FEDERAL TRADE COMMISSION'S BUREAU OF COMPETITION AND THE U.S. DEPARTMENT OF JUSTICE'S ANTITRUST DIVISION

HEARING

BEFORE THE

SUBCOMMITTEE ON COURTS AND COMPETITION POLICY

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

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FEDERAL TRADE COMMISSION'S BUREAU OF COMPETITION AND THE U.S. DEPARTMENT OF JUSTICE'S ANTITRUST DIVISION

TUESDAY, JULY 27, 2010

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS AND
COMPETITION POLICY
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:30 a.m., in room 2141, Rayburn House Office Building, the Honorable Henry C. "Hank" Johnson, Jr. (Chairman of the Subcommittee) presiding.

Present: Representatives Johnson, Conyers, Gonzalez, Quigley, Polis, Coble, Chaffetz, Smith, Goodlatte, and Issa.

Mr. JOHNSON. All right right. This hearing of the Committee on the Judiciary, Subcommittee on Courts and Competition Policy will now come to order. Without objection the Chair is authorized to declare a recess. And let me take the opportunity to apologize for being dilatory. What can I say?

Today's hearing is our first oversight hearing over the antitrust enforcement agencies under this Administration. For me, the antitrust laws are fundamentally about fairness.

We need to ask ourselves: Are we keeping the playing field level? The next Bill Gates or Sergey Brin could be in the audience right now or in school, yet he or she will never be able to become this country's next great entrepreneur if we allow anticompetitive practices to keep them out of the market. Our economy and our workers will be worse off for it.

For these reasons our antitrust agencies must remain ever vigilant. Over the past few decades fairness has been compromised by ideological shifts in antitrust law. We have seen a gradual adoption of certain free market reasoning by the courts and the enforcements agencies alike that has chipped away at the ability of plaintiffs to access the courthouses.

Namely, 6 years ago Congress created the Federal Trade Commission because it felt that the Supreme Court was limiting the effectiveness of the antitrust laws and too deferential to big business. In the past decade we have seen a movement away from strict prohibitions under the antitrust law and decisions like the Trinko and Credit Suisse cases, which suggest that there is less of a need for antitrust in the business world.

Personally, I am not convinced. I have been active on several of these issues trying to reopen the doors that courthouses have closed. I have also been instrumental in getting the DOJ the tools they need for criminal prosecution, but balancing that with the need for civil suits. I want to thank the DOJ for working with us on this during the reauthorization of ACPERA.

Now, before we move on let me just say a word about the scope of this hearing. Certainly one of the areas of greatest interest is merger enforcement. This Subcommittee has examined the implications of a number merges, such as NBC-Comcast and Ticketmaster-Live Nation on their industries, and while it is fair game to ask our witnesses for their thoughts on broad issues of merger policy, let us respect the fact that they aren't able to discuss the specifics of any ongoing merger review or make any sort of commitment about the future outcome of a merger review.

I now recognize my colleague, Howard Coble, the distinguished Ranking Member of the Subcommittee, for his opening remarks.

Mr. COBLE. Thank you, Mr. Chairman.

Good morning to all.

Antitrust law affects every industry, as is evident from the wide variety of hearings that the House Judiciary Committee has held under its antitrust jurisdiction. In the last few years the Committee has held hearings on the role of antitrust in telecommunications, sports, oil, and gas, airlines, financial services, and railroads, among other industries.

Given the impact, Mr. Chairman, of antitrust law on the American economy it is vital, in my opinion, to reexamine how well these laws are working, particularly in the light of the innovation that today's high-tech economy has brought forward. Today's hearing gives us the opportunity to see how these laws are being enforced and whether there are areas where congressional intervention would be appropriate.

For example, the antitrust agencies are in the best position to assess recent trends in international antitrust enforcement and to provide Congress with guidance on how best to promote comity between the multiple antitrust enforcement agencies around the world. While I respect the professionalism and rigor with which the Department of Justice and the Federal Trade Commission pursue antitrust enforcement, I have some concerns as well.

For example, my district judge in the District of Columbia recently ruled against the FTC and a discovery dispute regarding reverse payments in the pharmaceutical industry. In that ruling the judge raised concern that the FTC may have disclosed confidential information to third parties and may have improperly coerced the parties into negotiations under the threat of legal action.

If in fact true, these allegations are serious. That said, I know that the FTC has challenged these assertions and I look forward to the Chairman's comments clarifying what actually did take place.

With respect to Assistant Attorney General Varney, I know that the Department of Justice and the Department of Agriculture have held a number of joint hearings in recent months on antitrust and agricultural issues. My own district back home in Carolina—North

Carolina—has a number of AG enterprises, and I look forward to hearing what the department recommends in this area.

Over the last 2 decades the Department of Justice and the Federal Trade Commission have issued a series of guidelines to help provide clarity to their enforcement approaches. Recently both agencies have released draft revisions in their merger guidelines. I look forward, as well, to hearing more about those changes and what they mean for business that plan to merge.

One set of guidelines that has not changed much, however, are the health care guidelines, which were released in August 1996. That was nearly a decade-and-a-half ago, and I know that there have been a host of changes in the medical marketplace since then.

I have heard complaints from medical professionals that these guidelines no longer reflect market realities. My question to each of our panelists is, why have these guidelines not been revised, and do you have any plans to do so?

I look forward to hearing the testimony from our two distinguished guests, Mr. Chairman. And, Mr. Chairman, for the record I would like to make a request that we invite the trade associations representing the pharmaceutical industry to respond, if they would, to the charge that appears before us, as I am particularly concerned about the projected cost to consumers from 2009 to 2019, if that would be in order, Mr. Chairman.

And with that I yield back.

Mr. JOHNSON. Point well taken, Mr. Coble. And I thank you for your opening remarks.

I will now turn to the gentleman from Michigan, John Conyers, the Chairman of the Committee on Judiciary, and a distinguished Member of this Subcommittee, for his comments.

Mr. CONYERS. Thank you very much, Mr. Chairman. Hank Johnson, I appreciate all that you and this Committee do.

Me and the Ranking Member are pleased to join you today. We think this is a very important discussion that we are having. And I join in with Howard Coble in thinking we might well examine the issue that he raised in his closing comments.

First of all, to have the assistant attorney general, Ms. Varney, and the chairman of the Federal Trade Commission, Mr. Leibowitz, together here is a very strong statement, and we look forward to a very important discussion.

Antitrust enforcement is critical to the capitalist system. Free and competitive markets are the foundation of an economy like ours so that when markets fail the economy fails. We have seen over and over the fact that Federal antitrust enforcement at either the Department of Justice or FTC have intervened to keep a balanced market protecting consumers all the way from the telephone monopoly, oil trusts, Microsoft—we have got another case hanging out there right now.

They are huge decisions, and it is important in this era because of the increasingly interconnected, high-tech system of doing business. It makes the implications of many of this conduct has far more influence and effect upon the economy because of the global, high-tech interconnectedness of many of the corporations and the subject matter.

The big issues in antitrust arise in highly technical fields and intersect with complex intellectual property issues. Consumers demand that diverse products made my different firms work together. The Internet must function as seamlessly as possible regardless of what products or services are being used, and that digital information be widely and conveniently available.

In many cases this interconnected economy requires that firms that might ordinarily be rivals share technical information or develop common standards to ensure that the products work together. And we have seen so often how high-tech firms quickly come to control huge markets. Usually the first ones there lay down some pretty large footprints that we spend a lot of time undoing.

In the 1990's Microsoft, Intel, and the new giants emerging today provide critical products and services but they present huge antitrust challenges. That is what we are here to talk about, and how these two important parts of our government relate to each other as well.

In high-tech agriculture the issues are the same. In the intersection of patent law and antitrust, where companies like Monsanto have patented critical genetic materials, we are faced with new challenges.

Now, the case for strong antitrust leadership has never been more important than it is now. As a matter of fact, we are coming off the ropes right now in that regard. As the 44th President said, we have had the worst period of antitrust enforcement since the last half of the last century.

There were no Title II cases brought during the entire 8 years of the previous Administration. There have been none brought now. And the global corporate giants keep getting larger and larger.

And so I think there are plenty of challenges to the Committee and to the heads of the branches of government that are with us today.

In the courts it has been even worse. Until the American Needle case the Supreme Court of the United States ruled for the defendants in 10 antitrust cases in a row; in the lower courts over 10 years, the defendants have won 221 out of 222 rule of reason cases.

At all levels of our Federal judicial system so-called "Chicago School theories" have taken root that make it difficult to establish antitrust violations in the first place. There is an assumption that business can be trusted to do the right thing and that the markets know best, which is almost incredible to repeat here in public in broad daylight.

Of course, leading them all is Citizens United. So that is why I have heartened—I have been heartened to see the FTC push to expand Section 5 authority to prohibit unfair competition, heartened to see the Department of Justice withdraw the ill-considered Section 2 report.

The question is, what are we doing, though, now that we have withdrawn the report? It is one thing to reject the report, but how do we—where do we go from there? And so I am looking forward to joining the Committee in this examination of these very critical issues.

I welcome and thank the witnesses for being here.

Mr. JOHNSON. Thank you, Mr. Chairman.

We will now turn to the respected and distinguished Member of the Judiciary Committee—the Ranking Member—and also Member of this Subcommittee, Mr. Lamar Smith, from Texas.

Mr. SMITH. Thank you, Mr. Chairman.

The Judiciary Committee has a long history of oversight to ensure that American markets retain healthy competition. At the heart of that competition is the Sherman Act, which the Supreme Court has dubbed the Magna Carta of free enterprise.

Antitrust laws are unusual in our legal regime in that they are enforced by two Federal executive branch agencies—the Department of Justice and the Federal Trade Commission. Antitrust enforcement has also expanded beyond America's borders. In 1890 the United States became the first country to codify an antitrust law. Today over 100 countries have some sort of competition law, including China.

This hearing gives us the opportunity to see how the two antitrust agencies are faring in enforcing U.S. antitrust laws in a globalized economy. During the campaign President Obama promised to reinvigorate antitrust enforcement, so my question for today's hearing is this: How have things changed from the previous Administration to this one? How, for example, are the two agencies responding to international enforcement efforts by countries like China?

At the Antitrust Division Assistant Attorney General Varney made a very public revocation of the previous Administration's Section 2 report. How as this affected your approach to Section 2 cases? Has this Antitrust Division brought any monopolization cases? How do those numbers compare with the previous Administration?

One area of strong enforcement by the previous Administration was criminal prosecution of price-fixing conspiracies. How many new criminal prosecutions has this Antitrust Division brought compared to the previous Administration? With respect to merger enforcement, how many more cases has this Administration brought than the previous one?

At the Federal Trade Commission I have similar questions about how enforcement has varied from the previous Administration to this one. For example, has the FTC brought more cases under Section 5 than during the previous Administration?

Of course, numbers tell only part of the story. There are also questions about the types of cases that are being brought and how they are being prosecuted.

In 2008 Chairman Conyers and I sent a letter to the FTC raising concerns about the different enforcement procedures and standards that the FTC uses in pursuing merger challenges. It is my understanding that the FTC has continued to argue for a lower preliminary injunction standard than the Department of Justice. This difference in approaches concerns me and it is something that I plan to follow up on.

I also have questions about the recent decision by a Federal magistrate judge in FTC v. Bisaro. The judge in that case has raised troubling questions about actions that the FTC allegedly took to negotiate a deal between two private companies.

I know that the FTC has responded to the interrogatories and has challenged the assertions made by one of the lawyers in the case. However, I would like Chairman Leibowitz to give us a further understanding of the facts in this matter.

I support robust antitrust enforcement. It is the key to maintaining competitive markets and ensuring that consumers have access to the most goods at the lowest prices possible.

However, antitrust enforcement should be fair and transparent. American businesses need to have clear rules of the road in order to compete effectively against each other and in world markets.

I look forward to hearing the testimony today of Chairman Leibowitz and Assistant Attorney General Varney on these and other matters, and I hope that they will respond to these questions either verbally or in writing after this hearing.

I thank you, Mr. Chairman. I will yield back.

Mr. JOHNSON. I thank the gentleman for his statement.

Without objection other Members' opening statements will be included in the record, and I am now pleased to introduce the witnesses for today's hearing.

Our first witness is Christine Varney, assistant attorney general for the Department of Justice's Antitrust Division. Ms. Varney was confirmed as assistant attorney general for the Antitrust Division in April of 2009.

Prior to joining the DOJ she was a partner at the law firm Hogan Lovells. From 1994 to 1997 she served as a commissioner of the Federal Trade Commission.

Our second witness is Jon Leibowitz, chairman of the Federal Trade Commission. Mr. Leibowitz was designated chairman of the FTC by President Obama in March of 2009, having served as a commissioner since 2004.

Prior to joining the FTC Chairman Leibowitz served as chief counsel to the Senate Antitrust Subcommittee as well as chief counsel to Senator Herbert Kohl. He has also previously worked as an attorney in private practice.

Thank you both for your willingness to participate in today's hearing. Without objection your written statement will be placed into the record and we would ask that you limit your oral remarks to 5 minutes.

You will note that we have a lighting system that starts with a green light. At 4 minutes it turns yellow, then red at 5 minutes. After each witness has presented his or her testimony, Subcommittee Members will be permitted to ask questions subject to the 5-minute limit.

Assistant Attorney General Varney, will you please begin?

Good morning.

TESTIMONY OF THE HONORABLE CHRISTINE A. VARNEY, ASSISTANT ATTORNEY GENERAL FOR ANTITRUST, U.S. DEPARTMENT OF JUSTICE, WASHINGTON, DC

Ms. VARNEY. Thank you, Mr. Chairman.

Chairman Conyers, Members of the Subcommittee, it is a pleasure to be here today on behalf of the Justice Department and discuss the Antitrust Division's work over the last year. Competition, as many of the Members have noted, is a cornerstone of our Na-

tion's economic foundation. At the Antitrust Division we use sound competition principles and antitrust precedents to evaluate each matter carefully, thoroughly, and in light of its particular facts.

Our enforcement helps keep markets competitive, promotes consumer welfare, and spurs innovation. We appreciate the Subcommittee's active interest in and strong support of our law enforcement mission—yes?

Mr. JOHNSON. Would you pull the microphone just a little closer? Thank you.

Ms. VARNEY. Thank you, Chairman.

Thank you, Chairman.

I am surrounded by chairmen.

We are particularly thankful that this Committee, with the support of the Obama administration, led the effort to eliminate antitrust immunity for the health insurance industry.

Merger enforcement continues to be a core priority for the division. We are committed to blocking mergers that will substantially reduce competition.

For instance, we are litigating a case involving the Nation's largest dairy processor seeking to restore competition so that schools, grocery stores, and consumers in Illinois, Michigan, and Wisconsin, will pay lower prices for milk. Our intended challenge to Blue Cross Blue Shield of Michigan's proposed acquisition of Physicians Health Plan led the parties to abandon their deal. In both matters we coordinated closely and successfully with the states' attorneys general.

We have also settled cases when our competitive concerns can be addressed. In the Ticketmaster settlement the merged company divested more ticketing assets than it gained from the merger and subjected itself to tough anti-retaliation and anticompetitive bundling restrictions.

