa — Okay, thank you.

Moderator — Thank you. We'll move to the line of Brenda Sandburg with the Pink Sheet. Please go ahead.

Brenda — Yes, I wondered how you came up with the cap on litigation expenses of $7 million in future pay-for-delay deals.

Chairwoman Ramirez That was arrived at based on some public information. If you want to get into some more details, I can certainly have Debbie address those, but generally speaking, it was based on publicly available information.

Brenda Thank you.

Moderator (Operator instructions.) We'll go to the line of Aayden Fry from *Generics Bulletin*. Please go ahead.

Aayden Good afternoon from the UK. Just a question on the permanent injunction, to what extent does this form a template in terms of the $7 million litigation expenses and the 30-day limit on business transaction for other cases, or was this tied specifically to this case?

Chairwoman Ramirez Well, I think generally speaking it does convey an important message about what we believe to be anti-competitive conduct, but I will say that the order was tailored to the particulars of this case so it doesn't purport to define every single situation that we believe might raise significant antitrust concerns. So, tailored to the case, it would be a template, but it's not an attempt to define everything that could be problematic industry-wide in connection with these types of arrangements.

Aayden Thank you.

Moderator And at this time, there are no further questions in queue.

Justin Cole Thank you. So, as there are no further questions, we'll end the press conference there. Thank you for attending today. If you have any further questions, please reach out to the Office of Public Affairs. Thank you.

Moderator Thank you, and that does conclude our conference for today. Thank you for your participation and for using AT&T Executive TeleConference. You may now disconnect.