At the same time I want to underscore that we are also committed to quickly closing investigations of mergers that do not threaten consumer harm, such as Oracle's acquisition of Sun and Microsoft's joint venture with Yahoo.

In our criminal program we continue to uncover and prosecute a number of cartels that inflict significant competitive harm. These efforts were recently enhanced by the Congress' extension of the Antitrust Criminal Penalty Enhancement and Reform Act, ACPERA. Again, we thank you for leading the effort to extend that program through a 10-year reauthorization.

Our recent prosecutions have resulted in significant fines and jail time. In 2009 the division obtained more than $1 billion in criminal fines.

Our civil non-merger program remains active as well. In addition to our ongoing investigations, which I cannot discuss, let me just mention two matters that have settled.

The first concerns the largest seller of electric capacity in New York City. In that case we alleged that Keyspan engaged in an anticompetitive swap transaction that likely increased electricity prices. That settlement, now pending, includes a $12 million disgorgement payment. The second case, which settlement is also pending, enjoins a group of Idaho surgeons who organized a boycott

of Idaho's worker compensation system, essentially refusing to treat injured workers.

The Antitrust Division has stepped up its efforts to strengthen markets and preserve economic freedom and fairness. Promoting competition principles through broad advocacy efforts and regulatory outreach is one of our highest priorities. The division works with a broad range of Federal and state agencies to promote competition across a number of vitally important industries, including transportation, energy, telecommunications, banking, and agriculture.

My first year in the department has been remarkable. Working at the Justice Department with Attorney General Holder and the dedicated men and women of the Antitrust Division, we are doing all we can to ensure that our markets are open and fair, giving business predictability and stability, consumers more and better choices, and spurring innovation. I have enjoyed a very close working relationship with Chairman Leibowitz, and we continue to address the Nation's anticompetitive problems together.

That concludes my remarks, and I have provided much longer written statement that describes some of our matters in more detail. I am grateful to have the opportunity to be here and look forward to answering your questions.

[The prepared statement of Ms. Varney follows:]

PREPARED STATEMENT OF THE HONORABLE CHRISTINE A. VARNEY

Department of Justice

STATEMENT

OF

CHRISTINE A. VARNEY
ASSISTANT ATTORNEY GENERAL
ANTITRUST DIVISION

BEFORE THE

SUBCOMMITTEE ON COURTS AND COMPETITION POLICY
COMMITTEE ON THE JUDICIARY
U.S. HOUSE OF REPRESENTATIVES

HEARING ENTITLED

"THE FEDERAL TRADE COMMISSION'S BUREAU OF COMPETITION AND THE U.S. DEPARTMENT OF JUSTICE'S ANTITRUST DIVISION"

PRESENTED ON

JULY 27, 2010

STATEMENT
OF
CHRISTINE A. VARNEY
ASSISTANT ATTORNEY GENERAL
ANTITRUST DIVISION
BEFORE THE
SUBCOMMITTEE ON THE COURTS AND COMPETITION POLICY
COMMITTEE ON THE JUDICIARY
U. S. HOUSE OF REPRESENTATIVES
OVERSIGHT HEARING ON
THE FEDERAL TRADE COMMISSION'S BUREAU OF COMPETITION
AND THE DEPARTMENT OF JUSTICE'S ANTITRUST DIVISION
PRESENTED
JULY 27, 2010

Good morning Chairman Johnson and members of the Subcommittee. It is a pleasure for me to appear before you today on behalf of the Department of Justice to discuss with you the work of the Division over the last year.

Competition is a cornerstone of our nation's economic foundation. The Department of Justice's Antitrust Division takes a measured approach to enforcement using sound competition principles, evaluating each matter carefully, thoroughly, and in light of its particular facts. Our enforcement helps keep markets competitive, thereby protecting consumers and spurring innovation. We appreciate this Committee's active interest in—and strong support of—our law enforcement mission. We are particularly thankful that this Committee, with the support of the Obama Administration, is leading the effort to eliminate antitrust immunity for the health-insurance industry.

The Antitrust Division is galvanizing the tremendous skills of our lawyers and economists to coordinate strong enforcement with thorough market and policy analysis, as part of a broad effort to encourage competition. In addition to our enforcement efforts, the Division plays a vital role within the government promoting competition. We are mindful that initiatives

in other parts of the government can often have significant competition implications, and we share our expertise throughout the government. We also listen to other parts of the government, academics, and marketplace leaders to learn from them and anticipate potential antitrust problems to better serve American consumers.

Merger enforcement continues to be a core priority for the Antitrust Division. We are committed to going to court to block those mergers that will substantially reduce competition. The commitment to litigate enhances our ability to negotiate settlements that simultaneously enable any procompetitive aspects of a deal to go forward yet also prevent harm to consumers. At the same time, we are also committed to quickly closing our investigations of mergers that do not threaten consumer harm so as not to unnecessarily impede business operations. Just as consumers rely on us to protect them against harmful business combinations, businesses should also be able to rely on us to quickly and efficiently clear their lawful transactions.

One enforcement action that remains in active litigation involves the nation's largest dairy processor. In January, the Division filed suit to undo the merger of Dean Foods and Foremost Dairy, alleging that the merger reduced competition for milk sold to schools, grocers, and retailers in Illinois, Michigan, and Wisconsin. The Department's suit seeks not only to undo the 2009 deal but also an order requiring Dean to notify the Department before any future acquisition involving a milk processing operation. More generally, this enforcement action is indicative of this Department of Justice's commitment to our nation's farming industries.

Investigation dynamics can be difficult in transactions, like the one between Dean and Foremost, where the pre-merger notification process under the HSR Act does not apply and the parties are free to close their transaction before review of the transaction is complete. Nevertheless, the Division continues to investigate and, where appropriate, take action against

transactions that do not require pre-merger notification. Another example of our law enforcement was the abandonment by Blue Cross-Blue Shield of Michigan of its proposed purchase of Physicians Health Plan of Mid-Michigan. Had that acquisition gone forward, it would have given Blue Cross control of nearly 90 percent of the commercial health insurance market in the Lansing, Michigan, area, resulting in higher prices, fewer choices, and a reduction in the quality of commercial health insurance plans purchased by Lansing area residents and their employers. The acquisition also would have given Blue Cross the ability to control physician reimbursement rates in a manner that could harm the quality of health care delivered to consumers. We informed the parties that we would file an antitrust suit to block the transaction, and the parties then abandoned the deal.

It is in the shadow of our willingness to litigate that we have also been able to obtain several settlements that simultaneously resolve our competitive concerns while permitting the parties to proceed with those parts of their transaction that do not threaten consumer welfare. For instance, in January, the Antitrust Division announced that it would require Ticketmaster, the world's largest ticketing company, to license its ticketing software, divest ticketing assets, and subject itself to anti-retaliation provisions in order to proceed with its proposed merger with Live Nation Inc. The remedy, which remains under Tunney Act review, will give concert venues more choice for their ticketing needs and will promote incentives for competitors to innovate and discount.

The proposed relief in the Ticketmaster matter is both structural and behavioral. The settlement requires Ticketmaster to divest more ticketing than it will gain through its acquisition of Live Nation. Simultaneously, the licensing solves a second competitive issue by giving AEG, an integrated competitor, the ability and incentive to compete with the combination of

Ticketmaster and Live Nation for concert promotion, venue management, and ticketing. Under the settlement, Ticketmaster will be required to license its ticketing software to AEG, which had been Ticketmaster's single largest customer. AEG will now have the opportunity and incentive to compete in primary ticketing, both in its own venues and third-party venues, thereby opening the door for AEG to become a vertically integrated competitor with competitive incentives similar to those of the merged company. In addition, Ticketmaster was required to divest Paciolan, an established ticketing business that sells tens of millions of tickets annually. Finally, the settlement provides tough, ten-year, anti-retaliation provisions that prohibit anticompetitive bundling and should keep the merged company in check. Those anti-retaliation provisions illustrate a slight shift of Division policy in realm of merger remedies. Although we generally prefer structural solutions, we are also committed to thinking creatively about market conditions and employing behavioral solutions, particularly when they are needed, in tandem with structural solutions, to protect against consumer harm.

Another transaction where we were able to obtain a consent decree resolving our competitive concerns involved Bemis's $1.2 billion acquisition of the Alcan Packaging Food Americas business from Rio Tinto. As originally proposed, the transaction would have combined Bemis and Alcan, two of the leading U.S. manufacturers of (1) flexible-packaging rollstock for chunk, sliced, and shredded natural cheese and (2) flexible-packaging shrink bags for fresh meat. Without divestitures, the acquisition would have led to higher prices, lower quality, less favorable supply-chain options, reduced technical support, and less innovation. The settlement, which has been approved by the court, requires the companies to divest Alcan contracts and intellectual property, plants located in Oklahoma and Wisconsin, and other assets necessary to the manufacture of flexible packaging for natural cheese and fresh meat.

Similarly, we moved quickly to remedy the combination of the nation's two largest providers of voting machines. Again, this transaction fell below the HSR-reporting thresholds, so our investigation began only after the parties had combined their assets and dismantled some of their pre-combination operating divisions. The settlement, which has been approved by the court, provides quick, effective relief resolving our competitive concerns and enabling local and state jurisdictions to obtain competitive bids for their immediate voting equipment needs.

Specifically, under the settlement, the acquirer, Election Systems & Software, was required to divest the means to produce Premier Voting Equipment Systems, including the necessary intellectual property, tooling, fixed assets, inventory of finished devices, and replacement parts. The settlement also prohibits ES&S from bidding on new voting equipment system contracts using the Premier equipment. Last month, Dominion Voting Systems purchased the Premier assets from ES&S. The divestiture allows Dominion to contract immediately with third party manufacturers, consistent with Premier's past practice, for the production of Premier devices and parts.

As mentioned earlier, the Antitrust Division is also committed to expeditiously closing those matters that do not threaten consumers. Unnecessary delay is simply unacceptable. For instance, the Justice Department did not challenge either the combination of Oracle and Sun or the collaboration between Microsoft and Yahoo!. In other words, we seek to ensure that our commitment to vigorous enforcement of the antitrust laws does not impede legitimate business transactions that do not run afoul of the antitrust laws.

On civil non-merger issues, we have two matters that remain under court review through the provisions of the Tunney Act. In the first, we allege that the then-largest seller of electricity capacity in the New York City market engaged in an anticompetitive swap transaction that likely

resulted in a price increase for retail electricity suppliers and, in turn, an increase in electricity prices for consumers. In the second, we allege that a group of Idaho orthopedic surgeons organized a boycott of Idaho's workers' compensation system, essentially refusing to treat injured workers. Our proposed decree would enjoin the conduct.

In our criminal program, we continue to uncover and prosecute a number of cartels that inflicted significant competitive harm. These efforts were significantly enhanced by the provisions of the Antitrust Criminal Penalty Enhancement and Reform Act, which supplements our leniency program, and we thank you for leading the effort to extend that program through a ten-year reauthorization.

Recently, we have prosecuted criminal cases against firms and individuals in several industries, including air transportation services, liquid crystal display panels, financial services, Internet services for disadvantaged schools and libraries, packaged ice, environmental services, and post-Hurricane Katrina remedial work. Those prosecutions resulted in significant fines. In our most recent fiscal year 2009, the Division obtained more than $1 billion in fines, which is the second highest amount of total fines ever obtained by the Division in a fiscal year. The bulk of those fines were the result of the Division's investigations of the air transportation and LCD industries. Recent fines in the air transportation area includes (1) a $119 million fine against Luxembourg-based Cargolux Airlines International, (2) a $109 million fine against LAN Cargo, a Chilean company, and a Brazilian company that it substantially owns, (3) a $50 million fine against Korea-based Asiana Airlines, (4) a $45 million fine against Japan-based Nippon Cargo Airlines, and (5) a $15.7 million fine against EL AL, an Israeli company. Recent fines in the LCD area include (1) a $400 million fine—the second largest fine in Antitrust Division history—against Korean LCD manufacturer LG Display and its California subsidiary, (2) a $220 million

fine against Taiwan manufacturer Chi Mei Optoelectronics, (3) a $120 million fine against Japanese manufacturer Sharp, (4) a $65 million fine against Taiwan manufacturer Chunghwa Picture Tubes, (5) a $31 million fine against Japanese manufacturer Hitachi Displays, and (6) a $26 million fine against Japanese manufacturer Epson Imaging Devices.

In addition to corporate fines, holding culpable individuals accountable by seeking jail sentences also remains an effective way to deter and punish cartel activity. Individuals prosecuted by the Division are being sent to jail with increasing frequency and for longer periods of time. In our most recent fiscal year, courts imposed more than 25,000 jail days against defendants in Antitrust Division matters. Defendants prosecuted by the Division are, on average, serving increasingly longer sentences, and they are also going to jail with increasing frequency. For instance, in the 1990s, 37 percent of defendants prosecuted by the Division were sentenced to jail on average. Last year, 80 percent were.

In addition to the threat of fines and jail time, rigorous internal compliance programs, where employers rigorously instruct their employees about the requirements of the antitrust laws and set up internal controls to protect against cartel activity, are another important deterrence mechanism that can prevent harmful cartel activity from occurring in the first place. As we move forward, we look forward to encouraging firms to undertake effective compliance programs and thinking creatively about ways to stimulate them. Early detection of criminal antitrust activity allows companies, where necessitated, to take advantage of the Division's criminal leniency program.

On the competition-advocacy front, the Antitrust Division has stepped up its efforts with various programs and initiatives directed at strengthening markets and preserving economic freedom and fairness. Promoting competition principles through broad advocacy efforts and

regulatory outreach is one of our highest priorities. As a result of our enforcement efforts, the Antitrust Division has gained enormous insight into the competitive dynamics of many industries. We are committed to sharing that expertise throughout the government to enhance pro-consumer outcomes. To that end, the Division works actively with a broad range of federal and state agencies to promote competition principles across a number of vitally important industries in our economy, including agriculture, telecommunications, energy, financial services, and healthcare.

Prominent among these efforts is our work in the agriculture industry. Earlier this year, the Department of Justice and the Department of Agriculture launched a series of workshops around the United States to discuss competition and regulatory issues in the agriculture industry. Both Attorney General Holder and Secretary of Agriculture Vilsack are personally participating in these unprecedented series of joint public workshops, which are the first-ever sponsored jointly by the Justice Department and the USDA to discuss competition and regulatory issues in the agriculture industry.

The first workshop was held in March of this year in Ankeny, Iowa, and featured panel discussions on a variety of topics important to America's farmers and ranchers, including competitive dynamics in the seed industry, trends in contracting, transparency, and buyer power, and concluded with public testimony. More than 700 citizens were in attendance. We had our second hearing in Normal, Alabama, where we addressed the concerns of poultry farmers, trends in poultry production, and related regulatory and enforcement issues. More than 500 farmers and other participants attended. A third hearing was held last month in Madison, Wisconsin, where we discussed trends in the dairy industry, market consolidation, and market transparency. Additional two hearings will be held later this year in Colorado and Washington, D.C. Among

other lessons, these hearings have impressed upon us the vital importance of effective co-operatives and family farms for well-functioning agriculture markets.

To maximize the effect of our learning from these hearings, the Justice Department has formed a joint task force with the USDA to help us determine how the government can best utilize what is learned from those hearings to help promote competition in our nation's agricultural markets. Even though antitrust is not the solution to all problems, we are committed to championing throughout the government pro-consumer principles that will promote competition in agriculture markets.

Another inter-agency task force that we are fully engaged on is the Financial Fraud Enforcement Task Force, which the President established to strengthen efforts to combat financial crime. Led by Attorney General Holder, the task force works with state and local partners to investigate and prosecute significant financial crimes, ensure just and effective punishment for those who perpetrate financial crimes, address discrimination in the lending and financial markets, and recover proceeds for victims. We are fully engaged in this effort.

In transportation, the Division has been working closely with the Department of Transportation, especially on issues related to antitrust immunity requests for airline alliances. We conducted thorough investigations and filed comments with the DOT addressing the competitive implications of immunity requests affecting the Star and oneworld alliance agreements. We also collaborated closely with our European counterparts in those matters. In addition, we provided to the DOT comments regarding the proposed transaction whereby Delta and USAir would swap their slots at LaGuardia and National airports. The DOT cited our submission extensively in its order requiring slot divestitures before the transaction could proceed.

We have been active in telecommunications as well. Earlier this year, the Division submitted comments promoting competition principles with the Federal Communications Commission regarding its national broadband plan inquiry. We are also collaborating closely with the FCC on our concurrent review of the proposed transaction involving Comcast and NBC in order to harmonize to the maximum extent possible government review of that deal.

In the energy sector, the Division, along with the Federal Trade Commission, recently held an internal workshop on competition in the energy markets, which involved collaboration with representatives from the Federal Energy Regulatory Commission, the Department of Energy, and several state regulatory agencies. That workshop was part of a broader effort to coordinate with state enforcers on various matters, including both particular industries and antitrust doctrine more broadly. We are also working closely with the FERC on proposed transactions in the energy industry in an effort to more closely align our efforts.

In intellectual property, the Division is committing significant attention to the Intellectual Property Task Force established by Attorney General Holder. The Task Force focuses on strengthening efforts to combat intellectual property crimes through close coordination with state and local law enforcement partners, as well as international counterparts. It also serves as an engine of policy development to address the evolving technological and legal landscape of this area of law enforcement. Moreover, we have been working closely with the Patent and Trademark Office on issues relating to the intersection between patent law and competition principles. As part of that effort, the Department, the Federal Trade Commission, and the PTO held a public workshop last month on the intersection of patent policy and competition policy and its implications for promoting innovation. The collaboration marked the first time that the

three groups had sponsored a public workshop on this vitally important aspect of today's economy.

In addition to collaborating on the workshop, the Division has collaborated efficiently and effectively with the Federal Trade Commission on a number of other fronts. For example, our joint, ongoing review of the Horizontal Merger Guidelines and examination of whether they need to be updated in light of changes in agency practice in the eighteen years since the Guidelines were last significantly revised has been a constructive and positive collaboration. We are also beginning to coordinate efforts to support effective implementation of the new health-care-reform legislation. During my confirmation hearing, I stressed the need for harmonizing relations between the Division and the Federal Trade Commission, and we are working actively on that.

Healthcare is a particular priority for the Department. We have been actively working on the complicated competitive issues surrounding clinical integration among doctors, and the resulting competitive dynamic with health insurers, in conjunction with the Federal Trade Commission. We are also working collaboratively with the Department of Health and Human Services on the new Affordable Care Act, seeking to proactively identify competitive issues relating, for instance, to administrative services organizations and the new marketplace dynamics that will be shaped by the reform.

Another important piece of the Division's commitment to advocate on behalf of competition and consumers is our amicus program where, often in conjunction with other parts of the Department and other parts of the government, we participate in the filing of amicus briefs in cases dealing important antitrust issues. For instance, the Division worked with the Department to articulate to the United States Court of Appeals for the Second Circuit our

competitive concerns about so-called "pay-for-delay" settlements in the pharmaceutical arena, whereby firms agree to delay the entry of generic-drug competition through settlement of a patent dispute.

Amicus briefs provide a valuable opportunity for the Department to offer courts the benefits of the Division's specialized competition knowledge and expertise. These briefs also increase public transparency and inform the business community and antitrust counselors about the Division's approach to key antitrust and competition issues. Through our amicus program, we also are able to articulate our views about the proper scope and reach of new and important decisions. In this regard, it is worth noting that the Federal Trade Commission, in its recent testimony before this Committee, has identified a "worse case" reading of the recent *Trinko* and *Credit Suisse* decisions. While we appreciate the Commission's concern about how these cases could be inappropriately applied in other contexts, we understand the Court's reasoning to be limited to the facts and circumstances presented in those particular cases. We are working diligently to enforce the antitrust laws consistent with our understanding of the Court's precedents.

A very recent milestone for our amicus program occurred earlier this year when the Supreme Court issued its American Needle decision, which accorded with the recommendation of the Solicitor General. The Court's unanimous decision was an important win for consumers. It clearly stated that competitors, including joint ventures involving sports leagues and teams, are subject to the antitrust laws and rejected an effort to create a broad immunity under the antitrust laws for agreements among competitors. The decision ensures that playing fields remain open and competitive, providing consumers with more choices.

Not only are we championing consumers and competition domestically, but we are also actively engaging with the global antitrust community, which has grown as the scope of international business operations have grown. The Division works with international competition groups, like the Organisation for Economic Co-operation and Development and the International Competition Network, as well as international competition agencies, to promote competition and consumer interests across the globe. Our efforts to spearhead this important priority have been particularly enhanced by the strong relationship we have with our counterparts in the European Union. By way of example, we recently had a particularly constructive working relationship with the European Commission analyzing the transaction between Cisco and Tandberg, and we aim to build upon that relationship going forward.

A particular priority has been promoting dialogue on the importance of transparency, due process, and fairness among international competition agencies. These efforts include participating in international workshops on a broad range of policy issues and contributing to guidance documents promulgated by organizations like the OECD and the ICN. The Division also consults bilaterally with a range of international jurisdictions on issues like adopting new antitrust laws, drafting guidelines, intellectual property licensing, and cooperation on international investigations and enforcement actions. Among many accomplishments, the Division and the FTC entered into a groundbreaking Memorandum of Understanding with the Russian Federal Anti-Monopoly Service in November 2009. We are also engaging actively with the relatively new Chinese and Indian competition authorities, and are establishing relationships there that will serve as springboards for future dialogue and discussion. For example, over the past year, the Division has had exchanges with Chinese agencies on their proposed regulations and guidelines, arranged a training program for eighty Chinese judges, and participated as

instructors in workshops on merger enforcement, cartels, and other topics. The Division also participates in the Administration's initiatives in China, including the U.S.-China Strategic and Economic Dialogue and the Investment Forum. These and related efforts seek to promote the adoption of sound competition principles and antitrust enforcement around the world.

My first year as AAG has been remarkable. Working within the Justice Department on Attorney General Holder's team and closely with the dedicated men and women of the Antitrust Division, we are doing all we can to ensure that the competitive playing field is open and fair, giving consumers more and better choices. I look forward to year two and am committed to further fulfillment of what we started.

Mr. Chairman, that concludes my remarks. I am grateful to have had the opportunity to speak with you, and am happy to answer any questions.

Mr. JOHNSON. Thank you, Ms. Varney.
Next we will hear from Chairman Leibowitz.
Please proceed.

TESTIMONY OF THE HONORABLE JON LEIBOWITZ, CHAIRMAN, FEDERAL TRADE COMMISSION, WASHINGTON, DC

Mr. LEIBOWITZ. I will move the mic closer, too.

Chairman Johnson, Chairman Conyers, Mr. Coble, Members of the Subcommittee, thank you so much for inviting me to testify here today. I am delighted to be here with my friend and colleague, Christine Varney. As you already have my written statement let me spend my allotted time talking about just a few of the interesting issues that we are focusing on right now at our agency.

To start, let me mention that after a several-year losing streak we recently won a handful of merger cases. These deals include the merger of Thoratec and HeartWare, which would have combined the only two producers of critical heart devices used by patients waiting for a heart transplant or experiencing severe heart problems. By challenging this transaction, which we believe to be a merger to a monopoly, we ensure that patients, including former Vice President Dick Cheney, would have more choices, prices would be reduced, and innovation increased.

We have also been aggressive when we find mergers that we think will decrease competition, but just as important, we are not afraid to hold off when we think a major deal is not going to cause consumer harm. A recent example of this is Google AdMob, which we investigated thoroughly but unanimously decided not to challenge. And most of our antitrust decisions have been unanimous to challenge or not to challenge.

We are not perfect, but I do believe we are striking the right balance to protect consumers yet still allow businesses latitude to combine when appropriate.

Right now our top competition priority at the commission is to stop pay for delay agreements between brand-name and generic drug makers. We estimate that these sweetheart deals will cost consumers—and do cost consumers—about $3.5 billion a year.

And, Mr. Coble, I think it was a terrific idea for you to ask the pharmaceutical industry to comment on these numbers. They have not done it and these numbers have been available for almost a year. I would like to see what they say.

By now you are all familiar with this story: Brand-name drug companies sue their generic competitors claiming that the generic has violated their patent and then they turn right around and they settle the case by paying off the generic not to compete—that is, to delay entering the market. It is win-win for the companies who get to keep monopoly profits, but it is lose-lose for consumers who are left holding the bag or footing the bill for medicines they may desperately need.

Because of our enforcement efforts there was not a single pay for delay agreement in 2004, but since 2005, after a few misguided court decisions, the number of agreements has steadily increased. In preparation for today's hearing we asked staff to check on the number of patent settlements filed so far this fiscal year and the numbers paint a bleak picture, as you can see from the chart. Within the first 9 months of fiscal year 2010 there have been 21 suspect agreements—21, which is more than the 19 filed for all of last year. Indeed, more than the number filed in any previous fiscal year.

The new settlements protected branded drug sales of over $9 billion, and that is almost an epidemic. Left untreated, these types of settlements will continue to insulate more and more drugs from competition and continue to raise the health care cost curve.

Every single FTC commissioner—Republican, Democrat, and Independent, going back through the Bush and to the Clinton administration—has called for an end to these unconscionable agreements, and more and more others are coming around to review. Under Christine Varney the Department of Justice position has evolved considerably, and it now agrees that pay for delay settlements are presumptively anticompetitive.

The Second Circuit recently encouraged plaintiffs in a pay for delay case to request an en banc review of a previous ruling allowing these deals, thanks in part to an excellent brief filed by the Department of Justice. As Members of this Committee know, circuit courts ask for an en banc very, very rarely.

But as we also know, litigation can take a long time and it would be much faster and more direct to enact legislation. Such legislation has now passed the House twice as well as the Senate Judiciary Committee. It has the endorsement of President Obama. So we are going to continue to work with Congress to finish the job and hopefully that will be later this year.

Let me also discuss the commission's increasing use of our Section 5 unfair methods of competition authority, which allows us to go beyond the ambit of the antitrust laws to protect consumers. Congress granted us this authority in 1914 and balanced it by limiting the availability of remedies under Section 5.

Now, in recent years Section 5 has been used sparingly, but since the 1970's and 1980's, as you mentioned, Mr. Conyers, the courts have restricted the range of antitrust, to some extent as a result of the Chicago School and to some extent, I think, in reaction to the costs of private treble damage litigation. Let me note, of course, that the Chicago School has in some ways improved antitrust enforcement by emphasizing rigorous economic analysis and efficiencies. However, the result of these changes has also been to limit the FTC, which has no treble damage authority, in our effort to protect competition and consumers.

Section 5, carefully applied, is practically tailor-made for this situation. It can effectively protect consumers but it is not an antitrust law and does not, on its own terms, create treble damage liability. So we have broad bipartisan support within the commission to use Section 5 in appropriate circumstances, and we are going out and doing it.

Mr. Chairman, I ask for an additional 30 seconds.

Mr. JOHNSON. Without objection.

Mr. LEIBOWITZ. Thank you.

In addition to consumer protection and antitrust the commission also has a statutory policy function going back to 1914. An upcoming policy project will focus on health care reform and competition policy. Another one focuses on the future of news in the Internet age, a topic this Committee considered at a hearing last year.

We are doing a lot of other important work that I would be glad to discuss, including, with Assistant Attorney General Varney, an

update of the Horizontal Merger Guidelines and a new rule prohibiting market manipulation in the petroleum industry.

But I will stop now; I know I have exceeded my time. And I am happy to answer questions.

[The prepared statement of Mr. Leibowitz follows:]

PREPARED STATEMENT OF THE HONORABLE JON LEIBOWITZ

Prepared Statement of
the Federal Trade Commission

Before the
United States House of Representatives
Committee on the Judiciary
Subcommittee on Courts and Competition Policy

Oversight of the Federal Trade Commission Bureau of Competition
and the Department of Justice Antitrust Division

Washington, D.C.
July 27, 2010

Introduction

Chairman Johnson, Ranking Member Coble, and Members of the Subcommittee, thank you for the opportunity to appear before you today. I am Jon Leibowitz, Chairman of the Federal Trade Commission, and I am pleased to testify on behalf of the FTC to discuss our competition enforcement activities and the many important antitrust issues under your jurisdiction.[1] Today, this testimony will highlight several key areas of our competition agenda: ending pay-for-delay pharmaceutical agreements that cost consumers at least $3.5 billion per year; blocking or modifying anticompetitive mergers; revising the Horizontal Merger Guidelines; developing policy guidance regarding the ongoing changes in news media markets; effectively using our enforcement authority under Section 5 of the Federal Trade Commission Act; and acting to promote competition in the energy sector.

As the Members of this Subcommittee know very well, free and open markets are the foundation of our economy, and competition is essential for those markets to function. Years of experience have proven that competitive markets work better than anything else to bring consumers lower prices, greater innovation, and choice among products and services. For that reason, one of the Commission's primary obligations is to remove the obstacles that impede competition, allowing its benefits to flow to consumers.

To meet that obligation, the Commission has an aggressive and active antitrust enforcement agenda. Our jurisdiction is broad, and we enforce the laws in a wide range of markets. In order to maximize the impact of our efforts we attempt to focus on areas that most

[1] The written statement represents the views of the Federal Trade Commission. My oral presentation and responses to questions are my own and do not necessarily reflect the views of the Commission or of any other Commissioner.

directly affect consumers and businesses, such as health care, energy, emerging technologies, real estate, and retail.

The Commission's competition agenda falls into three broad categories: merger review; investigations of anticompetitive unilateral and coordinated conduct; and competition policy analysis.

With regard to mergers, Commission staff reviews proposed and consummated deals to ensure that they do not "substantially lessen competition." As necessary, the Commission files complaints to enjoin anticompetitive mergers, or, if we have reason to believe that only some aspects of a merger are likely to have adverse competitive effects, we negotiate remedies that address those concerns.

Of course, businesses engage in a range of other activities, some of which have implications for competition, and the Commission is always on the lookout for potentially anticompetitive conduct. This conduct may be unilateral – for example, when a monopolist requires exclusivity from its customers in a way that harms the ability of other suppliers to compete fairly for those customers. Or the conduct might be coordinated – for example, when a brand pharmaceutical company pays a generic pharmaceutical company to keep its product off the market.

Congress also has empowered the Commission to provide substantive policy analysis and guidance, and we focus significant resources on fulfilling this part of our mission. The Commission analyzes a wide variety of competition issues via research, workshops, and hearings, and these efforts result in a steady stream of detailed and thoughtful reports, studies, advocacy filings, and *amicus* briefs.

The Commission is gratified that we can now fulfill our broad range of responsibilities with a full Commission, including our two newest Commissioners, Julie Brill and Edith Ramirez. As a Commission, we are working together in a bipartisan manner to bring enforcement actions – whether in large or small markets – that will benefit consumers and protect competition. Of course, it should go without saying that we are careful to avoid interfering with the kind of aggressive, rough-and-tumble competition that has long been the hallmark of our dynamic economy. At the same time, however, we will act against mergers and conduct that go over the line and threaten competition – even if those cases are difficult ones, and even when they involve some of our country's most successful companies.

I. Ending Pay-for-Delay Pharmaceutical Agreements

One of the Commission's top competition priorities is stopping "pay-for-delay" agreements between brand-name pharmaceutical companies and generic competitors that delay the entry of lower-priced generic drugs into the market. These are settlements of patent litigation in which the brand-name drug firm pays its potential generic competitor to abandon a patent challenge and delay entering the market. Such settlements, known as pay-for-delay, exclusion payments, or reverse payments, effectively buy more protection from competition than the assertion of the patent alone provides. And they do so at the expense of consumers, whose access to lower-priced generic drugs is delayed, sometimes for many years.

Agreements to eliminate potential competition and share the resulting profits are at the core of what the antitrust laws proscribe, and for that reason the Commission believes strongly that these pay-for-delay settlements are prohibited under the antitrust laws. We are making some progress in our efforts to block these deals, but a number of obstacles remain and the legal

environment remains unsettled. In 2005, several courts took, what is in our view, an unduly lenient approach to such agreements in drug patent settlements. As a result, it became increasingly difficult to halt pay-for-delay settlements through litigation, and such settlements have now become a common industry strategy.

These developments are extremely troubling. Delays in generic competition harm all those who pay for prescription drugs: individual consumers, the federal government (which purchases roughly one-third of all prescriptions), state governments struggling with the cost of providing access to health care, and American businesses striving to compete in a global economy. This year, a comprehensive FTC staff report studied this problem, and found:

- The number of these agreements is increasing, from zero in fiscal year 2004 to 19 in fiscal year 2009;
- These deals currently protect at least $20 billion in sales of branded drugs from generic competition;
- On average, the deals delay the availability of cost-saving generics by 17 months; and
- If not stopped, pay-for-delay deals will, even using conservative assumptions, cost consumers $3.5 billion a year.[2]

In simple terms, the numbers document how these sweetheart deals increase prescription drug costs for American consumers.

Unfortunately, the most recent data confirms that these deals are a growing problem. Based on a preliminary analysis, already, in the first nine months of FY 2010, there have been

[2] "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions," FTC Staff Study (Jan. 2010), www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. In addition, the Commission staff releases detailed annual summaries on the type of settlements brand and generic companies are entering. *See* www.ftc.gov/os/2010/01/100113mpdim2003rpt.pdf.

more brand-generic settlements involving some sort of compensation – 21 – than in any prior full fiscal year. Those settlements protect $9 billion in prescription drug sales. At the same time, the settlement filings confirm that brand and generic companies can settle their disputes without brand companies paying their generic competitors not to compete. Seventy-five percent of all final patent settlements – 63 – did not involve compensation from the brand company to the generic combined with a delay in generic entry.

Because of the inherently anticompetitive nature of these deals and the enormous consumer harm caused by pay-for-delay, the Commission continues to challenge them despite some earlier setbacks in the courts. For example, we are still actively pursuing two major pay-for-delay cases: one against Solvay Pharmaceuticals (owned by Abbott Laboratories) and generic manufacturers (Watson Pharmaceuticals, Par Pharmaceutical, and Paddock Laboratories) regarding AndroGel, a testosterone replacement drug often used by victims of testicular cancer, and the other against Cephalon regarding the drug Provigil, a sleep disorder medication with nearly $1 billion in annual U.S. sales.[3] In addition, Commission staff are continuing to initiate new investigations into other pay-for-delay agreements.

And we have reason to believe that the tide may be turning, both in the courts and in Congress. A few months ago, an appellate panel in the Second Circuit, which previously had adopted a permissive approach to pay-for-delay settlements, took the extraordinary step of questioning its own standard and explicitly encouraged consumer plaintiffs to request the court's

[3] *In re AndroGel Antitrust Litig.* (No. II), 1:09-MD-2084-TWT (N.D. Ga. Feb. 22, 2010) (granting defendants' motion to dismiss); *FTC v. Cephalon, Inc.*, No. 2:08-cv-2141 (E.D. Pa. Mar. 29, 2010) (denying motion to dismiss), www.ftc.gov/os/caselist/0610182/index.shtm.

en banc re-consideration of the pay-for-delay issue.[4] Both the Federal Trade Commission and the Department of Justice filed briefs with the Second Circuit advocating that the full court revisit this issue.[5] In another promising development, in March 2010, a federal district court judge in Philadelphia denied a defense motion to dismiss the Commission's case against Cephalon. That case is now in the discovery phase.

Solving this problem through the courts, however, will take time, and American consumers will suffer higher costs for prescription drugs. Therefore, even as we fight against pay-for-delay settlements in the courts, we are working to help find a legislative solution to the problem. Legislation would be the most effective way to stop these deals. We know the Administration supports a legislative fix as a critical part of President Obama's health care plan, and the Commission will continue to work with Congress to address this issue. In the meantime, the agency will continue to aggressively pursue our investigations and enforcement actions.

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[4] *See Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, Nos. 05-2851-cv(L), 05-2852-cv(CON) (2d Cir. Apr. 29, 2010) (affirming summary judgment for defendants but inviting plaintiffs to petition for rehearing en banc).

[5] Consumer organizations; state attorneys general; and law, economics, and business professors also submitted strong amici briefs advocating for a full court review. *See* Brief of American Antitrust Institute as Amicus Curiae Supporting Appellants; Brief of AARP et al. as Amici Curiae Supporting Appellants; Brief of Consumers Union et al. as Amici Curiae Supporting Appellants; Brief of 34 State Attorneys General as Amici Curiae Supporting Appellants; Brief of 86 Law, Economics, Public Policy, and Business Professors as Amici Curiae Supporting Appellants, *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, Nos. 05-2851-cv(L), 05-2852-cv(CON) (2d Cir. May 20, 2010).

II. Stopping Anticompetitive Mergers

The Commission's merger review program is critical to maintaining competitive markets. Merger filings have rebounded over the last year, and the Commission continues to carefully review transactions for potential anticompetitive effects, and to challenge mergers in appropriate circumstances. During fiscal year 2009, the Commission challenged 19 mergers. In nine of those cases the parties agreed to a consent order, in three they abandoned the deal, and in a record seven cases we authorized staff to file a complaint in federal district court or in an administrative proceeding.[6] Additionally, through the first three-quarters of fiscal year 2010, the Commission has brought 14 merger enforcement actions. These challenges covered a wide range of markets, including pharmaceuticals and medical devices, truck stops, fertilizer, marketing databases, the funeral services industry, and the chemical industry.

Just as important, when after a thorough investigation we determine that a deal is not anticompetitive, we do not hesitate to close the investigation and allow the parties to move forward with their transaction. This happens as a matter of course on a wide range of mergers, but one prominent recent example is the Google/Admob deal, where the Commission also issued a statement explaining why it closed the investigation. We will continue to employ our resources effectively by focusing our efforts on deals that have a significant potential to lessen competition and harm consumers.

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[6] *See* FTC Competition Enforcement Database, Merger Enforcement Actions, www.ftc.gov/bc/caselist/merger/index.shtml.

III. Proposed Revisions to the Horizontal Merger Guidelines

In April, the Commission, in conjunction with the Antitrust Division of the Department of Justice, released for public comment a proposed update of the Horizontal Merger Guidelines.[7] The Guidelines outline for courts and practitioners how the federal antitrust agencies evaluate the likely competitive impact of mergers and whether those mergers comply with U.S. antitrust law. The last major revision to the Guidelines was in 1992, and they have been widely used and quoted in the intervening years. Advances in economic understanding and additional experience, however, have gradually modified the way that the agencies evaluate and investigate mergers. As a result, the 1992 Guidelines no longer offer an entirely accurate representation of agency practices. To ensure that the Guidelines remain a useful tool, the Commission and the Antitrust Division have worked together to revise the Guidelines to more accurately reflect the way the FTC and DOJ currently conduct merger reviews. These proposed Guidelines will assist the business community and antitrust practitioners by increasing the transparency of the analytical process underlying the agencies' enforcement decisions.

This update of the Guidelines is also notable for the transparency of the process. The proposed revisions were issued after consideration of public comments and input received during a series of five joint FTC/DOJ workshops held over the past six months, which were open to the public and attended by attorneys, academics, economists, consumer groups, and businesses.[8]

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[7] Horizontal Merger Guidelines For Public Comment (Apr. 20, 2010), www.ftc.gov/opa/2010/04/hmg.shtm.

[8] Horizontal Merger Guidelines Review Project Website, www.ftc.gov/bc/workshops/hmg/index.shtml.

The result is a revised version of the Guidelines that more closely reflects the current practice of the antitrust agencies. One of the key differences is that the proposed Guidelines clarify that merger analysis does not use a single methodology, but is instead a fact-specific process, using a variety of tools to analyze the evidence. The Guidelines also explain that market definition is not an end in and of itself, nor always the starting point of merger analysis, but instead a tool used to illuminate the potential competitive effects of the proposed merger. Another highlight is the increase in the Herfindahl-Hirschmann Index ("HHI") concentration levels likely to warrant either further scrutiny or challenge from the agencies; again, this update more accurately reflects current agency practice, and provides a more useful benchmark for businesses considering potential deals.

We have been gratified by the reaction from the legal and business community. The Guidelines have been warmly received by a wide range of practitioners, consumer groups, businesses and academics. We received 31 comments on the proposed revisions and are currently considering those viewpoints as the Commission and the DOJ work to finalize the new Horizontal Merger Guidelines. Of course, we welcome any comments and questions from the Members of the Committee.

IV. Policy Projects

The Commission continues to pursue an active policy and research agenda, and as a part of these efforts the FTC regularly holds hearings and workshops to examine important economic and competition issues affecting businesses and consumers. A recent example is a series of workshops entitled "How Will Journalism Survive the Internet Age?" We are holding this series of workshops because the expansion of electronic commerce and media is challenging

conventional journalism business models. This is a sea change that has implications both for competition among media outlets and our democratic society. The Commission's workshops have been designed to focus attention on this emerging dynamic, assess the range of economic and policy issues raised by the changes in the market, and explore how competition can be used to enhance consumer welfare.

The FTC held the first workshop in December 2009, and the opening session featured contributions from a diverse group of well-informed participants, from Rupert Murdoch to Arianna Huffington. Owners of news organizations, journalists, bloggers, technologists, economists, and other academics discussed the changing dynamics of the news business and considered what new journalism business models might evolve in the future. The workshops continued in March 2010, when experts in a variety of fields discussed the pros and cons of a number of proposals to increase the efficiency and profitability of journalism, including: more accessible and more manageable government data; possible changes to copyright law, various new business models, and collaborations among news organizations. And in June, the Commission held a final public workshop to compare the policy options put forth by various industry stakeholders. The Commission plans to issue a report on this project in the fall.

An upcoming policy project will focus on health care reform and competition policy. The Patient Protection and Affordable Care Act, the health care reform law, establishes new programs for Medicare (and some Medicaid beneficiaries) called "accountable care organizations," or ACOs. The purpose of ACOs is to foster higher quality and more efficient provision of health care services through, among other things, coordination of care among providers. This fall, the FTC will sponsor a workshop to focus on how ACOs could affect competition in commercial health care markets.

V. Section 5 of the Federal Trade Commission Act

As the Members of this Committee are well aware, the Federal Trade Commission has enforcement authority beyond that of the Sherman and Clayton Acts. When Congress created the FTC in 1914, it empowered the agency to prevent "unfair methods of competition" through Section 5 of the Federal Trade Commission Act.[9] Congress was dissatisfied with the state of antitrust enforcement at that time, and its goal was to create an agency with broader jurisdiction than the Department of Justice. At the same time, Congress sought to balance that broader jurisdiction with a limitation on the actions that may be taken under the new law. Specifically, the Commission is not entitled to treble damages, and Section 5 does not provide for a private right of action. Thus Section 5 provides somewhat limited remedies but allows the Commission to reach a broader range of anticompetitive conduct – such as conduct that undermines competition without necessarily violating the Sherman Act.

This broad authority is clear in the legislative history of the FTC Act, which shows that Section 5 was not enacted merely to mirror the Sherman Act. Rather, as Congressman Stevens of New Hampshire, who later became an FTC Commissioner, stated, a principal impetus behind the Act was that "it [would] give to this commission the power of preventing in their conception and in their beginning some of these unfair processes in competition which have been the chief source of monopoly."[10] The Supreme Court subsequently has confirmed a broad view of Section

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[9] 15 U.S.C. § 45.

[10] 51 Cong. Rec. 13,118 (1914). Senator Cummins, one of the bill's main proponents, squarely stated on the Senate floor: "[t]hat is the only purpose of Section 5 – to make some things punishable, to prevent some things, that can not [sic] be punished or prevented under the antitrust law." 51 Cong. Rec. 12,454 (1914).

5,[11] but lower courts in the 1970s and 1980s struck down several FTC efforts to use this authority in cases that went well beyond the confines of the Sherman Act. After those cases, until recently, the Commission had generally limited use of its Section 5 authority.

However, developments in antitrust jurisprudence have prompted a reconsideration of the Commission's approach to Section 5 enforcement. Since the 1970s, the Supreme Court has increasingly narrowed the scope of the Sherman Act, in part due to concerns that private class-action antitrust litigation and the impact of treble damage awards will tend to deter legitimate, competitive activity.[12] But whatever the reason, the result is that the antitrust agencies find themselves limited in their ability to challenge anticompetitive conduct that harms consumers – even though the use of Section 5 by the Commission should limit the remedial and follow-on litigation concerns that may be raised by the use of the Sherman Act.

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[11] *FTC v. Sperry & Hutchinson*, 405 U.S. 233, 240 (1972). Also, the Supreme Court observed in *Indiana Federation of Dentists* that the "standard of 'unfairness' under the FTC Act is, by necessity, an elusive one, encompassing not only practices that violate the Sherman Act and the other antitrust laws but also practices that the Commission determines are against public policy for other reasons." *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 454 (1986).

[12] *See, e.g., Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955 (2007); *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004); *State Oil Co. v. Khan*, 522 U.S. 3 (1997); *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209 (1992); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986); *Monsanto v. Spray-Rite Serv. Co.*, 465 U.S. 752 (1984); *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36 (1977). As indicated in the FTC testimony submitted to this Subcommittee on June 15, 2010, two recent cases, *Credit Suisse v. Billing*, 551 U.S. 264 (2007), and *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko*, LLP, 540 U.S. 398 (2004), could be read to make it more difficult to bring important antitrust cases in regulated sectors. If concerns about the costs and benefits of private antitrust enforcement in such industries were to inhibit public antitrust enforcement, that would be an unfortunate result, and one that would make it all the more important that the Commission make appropriate use of Section 5 in the manner provided for by Congress.

Accordingly, the Commission is actively considering how it can best use Section 5 to enhance enforcement in a responsible and transparent manner. We have held a workshop[13] to assess the best uses of Section 5, and are planning to issue a report with our conclusions. Our recent case against Intel included a free-standing unfair method of competition claim,[14] and last month, the Commission filed a Section 5 case against, and reached a settlement with, U-Haul.[15] The Commission charged that U-Haul invited its competitor to collude by suggesting price increases on rental trucks - something that affects everyday consumers directly. The Commission will not hesitate to aggressively enforce Section 5 against conduct like this.

Of course, in using our Section 5 authority the Commission will focus on bringing cases where there is clear harm to the competitive process and to consumers. Broad bipartisan support exists within the Commission to use Section 5 in appropriate circumstances. We are confident that Section 5 will prove to be an effective mechanism to block anticompetitive behavior, and will allow the Commission to aggressively protect consumers without sparking concerns in the courts.

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[13] "Section 5 of the FTC Act as a Competition Statute," Workshop Website, www.ftc.gov/bc/workshops/section5/index.shtml.

[14] *In the Matter of Intel Corporation*, Dkt. No. 9341 (issued Dec. 16, 2009), www.ftc.gov/os/adjpro/d9341/091216intelcmpt.pdf.

[15] FTC Press Release, "U-Haul and its Parent Company Settle FTC Charges That They Invited Competitors to Fix Prices on Truck Rentals," (June 30, 2010) http://www.ftc.gov/opa/2010/06/uhaul.shtm

VI. Energy

The petroleum industry plays a crucial role in our economy, and few issues are more important to consumers and businesses than the prices they pay for gasoline and energy to heat and light their homes and businesses. Because of this, the Commission carefully monitors energy markets and devotes significant resources to maintain and protect competition across a wide range of industry activities. This work is undertaken by a large number of economists and attorneys who specialize in the energy sector.

Merger review is an essential part of this effort, and in 2009 the Commission reviewed proposed acquisitions involving refined petroleum products, pipelines and terminals, liquefied petroleum gas (propane), lubricant oils, natural gas, and natural gas liquids storage and transportation. A proposed consent decree resolving a recent merger enforcement action against the proposed $1.8 billion acquisition of Flying J by Pilot Corporation would result in divestitures to preserve competition in the travel center business, which provides diesel fuel and other services to long-haul trucking fleets. Under the terms of the proposed FTC consent agreement, Pilot, which operates the nation's largest travel center network, would sell 26 locations to another competitor as a condition of the acquisition. This divestiture would preserve competition in over-the-road sales of diesel fuel to long-haul trucking fleets that otherwise would have been lost.

In addition, the Commission is continuing its efforts on the "Gas Price Monitoring Project" that began in 2002. The monitoring project is a daily, in-depth review of retail and wholesale prices of gasoline and diesel fuel in 20 wholesale regions and approximately 360 retail areas across the United States. This daily monitoring provides information that helps the

Commission to investigate potentially anticompetitive conduct in fuel markets and serves as an early-warning system to alert our experts to unusual pricing activity.[16]

Last November, the Commission added another tool to its arsenal. Pursuant to authority granted by Congress under the Energy Independence and Security Act of 2007, the Commission issued the Petroleum Market Manipulation Rule, which prohibits fraud or deceit in wholesale petroleum markets.[17] The agency conducted an extensive rulemaking proceeding to decide whether and how to craft such a rule, holding a public workshop with participants representing industry, government agencies, academics, and consumers; holding numerous meetings with consumer groups, trade associations, and businesses; and considering over 150 written comments from consumers and businesses. The Commission worked diligently on this issue for 16 months and promulgated a rule that meets the goal of Congress. Importantly, the rule prohibits not only false statements but also statements that intentionally omit material information and are likely to distort petroleum markets. Commission staff has prepared a compliance guide for businesses, which explains the rule in depth and provides examples of the type of actions that would violate it.[18] Examples of potential violations include: false public announcements of planned pricing or output decisions, false statistical or data reporting, and wash sales intended to disguise the actual liquidity of a market or the price of a particular

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[16] *See* Gasoline and Diesel Price Monitoring, www.ftc.gov/ftc/oilgas/gas_price.htm.

[17] *See* FTC Press Release, New FTC Rule Prohibits Petroleum Market Manipulation (Aug. 6, 2009), www.ftc.gov/opa/2009/08/mmr.shtm; 74 Fed. Reg. 40686 (Aug. 12, 2009).

[18] Guide to Complying with Petroleum Market Manipulation Regulations, www.ftc.gov/os/2009/11/091113mmrguide.pdf.

product. The Market Manipulation Rule has only been in effect for a short time, and the agency plans to aggressively enforce the rule as needed.

In addition to these actions, Commission economists and attorneys issue reports on energy matters, including market statistics and trends, for use by Congress and other policymakers. For example, the Bureau of Economics recently released three working papers related to petroleum.[19] In addition, the Commission has submitted multiple comments to the Federal Energy Regulatory Commission (FERC) on a broad range of competition-related issues.[20]

The Commission will continue to utilize its expertise in all of these ways to promote competition in the energy sector and pursue potential illegal conduct that harms consumers.

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[19] In Working Paper No. 300, entitled *Petroleum Mergers and Competition in the Northeast United States*, the Bureau reported on a retrospective evaluation of two consummated transactions – Sunoco's 2004 acquisition of El Paso's New Jersey petroleum refinery and Valero's 2005 acquisition of Premcor's Delaware refinery. Working Paper No. 302, *Asymmetric Pass-Through in U.S. Gasoline Prices*, presented new evidence that upward cost shocks are passed through more quickly than downward cost shocks in United States gasoline prices. Working Paper No. 303, *Edgeworth Price Cycles in Gasoline: Evidence from the U.S.*, used multiple methods to identify price cycles in retail gasoline and diesel price. The reports are available at http://www.ftc.gov/be/econrpt.shtm.

[20] *See* Comment of the Federal Trade Commission on *Control and Affiliation for Purposes of the Commission's Market-Based Rate Requirements Under Section 205 of the Federal Power Act and the Requirements of Section 203 of the Federal Power Act,* FERC Docket No. RM09-16-000 (Mar. 29, 2010); Comment of the Federal Trade Commission on *Control and Affiliation for Purposes of the Commission's Market-Based Rate Requirements Under Section 205 of the Federal Power Act and the Requirements of Section 203 of the Federal Power Act*, FERC Docket No. PL09-3-000 (Apr. 28, 2009); Reply Comment of the Federal Trade Commission on *Transmission Planning Processes Under Order No. 890*, FERC Docket No. AD09-8-000 (Dec. 3, 2009). The comments are available at http://www.ftc.gov/opp/advocacy_date.shtm.

VII. Consumer Protection

On the consumer protection front, the Commission continues to use aggressive law enforcement, innovative consumer and business education, and partnerships with other federal and state law enforcement agencies to further the reach of our initiatives. In particular, the FTC has increased its emphasis on protecting consumers in financial distress. Since January 2009, the FTC has brought 40 law enforcement actions against defendants who engaged in unfair or deceptive practices against financially-distressed consumers, and the agency continues its rulemaking and consumer education efforts related to financial services. By working closely with state attorneys general, we have expanded the reach of these efforts through the filing of more than 200 enforcement actions by our state partners.

The FTC continues to vigorously enforce the rule prohibiting marketing calls to consumers who have signed up for the National Do Not Call Registry – which now covers more than 200 million phone numbers. The Commission also takes enforcement action against deceptive telemarketing. For example, during the past year, the Commission filed ten new actions that attack the use of harassing "robocalls" – the automated delivery of prerecorded messages – to deliver deceptive telemarketing pitches promising such things as extended auto warranties and credit card interest rate reduction services.[21]

Privacy also remains a significant priority. Consumers recognize and value the Commission's leadership on privacy matters. In a recent survey, the Commission came in second in a ranking of the government agencies consumers trust with their personal information. The Ponemon Institute asked consumers to rank 75 federal agencies on how well they handle the

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[21] *See, e.g.*, FTC Press Release, At FTC's Request, Court Halts Massive Robocall Operation (June 10, 2010), http://www.ftc.gov/opa/2010/06/asiapacific.shtm.

challenge of keeping personal information private, and reported that the FTC is the second-most trusted agency for privacy protection (behind only the U.S. Postal Service).[22] But there is still work to be done, and the Commission will continue to lead the way in developing and promoting policies and practices that safeguard consumers' privacy. In addition to the agency's 29 enforcement actions against businesses that failed to protect consumers' personal information, the FTC is actively engaged in an effort to examine privacy issues more broadly. FTC staff convened three public roundtables to explore concerns about consumer privacy and ensure that the Commission's approach to privacy keeps pace with the latest technologies and emerging business models.[23] The Commission plans to release recommendations for public comment later this year.

VIII. Conclusion

The Commission is active in a number of other areas that may be of interest to the Subcommittee, such as clinical integration of medical practices and consideration of the use of Resale Price Maintenance policies in light of the recent Supreme Court decision in *Leegin*.

Thank you for this opportunity to share highlights of the Commission's recent work to promote and protect competition in the marketplace. The Commission looks forward to continuing to work with the Subcommittee to ensure that our antitrust laws and policies are sound and that they benefit consumers without unduly burdening businesses.

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[22] http://www.ponemon.org/news-2/32

[23] *See generally* FTC Exploring Privacy Website, www.ftc.gov/bcp/workshops/privacyroundtables/index.shtml.

Mr. JOHNSON. Thank you, Chairman Leibowitz.

And now we will begin with the questioning, and I will take the first round. Given the shifts to rule of reason analysis and the decisions Trinko, Twombly, and Credit Suisse, is it harder to bring an antitrust case now than it was 10 years ago? And what do you think is the effect on the American public?

Ms. VARNEY. Congressman, our view at the department is that, while Supreme Court precedent is always paramount in our analysis of particular facts, the cases that you mentioned we believe are limited to the facts presented in those cases. And we have not necessarily found them, at this point, to be a barrier to bringing cases, as we have many investigations, which I cannot comment on.

As those investigations come to fruition and you see cases I may be back to you with a view as to whether or not those Supreme Court precedents have inhibited our enforcement of the law. But at this time we view those cases as limited to their facts.

Mr. LEIBOWITZ. Reasonable people can disagree about the effects of Trinko and Credit Suisse and some of the other decisions by the Supreme Court. We think it is a potential impediment, and so that is part of the reason why we have moved to using our Section 5 unfair methods of competition authority, which is sort of penumbra around the antitrust laws because we are in the business of trying to stop anticompetitive behavior that harms consumers, and this is a tool in our arsenal.

But as Assistant Attorney General Varney mentions, some of this will depend on the cases we bring and the responses we get from the courts. And so we are all working together to try to move forward on protecting competition and consumers.

Mr. JOHNSON. Thank you.

Mr. Chairman, I find that as I get to the—towards the top of my lifespan that my hearing is starting to be a little bit lessened as a result, and so I would strongly urge you to speak directly into the microphone, kind of like what I am doing, and that way at least I will be able to hear you. And I appreciate it.

Intellectual property rights standards and antitrust are critical interrelated issues internationally. Given discussions in Europe, China, the OECD, and the WIPO, the amount of emphasis the U.S. government has placed on defending I.P. rights around the world and the challenges we face in China and elsewhere in ensuring protection for American intellectual property, what is the Administration's strategy going forward, and how are we actually managing the dialogue on these critical issues abroad, and you coordinating a message on these issues with commerce, USTR, USPTO, State, and others?

Ms. VARNEY. As you may know, Chairman, the White House has established an I.P. working group and task force that is headed and run out of the White House. That task force includes members from the PTO, from the Department of Commerce, the Department of State, USTR, the Department of Justice—we are all there and we are committed to protecting intellectual property here and abroad. We work very closely on that matter.

When it comes to the intersection of antitrust and intellectual property, I think the chairman does an incredible job of providing technical assistance, which I am sure he will speak to, to a lot of emerging antitrust regimes, and we try to work very closely with their technical assistance programs in a lot of the emerging antitrust regimes.

We want to be sure that the laws reflect what is antitrust and is not used in any way to inhibit American entry into markets when intellectual property is present. So we see an intersection be-

tween intellectual property and antitrust, but we do not want to see antitrust laws around the world used in any way to inhibit trade and competition.

Mr. LEIBOWITZ. Yes. And I agree with everything that Assistant Attorney General Varney said.

We do do a lot of technical assistance with countries. We do help them write their antitrust law, which we think generally reflect best practices of antitrust. Usually they use the American antitrust laws and sometimes the European antitrust laws as a guidepost.

We were very, very involved with helping China write its antitrust laws, which have just been implemented, and we will see how well they work.

And again, you know, we feel very, very strongly that the more competition you have in foreign countries the better it is for all consumers, and particularly American consumers and American businesses.

Mr. JOHNSON. Thank you.

I will now turn to Mr. Coble for questions.

Mr. COBLE. Thank you, Mr. Chairman.

Ms. Varney, good to have you and the chairman on the Hill today.

Mr. Chairman, in the—regarding the reverse payment context, I have heard that the FTC has suggested that the courts should not have the authority to review these settlements because the courts have an incentive to approve settlements that the commission does not have—that is, namely, that the courts are too busy. What do you say to that assertion, and if so, do you—if you support it do you have examples of that having actually occurred?

Mr. LEIBOWITZ. Well, I would make a couple of points: Whenever we bring a case, and we have two cases pending: one in the district court in the Third Circuit involving a drug called Provigil, which is a wakefulness drug used by people in the armed services on long missions, narcoleptics, and children; and another in the 11th Circuit—we go to court, and we have to prove our case.

I would say this—and this is true well beyond the pay for delay settlement issue a lot of times judges, they have busy dockets, they have to put criminal matters first, and I think that settlements are generally something they look favorably on.

And when you have two companies that were in litigation, a brand and a generic, and they both turn around and say, "We have a settlement," there is an incentive, for courts to agree with that, and consumers are the ones who aren't at the table who aren't making the deal, and they are the ones who lose from these reverse payment settlements or pay for delay settlements, which we believe cost consumers $3.5 billion a year.

And then the only other point I want to make is that the 21 deals that we have seen in the first three quarters of this fiscal year is the highest number we have seen so far in any fiscal year. These are deals that we believe delay generic competition and cost all of us more money, whether it is embedded in our health care costs, as a cost of health care insurance, or whether we have to go out and buy drugs because we don't have insurance, and there are still 40-plus million uninsured Americans.

Mr. COBLE. Well, thank you, Mr. Chairman.

Ms. Varney, I will start with you, and either of you may answer. There have been a lot of recent news reports over Google's behavior in collecting personal information from WiFi networks from specially designed automobiles or vehicles roaming through the streets. More than 30 state attorneys general, led by Attorney General Blumenthal, of Connecticut, have announced an investigation in this matter, and I think they joined probably a dozen or so nations who are also investigating.

Since Google acknowledges that it roamed in each of the 50 states it is probably irrelevant to every Member of this Committee if, in fact, the rights of our constituents have been violated. To date, however, I believe neither the Department of Justice nor the Federal Trade Commission has commented on the so-called SpyFi issues. Is either of you all involved with cooperating with the various state attorneys general on this matter?

Mr. LEIBOWITZ. Well, we don't confirm investigations unless companies do, but we have said that we are taking a close look at this matter.

Mr. COBLE. Ms. Varney?

Ms. VARNEY. Chairman, that is outside my jurisdiction. That is a privacy and tracking matter, and unless it is brought to our attention that there is some anticompetitive conduct involved there, that is probably something that would be best looked at by the Federal Trade Commission.

Mr. COBLE. I got you.

One more question, if I may, Mr. Chairman?

Mr. LEIBOWITZ. Yes, sir.

Mr. COBLE. Google recently announced it was entering the travel business with the purchase of ITA. ITA, as we know, supplies information to a variety of Web sites that benefit consumers, such as Expedia, Travelocity, and Priceline. These travel sites benefit consumers by offering them real choices, and they are obviously concerned about the prospect of the world's largest Internet company entering their respective businesses.

Which of your agencies plan to review this matter, and do you have a timeline on that?

Ms. VARNEY. Obviously we don't comment on any pending investigations, either the chairman or myself, so I can assure you that should this transaction go forward and is reportable under the Hart-Scott-Rodino procedures to report transactions under—and be reviewed under the Clayton Act, Section 7, we will carefully evaluate which agency has the best expertise to review the transaction, and we will do so. And I am sure, actually, no matter which agency is reviewing the transaction, we will call on each other's expertise.

Mr. LEIBOWITZ. We will.

Mr. COBLE. Thank you both.

I yield back, Mr. Chairman.

Mr. JOHNSON. Thank you, Mr. Coble.

I will next turn to the Chairman of the Judiciary Committee for his questions.

Mr. CONYERS. Thank you for your statements. Let's look historically at where we are now.

Were the railroad cases the first big antitrust cases followed by the telephone cases?

Mr. LEIBOWITZ. And oil, yes.

Mr. CONYERS. Oil.

But the mergers keep coming; the anticompetitive activity is still roaring down the runway. Corporate power globally is increasing. The lives of everybody now are impacted, and even governments are impacted.

I can remember, Mr. Chairman, when I made my first trip to the African continent. Most of the companies there were larger than the companies—most of the companies there were larger than the countries that they were in, in terms of power and influence. In many instances it hasn't changed that much.

Do you agree with this trend that I am—this picture that I am summarizing, that corporations keep getting bigger and keep affecting more control and power over not only the people on the planet, but the countries that govern the people in the various, what is it, 132 nations in the world—192? Let's talk about that, ladies and gentlemen.

Ms. VARNEY. Certainly, Chairman, in my travels around the world, which have been far less extensive than yours, we see the increasing importance of corporations in a global and increasingly interconnected and dependent world. And I see it everywhere I travel.

And there are corporations, certainly, that have enormous influence in economies everywhere. At the same time I, not too long ago, was in sub-Saharan Africa, and I was informed—I don't know that this is accurate, but I was informed at the time that China is actually the largest investor right now in sub-Saharan Africa.

So I think it is an increasingly complex, increasingly interconnected, and increasingly global world where some participants, be they governments or be they private sector participants, are having influence beyond what you would have seen at the turn of the century when you referenced the very first big antitrust cases.

Mr. LEIBOWITZ. Yes. And I would agree with everything that Assistant Attorney General Varney said. I would just add this: When you look at the origins of the Sherman Act in 1890, I think part of what Congress was trying to reach was sort of the undue influence of corporations.

Of course, corporations also provide enormous benefits to American consumers and to consumers around the world. I would say this, you have asked us sort of a meta-question that goes well beyond the jurisdiction of our agencies. There was a piece in the, National Law Journal yesterday—I will put it in for the record—that really talked about how active the two agencies have been——

Mr. CONYERS. Yes.

Mr. LEIBOWITZ. And so within the narrower confines of the work that we do I think we have done a pretty good job. I can say that about the Antitrust Division. I can't necessarily say that about the Commission—I don't have quite as much objectivity with respect to the FTC.

Mr. CONYERS. Well, when are we going to get a Section 2 case? We haven't got any so far.

Mr. LEIBOWITZ. Actually, and I hate to correct the Chairman of the Committee on a factual matter, we have a Section 2 case. Actually, we have several Section 2 cases right now. One is a pharma-

ceutical reverse payment case; that is the Third Circuit case involving Cephalon. Another is a case we have brought using both Section 2 monopolization and Section 5 unfair methods of competition, as well as unfair and deceptive acts or practices against Intel.

And then, during the Bush administration we actually had a very significant standard-setting case that was a monopolization case involving a company called Rambus. We lost that in the D.C. Circuit, but we are going to continue to look around for a——

Mr. CONYERS. I stand corrected.

Attorney General, when are you going to get into that?

Ms. VARNEY. Mr. Chairman, you will have a case from us when we have the facts and evidence ready to bring the case. We have many investigations, which I can't comment on, going on right now.

We have also been very active in stopping anticompetitive mergers, in fixing—allowing parties to cure potential anticompetitive effects of mergers. So I think we are very active, and I—you know, Section 2 cases take, as I think the Chairman——

Mr. CONYERS. Of course.

Ms. VARNEY [continuing]. Quite a bit of time to develop the facts and the evidence.

Mr. CONYERS. They are complex.

But just closing, Mr. Leibowitz, you know, telling me about how much good corporations are doing are balanced by how much bad some are getting away with. That is two different subjects.

I mean, I applaud capitalism under regulation, but this picture is getting more and more bleak. The mergers are still roaring ahead, which, incidentally, after all of our prattling about small business, that makes it that much harder for small business to ever get started in this kind of atmosphere.

Mr. JOHNSON. Thank you, Mr. Chairman.

Next I would recognize my good friend from Utah, Mr. Chaffetz.

Mr. CHAFFETZ. Thank you, Mr. Chairman.

And thank you both for being here.

Mr. Leibowitz, if we could start with you just real quickly, let me talk just for a moment about the Cephalon situation, where we have—my understanding is a D.C. Federal court—district court Judge Kay, for the first time, my understanding is, in 33 years actually offering some limited discovery into that case. Can you expand—I mean, is this—I think you know the situation that we are talking about, but is this something that the FTC does, and this type of activity, in terms of getting in the middle the way that it did?

Mr. LEIBOWITZ. It is a very fair question, and let me respond to it. Let me respond to it first by bifurcating it a little bit.

Again, we take a perspective at the FTC—and we are very, very bipartisan—to try to get the greatest good for the greatest number of people, and that is how we came up with or decided to make pay for delay settlements a major commission issue.

We believe—or our Bureau of Economics reported—that it costs consumers $3.5 billion a year, and we are going to be resolute in trying to stop these deals, whether by getting a case to the Supreme Court or by trying to pass legislation in Congress.

As for the issue involving Watson and Mr. Bisaro's deposition, let me make a couple of points. We play by the rules at the FTC, when

the magistrate issued the opinion and he asked for limited discovery of the commission we decided—and this is almost unprecedented—to make our interrogatories public. It was a vote of the commission; it was a five to zero vote. And we did that because we thought it was important to get all the facts out.

Again, I believe we play by the rules. I think as the facts do come out you will see that we didn't do anything wrong.

I will say this: Mr. Bisaro, who is the person who has avoided our subpoena, our deposition, for almost a year now—you know, I just don't quite understand this. If this Committee were doing an investigation—if your Committee were doing an investigation, as a routine investigation, which this is—or a typical investigation—and someone refused to come and testify, I think you would be upset with it. And I think there——

Mr. CHAFFETZ. I may be upset, but, you know, you have a Federal judge who for the first time in 33 years decided that they were going to go ahead and allow some additional discovery——

Mr. LEIBOWITZ [continuing]. We are happy, Mr. Chaffetz, to have some discovery, because we don't think we did anything wrong. We think that Watson has just been slinging mud at us, and some of it will stick occasionally.

Mr. CHAFFETZ. Okay. Fair enough.

Let's go back to the Google situation. And I found it very interesting that Ms. Varney gave an answer for we—us—talking about two different agencies. And that is part of the question as to which agency does it go to? How do you make the determination as to who is going to do what?

You seem very capable of answering the question for the FTC, but for those businesses and organizations that are trying to figure out how to move forward with their regulators how do you make these types of determinations? I mean, is this——

Ms. VARNEY. I think, Mr. Chaffetz, that generally I would say—in 98 percent of the matters it is very clear to the parties which agency, based on history and expertise——

Mr. CHAFFETZ. But for that extra 10 percent——

Ms. VARNEY. The extra 2 percent——

Mr. CHAFFETZ. Two percent. Sorry—98 percent, okay.

Ms. VARNEY. It is difficult. It is absolutely difficult to know with certainty which agency is likely to have the right expertise——

Mr. CHAFFETZ. So if somebody calls in and says, hey, you know, and they think it is at Justice and maybe it is a—how do you deal—do you have procedures in place for both agencies to——

Ms. VARNEY. Very efficiently. And the reason that either one of us can answer for both is because this—what you are talking about is something that is called preclearance, and it is a process that is housed at the FTC but is actually run with both of us present. So if a party or parties are merging and they want to come in and it is not clear which agency will review the merger, both our staffs sit down with the merging parties on the front end and hear the presentation, and we work very——

Mr. CHAFFETZ. The customer part of it—if there is a customer complaint does the same process work in place?

Ms. VARNEY. Generally we try and resolve which agency is going to be reviewing a matter relatively quickly so that one of us can

get our staffs out there and talking to customers and suppliers and competitors and the parties.

Mr. LEIBOWITZ. So, but just to follow up on——

Mr. CHAFFETZ. Yes.

Mr. LEIBOWITZ [continuing]. Assistant Attorney General Varney's point, you know, she was an FTC commissioner in the 1990's, and a terrific one, we try very hard and—our staffs try hard and we try very hard to make sure our staffs resolve those handful of cases where there is—effectively a jump ball quickly, because companies deserve a quick resolution. And I went back and I looked at the statistics which we provided to the Committee, and of the handful of contested clearance agreements not a single one of them went past 15 days.

And we can still do a better job because I think we want to keep it down to a week, and a few went over a week. But believe me, if she and I had to deal with a lot of clearance disputes our head would be exploding, or our heads would be exploding right here in front of you. So we try to do a good job; we are not perfect. But——

Mr. CHAFFETZ. If you could understand how that works a little bit more clearly I would appreciate it.

Thank you, Mr. Chairman.

Mr. CONYERS. Mr. Chairman, I ask unanimous consent to put into the record the article that Mr. Leibowitz referenced, "FTC Antitrust Blitz," written only yesterday in the National Journal newspaper.

Mr. JOHNSON. Without objection.

And we will next turn to the distinguished gentleman from Texas, Mr. Gonzalez.

Mr. GONZALEZ. Thank you very much, Mr. Chairman.

And I take it from the witnesses' testimony—correct me if I am wrong—no determination has been made as to who is going to be looking into the proposed Google-ITA business deal. Is that correct?

Ms. VARNEY. Congressman, our confidentiality rules do not permit us to even comment on whether or not a particular merger has been filed. So we can't comment. The parties can, but we can't comment on that.

Mr. GONZALEZ. All right.

Mr. LEIBOWITZ. And Google, by the way, has generally acknowledged publicly which agency gets an agreement or a merger proposal, and once they do we can confirm it.

Mr. GONZALEZ. So let's just go ahead on what has already been reported in every major newspaper in the United States. And let's go in New York Times, July the 6th, "Regulators Prepare to Dig Into Google-ITA Deal," quote—and this is by Brad Stone—"It's no secret that United States antitrust enforcers are looking closely at Google's business practices and the way it leverages its dominance in Web search into other Internet markets."

So we are going to assume someone is going to be looking at it. And it is not just Google, and we need to preface—or I need to preface my remarks—it is just not Google. It is the whole technology that is going on out there. What happened with Microsoft years ago and the advancing of a temporary monopoly argument—on and on. So you have got to deal with all that, but it is very interesting to

figure out that particular business model and its activities and its potential spillover to other areas.

So I will go to New York Times, July 1st, "France Calls Google a Monopoly." "This week the French Competition Authority officially declared Google a monopoly." "Google holds the dominate position on the advertising market related to online searches," and then it went on to expand.

But this is the most important part of the story: "Google's position, rejected by the French, is that the relevant market is all of advertising, in which Google has a tiny share, rather than online search ads in which it is dominant. It appears that if the French authorities do not reverse that conclusion in their final ruling it will be the first official precedent rejecting Google's argument"—the general argument.

"In the United States the Federal Trade Commission said in 2007 that it was possible that search ads could be a defined market for antitrust purposes, but it did not reach a conclusion on the issue as it approved Google's acquisition of DoubleClick, in advertising distribution network."

So my question, to the extent that you can answer it: When does kind of general market share translate into something that should be drawing your concern? When do you have, as Google has advanced—look, you have got to look at all advertising. Just don't look to that which is search-generated.

But the truth is, as technology moves forward and where advertising is going, is it, in fact, something that should be isolated and recognized as standing on its own for consideration?

Mr. LEIBOWITZ. So, let me take that question first. I saw that article from a few days ago about the activity of the French government. It would be hard for me to understand how Google could have a dominant position in all advertising. I think it is pretty clear they have a monopoly position in search ads, and as that article noted, we looked at Google AdMob recently; we looked at Google DoubleClick several years ago.

Again, when you are up in the 70 percent market share, as I think they are on search, I think everyone would believe that is a monopoly position. It doesn't control the entire market, but it is dominant, as the Europeans would say.

But I would also point this out, and obviously we have had reviews of Google-related activities and the Justice Department is involved in the Google book search. Just by virtue of being a monopoly, that is not illegal under the antitrust laws. You have to engage in some sort of bad conduct beyond that.

And, I think if you acquire a monopoly position by virtue of your terrific products or your terrific marketing that is okay generally. It is only when you go beyond that and try to stifle competition or engage in exclusionary practices that you are engaging in some sort of illegal monopolization.

Again, courts have pared back the ability to win monopolization cases in the last several decades. That is no surprise to anyone. And it's part of the reason why we are using our unfair methods of competition authority, which is a penumbra around the antitrust laws—when you created the FTC you wanted an agency with very broad jurisdiction and very weak remedies.

We don't put people in jail, right? We can't fine malefactors. But part of the reason why we are using this authority that we have had since 1914 more often is because we want to stop anticompetitive behavior that harms consumers.

Mr. GONZALEZ. But you are saying they would have to have an affirmative act by a company on exclusionary practices before it would be legitimate to look at it.

Mr. LEIBOWITZ. I mean, "look at it is" a non-legal term, so, we are aware of the dominant position that certain companies have in certain markets—Intel has in chips, Google has in search. But you would want to see some sort of acts or an act that was designed to unfairly, denigrate competitors before you would bring action.

Mr. GONZALEZ. And whether you had that intention or not, but it is the result, would that matter?

Mr. LEIBOWITZ. Yes.

Mr. CONYERS. I ask that the gentleman gain an additional minute.

Mr. JOHNSON. Without objection.

Mr. GONZALEZ. And I appreciate it, and I will give Ms. Varney an opportunity to respond.

Ms. VARNEY. I think your question, Congressman, started with basically a merger analysis question, and without commenting on any particular potential merger or current merger, it is not unusual for us to examine what is actually a relevant market. It is very tough in many circumstances. I think you saw that in the XM-Sirius merger. There was a question as to whether satellite radio was, in and of itself, a distinguishable market.

We see that often. In my time at the Department of Justice in the many of the mergers we have reviewed the parties have argued that the markets that the merged parties were competing in were separate markets.

This is not an issue that we are in any way unfamiliar with. We have tools that we use to help us assess and understand what are the relevant markets. I am sure you won't be surprised to know that in virtually every merger where there is competitive overlap the parties routinely argue that they are not in the same market.

So that is a threshold question. We have lots of tools—our revised merger guidelines give lots of transparency to parties and to practitioners as to how we assess what particular tools we will use to try and determine what is an actionable antitrust market.

As the chairman went through the standards he was, I think, essentially talking about single firm conduct. I am talking about the tools you use to do a merger analysis.

Mr. GONZALEZ. Thank you very much.

Thank you for your indulgence, Mr. Chairman.

Mr. JOHNSON. Thank you, Mr. Gonzalez.

Next we will have questions from the distinguished gentleman from Virginia, a man who never smiles and his—is both respected and feared by witnesses who appear before this Subcommittee, Mr. Bob Goodlatte?

Mr. GOODLATTE. Well, thank you, Mr. Chairman. You always bring a smile to my face. [Laughter.]

I want to welcome the witnesses and, I must say, I am strongly in favor of our Nation's antitrust laws and believe they should be

enforced to the fullest extent of the law. And I prefer them, generally, over regulations, wherever possible, because I think that if you set parameters and tell companies that if they operate within these parameters they are okay then it creates, I think, the maximum amount of competition and the maximum amount of creativity, whereas regulations often result in unintended consequences that can stifle creativity in ways that simply were not intended by the regulators.

However, the Administration enforcing these laws has to be fair, has to be predictable, has to be uniform so that businesses know that the ground rules, regardless of which industry they happen to be and thus which agency reviews their activities. I also believe that the law should be enforced objectively and not subjectively.

And I have been looking into ways to ensure that the basic framework of the antitrust enforcement process is fair, and I hope that the witnesses here today will join me in that effort.

So first, I direct this primarily to you, Mr. Leibowitz: One area that I have been looking into is the different procedural tools that the FTC and the Department of Justice posses. The FTC has different procedural tools available to it to challenge mergers. Like the Department of Justice you can pursue a preliminary injunction in Federal district court; however, unlike the Department of Justice, which combines its preliminary injunction case with a merits trial in Federal district court, the FTC can pursue a separate administrative case within the FTC.

To me, this raises questions of fairness. First of all, why should mergers be subject to different procedural standards given that the Department of Justice and the Federal Trade Commission sometimes decide who will review a merger based on basically a coin flip or a possession arrow? You want to tackle that first and then we will ask Ms. Varney?

Mr. LEIBOWITZ. Yes. Let me start by saying as a general matter I agree with you that enforcement is a better approach than regulation. And, we consider ourselves to be an enforcement agency. We occasionally do write rules, but that is the exception rather than the rule.

And then let me also let the record note that I have seen you smile many times in the past. [Laughter.]

I understand this argument, and I have certainly heard it a fair amount, particularly from the Antitrust Bar. But I actually think ultimately the standards are more alike than not, and here is why: So, if we go to court and we ask for preliminary injunction, the Antitrust Division asks for a permanent injunction. We then have to show in different circuits different standards.

Outside of the D.C. Circuit we have to show likelihood of success on the merits in most circuits. In D.C. Circuit we have to show questions that are very serious and very substantial. That is the language from the *Heinz* case.

And then, if a company wants to come back to the FTC, which is an expert body that was created by Congress, we have to show ultimately that we will win on the merits. So we ask for preliminary injunction.

Sometimes that is done very quickly. In a case involving an Inova acquisition of Prince William Hospital—you are familiar with

that—the judge just sent it over to the FTC—the district court judge in Alexandria—to do the entire review.

And the other thing I would say for companies is that we recently dramatically accelerated our procedures at the FTC, so if a company wanted to immediately come to the FTC and get a full trial, which is more than a preliminary injunction or a permanent injunction, they can have that in 5 months with a review in several more months—in 2 more months—by the commission, and that is actually as fast as you would get a review in the district court.

Mr. GOODLATTE. Do you have the ability to bring a combined preliminary injunction and merits case like the department does?

Mr. LEIBOWITZ. We probably do have that——

Mr. GOODLATTE. Have you ever used it?

Mr. LEIBOWITZ. No, no, no. I mean, going back through Administrations and commissions we have always gone to court to ask for preliminary injunction and then the case has gone to what we call part three internally. But if a company wants to come first——

Mr. GOODLATTE. But if you wanted to bring it through the courts as opposed to your internal process you could do that?

Mr. LEIBOWITZ. If a company wants us to we would do that.

Oh, through the courts? We always go to court because we need to get a preliminary injunction——

Mr. GOODLATTE. I understand.

Mr. LEIBOWITZ [continuing]. To stop the merger from proceeding.

Mr. GOODLATTE. But then do you ever ask the court to rule on the merits of the case?

Mr. LEIBOWITZ. Well, what we ask the court to do is to stop the proceeding. Now, courts will sometimes use a likelihood of success on the merits standard and sometimes they will use, as the D.C. Circuit does, questions so serious and so substantial they go to the heart of the matter, and then it comes to the commission.

Mr. GOODLATTE. How many times does the administrative law judge rule against the FTC staff in a merger case?

Mr. LEIBOWITZ. Against the FTC staff?

Mr. GOODLATTE. Yes.

Mr. LEIBOWITZ. Quite often, in cases generally. I will get you that information.

Mr. GOODLATTE. I would like to see that——

Mr. LEIBOWITZ. And also in conduct cases, as well. I want to say this: I know in conduct cases they have ruled against the FTC staff on several recent occasions, including our Rambus case several years ago.

On merger cases, I will go back, and I will get you and I will get the Committee the answer. That is a good question.

Mr. GOODLATTE. And finally, on appeal how many times have the five commissioners ruled against the FTC?

Mr. LEIBOWITZ. I will get you that information. I mean, you raise a real question, and I don't disagree with that, but I like to think at its bottom line in merger cases that ultimately the result of the merger is never—and I don't think anyone has ever alleged this even from the Antitrust Merger Bar—the outcome isn't determined by who you go to, and the standards are ultimately the same.

Mr. GOODLATTE. Thank you.

Ms. Varney, do you have any comment on that?

Ms. VARNEY. Only I can speak to the Department of Justice, Mr. Goodlatte. We can seek a preliminary injunction; we can seek to have that preliminary injunction combined with a permanent injunction trial on the merits; or we can seek a preliminary injunction and then proceed down the road after discovery to a permanent injunction, which is a full trial on the merits.

So our system is slightly different and we, of course, as you have noted, are held to the common law standard in every circuit that requires for a preliminary injunction likelihood of success on the merits and irreparable harm if the injunction is not granted. If we get the injunction separate from a permanent injunction we then—generally the parties will withdraw and everybody will go home.

You can often get the parties to agree to not proceed with the transaction until the court schedules a full trial on the merits. So there are occasions where we simply don't go through the preliminary injunction standard, where we go after discovery to a direct trial on the merits and then all of the standards of Section 7 of the Clayton Act and the court precedent on merger analysis kick in. So it is a slightly different system.

Mr. LEIBOWITZ. Mr. Goodlatte, if I could just add one more brief point, when Congress—when you or your predecessors—created the FTC you wanted to create an expert agency, and so I think theoretically—and I will go back and get you some research on this, too—I think theoretically you probably wanted all the merger reviews to go through the FTC internally as opposed to into court for, a preliminary injunction. But let me get back to you.

But part of the idea of putting things into our ALJ process and internally into the commission is we are supposed to be an expert agency; we are supposed to build records; we are supposed to learn from the cases we bring and the actions we take.

Mr. GOODLATTE. Ms. Varney, does the Antitrust Division not have the expertise that we think you have to——

Ms. VARNEY. I think that the division and the courts and the FTC all have terrific expertise in doing anticompetitive analysis. I think, as Chairman Leibowitz pointed out, the Federal Trade Commission is a creature of Congress, and I have no basis to go through the legislative history of what Congress intends the FTC to do and not do, or how to do it. I think that is a question reserved for you and the chairman.

Mr. GOODLATTE. Well, I am just concerned about the lack of consistency here, and from looking at it from the outside you would have a considerable question about, you know, why we are going two separate directions here on antitrust law and how there is kind of predictability and fairness that a business trying to make a decision before they ever get to the point of being before that court for that preliminary injunction has to make. It just compounds the problem, and I would think it would be stifling on investment and creativity and doing business in the United States. Thank you.

Mr. Chairman, my time is expired. Are you going to do a second round, or—I do have another area I wanted to get into, but I don't want to keep Mr. Issa from getting his shot here first.

Mr. JOHNSON. I certainly have abundant respect for Mr. Issa's brain power, and you both sit next to each other. Perhaps he will

ask the same exact questions that you had on your mind. And so let's wait and see what Mr. Issa brings to the table.

The distinguished gentleman from California, please?

Mr. ISSA. Thank you, Chairman. As you know, my questions usually lead to more questions, so I suspect a second round will be essential as a result.

Chairman, we are considering—since you are a creation of ours and you are our bastion of expertise—we are considering a bill that probably won't happen in this Congress, but these things tend to come back—H.R. 5034. And I would like your view on the legislation itself and on the problems that it make create from a stand—because it clearly deals with antitrust questions, interstate commerce, and not only the history of litigation that has already gone on and court decisions, but the 21st Amendment.

To the extent that you are familiar with the legislation, could you comment on——

Mr. LEIBOWITZ. Is it the alcohol——

Mr. ISSA. Yes, sir.

Mr. LEIBOWITZ. I am aware of that legislation——

Mr. ISSA. And your Web site makes us think that you are not very keen on it, but I would like a delineation a little more.

Mr. LEIBOWITZ. I don't believe that we have testified on or taken a position on the legislation——

Mr. ISSA. This is your chance.

Mr. LEIBOWITZ [continuing]. And I will—you know, we are a very bipartisan, consensus-driven group, and I am going to go back to the commissioners and talk to them, and I will get you an answer. But I would say this: My recollection of this legislation is that it would preempt the ability of Federal antitrust authorities as a practical matter under most circumstances from reviewing competition problems within alcohol distribution.

And so, we generally believe as I know you do—that competition is the best approach, and when you have Federal antitrust enforcement under appropriate circumstances that is usually a good thing in terms of bringing competition, more choice, and lower prices to consumers. But let me get back to you with some more grounding. I don't want to speculate too much until I go back and read the bill.

Mr. ISSA. Okay. And as you can imagine, this is a bipartisan piece of legislation, particularly to those of us who have both beer producers and wine producers in our district, both manufacturers and, if you will, distributors. So even if you don't take a final position on it, some of the pitfalls that you believe it might—from your oversight standpoint going forward—might represent would be very, very helpful. I am looking forward to that answer the—a great deal.

Let me ask another question. Now, I am one of the non-lawyers on this Committee, and my antitrust experience really goes to being told by the courts years ago that at a Chrysler dealership if Chrysler decided not to let anyone else sell radios there except Chrysler radios that it wasn't an antitrust violation even though they had 100 percent control over that franchisee because the relevant market were all car companies and there were only 10 percent Chryslers, and less later.

I thought that was a rotten decision. It should never have stood; it ultimately was one of those where we won on a three-judge panel and lost en banc, and denied cert. It was the Town Sound case here in one of the eastern circuits. Terrible decision.

So I have always looked at relevant market barrier to entries to try to figure out the other part, the other legs of stools—legs of the stool. And one of the questions I am starting to have in the Internet—and earlier Mr. Chaffetz talked about, he was getting into Google and some of these other issues. If we assume for a moment that the Internet has no barrier to entry, that just anyone with $1,000 and a college kid to write a piece of software can someday be a major player on the Internet, then that leg of the stool just doesn't exist, and that means that the test is there is no antitrust.

On the other hand, when we look at powerful players who, for example, have a dominant position and then give away lots of software—and Gmail is highly recognized and some of the services Google do, but I am not trying to pick on just them. When are we going to either see the courts make decisions that they may or may not be empowered to make or a direction back to those of us on this side saying that we have got to rewrite antitrust law to deal with, if you will, market power without a barrier to entry, potentially, and yet a tie-in that effectively is anticompetitive?

And this could be a question for both of you because I view it as clearly anticompetitive potentially. I view it as locking—free always locks out other innovation, almost always. And yet, right now I feel like current law probably doesn't support your being more activist in those kinds of areas.

Ms. VARNEY. Well, I have not sure——

Mr. ISSA. Ms. Varney, I was glad to see your head shaking, so I——

Ms. VARNEY. I am not sure that I feel that current law doesn't allow us to prosecute anticompetitive behavior in any industry, including technology. I think I will——

Mr. ISSA. So if Google has market power and they are giving something away, and therefore their giving away promotes a product in which they have a dominant position while eroding other people's ability to have profit, why wouldn't that already be the subject of your investigations and enforcement?

Ms. VARNEY. Again, without commenting on any potential current——

Mr. ISSA. Let's just say your historic and as of yet revealed——

Ms. VARNEY. Well, actually that is what I am going to do, is I am going to take you back a little. But first I am going to promise you that I am going to read your case so that I understand the facts of your case.

But I would also like to take you back to U.S. v. Microsoft.

Mr. ISSA. By the way, I was not a plaintiff in Town Sound. I was the nonpaid chairman of a trade association that supported it. I was actually in security, not car radios. But you follow these things on behalf of your trade association——

Ms. VARNEY. Well, I will look forward to discussing that case with you after I have read it.

But in the interim I would direct you to U.S. v. Microsoft, both the court of appeals here in D.C. and the trial court opinion, which

dealt precisely with the issues that you are talking about—barriers to entry, is free predatory pricing, when does lockout occur, what is a tipping point, what is a leveraged market, what is an adjacent market—all of these questions were dealt with, I think, quite successfully and quite appropriately in the U.S. court of appeals for the District of Columbia in U.S. v. Microsoft.

So I believe at the moment we have the tools we need. If that turns out not to be true I will be back to you in a heartbeat telling you we don't have the tools we need.

Mr. LEIBOWITZ. And I guess just to——

Mr. ISSA. Although in that case they found barriers to entry which I think we could make the case that in the cloud you can have a zero barrier to entry, potentially—a threshold of a few thousand dollars to give you——

Ms. VARNEY. Yes. At the time one of the arguments that many were making is that there were no barriers to write new applications that browsers could then, indeed, locate.

Mr. ISSA. Right. But the software was sitting on the product at the time delivered in a tie-in with Intel, AMD, and so on. So there were a much more conventional set of circumstances of hardware-software than we are now seeing in cloud computing.

Ms. VARNEY. Well, at the time, Congressman, I was in—as you were in your case—I was very involved in this case. I was the attorney for Netscape, which was the company that made the browser.

Mr. ISSA. Oh, yes.

Ms. VARNEY. And at the time it was not at all clear. It wasn't conventional. This was the operating system and software sitting on the operating system I actually came up to the Hill to demonstrate to some Members of the other body what was the relationship between the browser and the software——

Mr. ISSA. Such a waste of time. You need to come here first. [Laughter.]

Ms. VARNEY [continuing]. And someone picked up the mouse and said, "Is this the browser?" So I think if you go back in time and you look at the situation when the government brought the U.S. v. Microsoft case it was a very, very new set of circumstances, set of industry players, set of industry facts.

People didn't understand the relationship between the intellectual property in the operating system, the construction of the operating system, whether or not the browser was integral to the functioning of the operating system, whether or not the browser could be a platform that could replace the operating system—these questions were all present in 1997 when we started the U.S. v. Microsoft case, and we managed to work our way through them I think to the right conclusion with the tools that we have and continue to have to this day.

Mr. LEIBOWITZ. Yes. I agree with Assistant Attorney General Varney, and I think the Microsoft case does encapsulate a lot of the elements that you have talked about.

I do think we have the tools to go ahead and bring cases against companies that engage in illegal monopolization. We have a major case against Intel now—we are actually in settlement talks, and of

course if we can settle to the benefit of consumers and competition and the public we will do that.

But we do have those tools. At the FTC we have an additional tool, which is our Section 5 unfair methods of competition authority that is this penumbra around the antitrust laws. The remedies are weak; we are not using it to break up companies; we are not using it to do anything but open the door to competition going forward.

So I think, as Assistant Attorney General Varney said, we will come back to you if we need additional tools, and there certainly have been some attempts, as you have alluded to, by the courts to circumscribe antitrust in recent years. But I think we will, when we do our next oversight hearing in a year or 2 hopefully we will have some pretty good cases and some pretty good settlements or results.

Mr. ISSA. I appreciate that, Mr. Chairman. I hope that that last comment will be stricken from the record—the part about a year or 2. I was hoping to see you much sooner.

Mr. LEIBOWITZ. We will come by and have an offline chat.

Mr. ISSA. Thank you.

I yield back.

Mr. JOHNSON. Thank you, Mr. Issa.

We now turn back to Mr. Goodlatte.

Mr. GOODLATTE. Well, thank you, Mr. Chairman.

The other area I wanted to get into is the one related to the chart that Mr. Leibowitz brought with him, and that is related to these patent settlement cases that are reviewed by the courts. You, or the FTC in general, has expressed concerns about the potential anticompetitive nature of some of these settlements, and you have indicated an interest in getting enhanced authority to challenge the settlements.

Don't the courts review the settlements that occur before them in other contexts? I mean, what about patent settlements are so unique that the Federal courts cannot understand them well enough to review them for their competitive impact, particularly if you are given, as you are, the authority to express your views as a part of the process?

Mr. LEIBOWITZ. Well, I would say, of course courts can review settlements, and they have the opportunity to do that, and I don't dispute that. And in fact, any cases that we have brought—and we have brought several; we have two pending now, one in Mr. Johnson's 11th Circuit in district court, one in the Third Circuit—they are reviewed by the courts and they are ones that we are involved in.

So we want to work with the courts. We think the trend is turning around, actually.

There was a Second Circuit decision in a case involving the drug Cipro; Assistant Attorney General Varney filed a terrific brief in it and in a very unusual result the three-judge panel questioned the previous permissive rule. So I think we are making progress in the courts. Just going back to your——

Mr. GOODLATTE. Let me just interrupt you there for a second, because, you know, I share some of your enthusiasm for these delay settlements and wanting to break into them, but here is the point: You indicated, "Well, in this case we are making some progress,"

but if you were to take a legislative approach that would internalize more of this in the FTC you are taking away the element of fairness that I think people expect from the Federal courts.

Now if the courts are lopsided in their review then maybe the Congress needs to review the standards by which they judge these cases or something like that, but I am not excited about moving away from the idea that the independent judiciary will be the final arbiter of these cases.

Mr. LEIBOWITZ. I think that is a great question. And remember, the first bill that the House passed as part of health care was what we call a bright-line test, what others call a per se ban on these deals.

The legislation that was passed as part the appropriations defense supplemental to offset, I believe, the teachers' money, and not passed by the Senate I think largely because of the teachers' money, was a presumption. And I think presumption approach works for us.

What it does is this: It says—and I think this is a pretty good approach. It is not everything that the commissioners would necessarily want or the commissioner wants, but I think it solves—takes care of the worst abuses.

It says simply, if a brand pharmaceutical company pays its generic competitor and the generic company delays entry then the burden of proof is reversed and it is a rebuttable presumption, essentially. And I think that is a pretty good approach, because remember, the pharmaceutical companies who were in litigation then settled have all the information, and if they can show—and I think in some cases they probably would—that the money that went for settlement didn't go for the delay then they can do their deal.

If this legislation is enacted this year, and of course we hope it will be, we will be bringing cases in the courts and we will have to show the money, the delay, and then there will be a rebuttable presumption. So you might be a little more comfortable with this compromised version, and that is the version I think, may be enacted this year.

Mr. GOODLATTE. The final financial reform bill did not include the provisions that would have expanded the FTC's authority in rulemaking, civil penalties, and aiding and abetting. Do you plan to continue to push for such authority?

Mr. LEIBOWITZ. Well, I would say this: It did not, and reasonable people can disagree about our expanded authority. On civil penalty authority I would say we bring a lot of fraud cases because the Justice Department has other priorities, and in those cases it would be very helpful for us to be able to go to the courts and ask to fine malefactors.

Caspar Weinberger, when he was the chairman of the FTC in the early 1970's, supported this, and again, I would be surprised if this is going to be a viable matter—this is going to be a viable issue going forward this year.

I think that there is going to be an FTC reauthorization next year; your Committee will be involved, Energy and Commerce will be involved. And so it will go through regular order, and we will have a bit of discussion and I think it is a good idea to have one—about the pros and cons of easier FTC rulemaking.

Mr. GOODLATTE. My understanding is that most of those changes were directed at the commission's consumer protection bureau.

Mr. LEIBOWITZ. Yes.

Mr. GOODLATTE. Would those changes have affected the commission's competition enforcement procedures and remedies?

Mr. LEIBOWITZ. The only one that would have had an effect on competition would be the provision that would have allowed us to immediately go to—and only in rare instances—would be the provision that would allow us to go to court and have independent litigating authority when we ask for civil penalties.

There are very few instances when we get civil penalties in the antitrust context. It is for violations of an order, and right now we have to go to the Justice Department, and the Justice Department files our case when we need civil penalty authority or when we are asking for a fine.

But it is a much bigger issue on the consumer protection side. On the consumer protection side and you were very involved in CAN-SPAM legislation and some of the other enhanced authorities that we have gotten over the years—we have a sort of Hobson's choice.

If someone is engaged in spamming or engaged in a do-not-call violation we want to go to court immediately to stop the ongoing harm, which we can do by ourselves, but then we have to forego the civil penalty authority. We just think it is efficient for us to be able to do that together, right, so we can both fine the malefactor or ask the court to fine the malefactor, and stop the harm.

Mr. GOODLATTE. And is the commission unanimous in these—in pushing for these changes?

Mr. LEIBOWITZ. It depends which change you are talking about. I think two of the four proposals——

Mr. GOODLATTE. The ones you didn't get.

Mr. LEIBOWITZ. Well, we didn't get any of the four, and I would say of the four the independent litigating authority is unanimous, the APA rulemaking authority and the civil fining authority has bipartisan supermajority of four to one, and we have a lot of respect for Bill Kovacic, the commissioner who was opposed to that. And again, reasonable people can disagree, and that is why we are happy to have the discussion in Congress about it.

Mr. GOODLATTE. Mr. Chairman, thank you. You have been generous with your time, and I thank our witnesses for enlightening us today.

Mr. JOHNSON. You are very welcome, sir.

I have no further questions, so I would like to thank all of the witnesses for their testimony today. And without objection Members will have 5 legislative days to submit any additional written questions, which we will forward to the witnesses and ask that you answer as promptly as you can to be made part of the record. Without objection the record will remain open for 5 legislative days for the submission of any additional materials.

I am encouraged by the testimony I have heard today, and I am impressed by two truly outstanding individuals who are leading the way for antitrust enforcement in this country, and it seems that you all have a great working relationship, and I think that that is the way the government should operate.

Nevertheless, perhaps we have grown too complacent in the face of shifting economic theories and deference to regulation. The antitrust laws should be keeping the playing field level for all players big and small, not just reinforcing the position of a handful that dominate.

And with that, this hearing of the Subcommittee on Courts and Competition Policy is adjourned.

[Whereupon, at 12:06 p.m., the Subcommittee was adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

QUESTIONS SUBMITTED TO
CHRISTINE A. VARNEY
ASSISTANT ATTORNEY GENERAL, ANTITRUST DIVISION
U.S. DEPARTMENT OF JUSTICE
BY
REPRESENTATIVE LAMAR SMITH
RANKING MEMBER, COMMITTEE ON THE JUDICIARY
EX-OFFICIO MEMBER, SUBCOMMITTEE ON COURTS AND COMPETITION POLICY

1. You revoked the Sherman Act Section 2 report when you took over the Antitrust Division. Do you intend to issue your own report? How has the revocation of the Section 2 report in 2009 changed the Department of Justice's approach to monopolization cases? Has the Division brought a monopolization case during your tenure? Do you anticipate doing so? How do those numbers compare with the last two years of the previous Administration?

Answer:

The Sherman Act Section 2 Report was withdrawn because it advocated extreme hesitancy in the face of potential abuses by monopoly firms and raised unnecessary hurdles to government enforcement of the antitrust laws, making it more difficult for the antitrust agencies to protect competition. The withdrawal of the Report signals a clear intent to follow Supreme Court and lower court precedents developed over decades, from *Aspen Skiing* to *U.S. v. Microsoft.*

The Antitrust Division brought no monopolization cases during the last years of the previous administration, and has not yet brought a monopolization case during my tenure. While I cannot comment on ongoing investigations, I can say that we are vigilantly evaluating on a case-by-case basis dominant firm unilateral conduct when we believe there may be a potential violation of the Sherman Act, and are prepared bring a Section 2 case if warranted by the facts. With regard to issuing a revised Section 2 Report, the Division is not at this time proposing any new test to govern all Section 2 cases. Generally speaking, however, following Supreme Court precedent and the D.C. Circuit's decision in *United States v. Microsoft*, the Division will in every case look closely at both the perceived procompetitive and anticompetitive aspects of a dominant firm's conduct, weigh these factors, and determine whether on balance the net effect of the conduct harms competition and consumers. The Division is committed to pursuing enforcement of Section 2 of the Sherman Act and will act vigorously against violations as they arise.

2. The Department has conducted a series of joint workshops with the Department of Agriculture on antitrust issues involving agricultural industries. Do you expect to issue a report on antitrust in agriculture following the workshops? If so, when? Do you have any interim ideas about what such a report should include?

Answer:

The agricultural sector is among the Department's highest priorities. The Department's joint workshops with the Department of Agriculture on competitive issues in agriculture industries have presented an opportunity to have an open and honest dialogue with farmers, processors, and industry experts about important trends in agricultural markets and the dynamics of competition in those markets. The Department embarked on these workshops with an open mind and did not prejudge any potential outcomes. The workshops have enabled us to become better informed on issues important to producers, processors, and other interested parties, and better equipped to do our job of vigorously enforcing the antitrust laws in this sector. The workshops' proceedings are being transcribed and, along with submissions and written comments received, placed on the public record. In addition, as a result of what we have heard at the workshops, the Department has formed a joint task force with USDA to determine how the two agencies can better work together to help promote competition in our nation's agricultural marketplaces. After the workshops conclude, the Department will take stock of what we have heard and consider how best to further our enforcement and competition advocacy efforts in the agricultural sector.

3. How many new criminal prosecutions have this Antitrust Division brought compared to the previous Administration? How do the amount of fines levied and length of jail sentences obtained by this Antitrust Division compare with the last two years of the previous Administration? What amount of the fines has been collected?

Answer:

The following chart indicates, for each year of fiscal years 2007 through 2010, the number of criminal cases filed by the Antitrust Division, the total amount of criminal fines imposed in Antitrust Division cases in millions of dollars, and the total number of days of incarceration imposed in Antitrust Division cases:

	FY 2007	FY 2008	FY 2009	FY 2010
Number Filed	40	54	72	60
Fines (millions)	$ 630.7	$ 696.5	$ 974.3	$554.8
Jail Days	31,391	14,331	25,396	26,046

Fiscal year 2007 runs from October 1, 2006 to September 30, 2007, and so forth. The average number of criminal cases filed by the Division per year during the time FY 2001 through FY 2008 is 40. The average amount of criminal fines imposed in Division cases per year from FY 2001 through FY 2008 is $372.7 million. The district court where the fine is imposed is responsible for the actual collection of the fine payments, and the U.S.

Attorney's Office in that district is responsible for monitoring the collection of fine payments. The average total number of days of incarceration imposed in Division cases per year from FY 2001 through FY 2008 is 12,029.

4. With respect to merger enforcement, how many cases has this Administration brought? How does that compare to the last two years of the previous Administration?

Answer:

Merger enforcement is vital to protecting American consumers and businesses. There are a number of factors that have a bearing on how many cases the agencies bring, including the economy and the volume of transactions, the types of transactions companies are pursuing, the transparency of the agencies' merger review process, and other factors exogenous to the agencies' policies and programs. Since our nation's economy—and indeed the global economy—experienced one of the largest downturns in decades, transaction volume fell significantly from the last two years of the previous administration. Accordingly, we have seen far fewer Hart-Scott-Rodino (HSR) filings, and I believe companies have been advised more effectively in the last two years not to pursue anticompetitive transactions. The previous administration filed 17 cases to block mergers in its last full year, and 8 cases in the year before that, and made announcements of its intent to block, leading the parties to abandon or restructure their transactions, 2 in its last year, and 4 the year before that. The current administration filed cases to block 4 mergers in its first year, and 7 in its second year so far, and parties abandoned or restructured transactions, including in response to an announcement to block, 6 in its first year, and 7 in the current year so far. Compared to the last two years of the previous administration, the statistics the Antitrust Division maintains indicate that the percentage of HSR filings that received a Second Request increased, and the percentage of HSR filings that face a challenge has increased. For example, in Fiscal Year 2007, the percentage of HSR transactions resulting in a Second Request was approximately 1.5%, in FY 2008 approximately 1.2%, in FY 2009 approximately 2.2%, and in FY 2010 approximately 1.9%. In addition, the average percentage of HSR transactions resulting in a merger challenge in Fiscal Years 2009 and 2010 more than doubled compared to the average percentage in Fiscal Years 2007 and 2008.

5. It is my understanding that the Federal Trade Commission usually brings enforcement actions against physicians and hospitals whose pricing behavior violates the 1996 guidelines. However, in your opening statement, you made reference to a case in Idaho in which DOJ enjoined a group boycott by a collection of Idaho surgeons. Why did DOJ bring that case, as opposed to the FTC?

Answer:

In the health care industry, as in most other industries, the agencies share enforcement authority. The 1996 Statements of Antitrust Enforcement Policy in Health Care were developed jointly by the Federal Trade Commission and the Department of Justice, and both agencies enforce the antitrust laws in various markets in the health care industry consistent with the Statements, including through the Department's Business Review letters and the FTC's advisory opinions, and enforcement actions brought by both agencies. For example, in October 2010, the Department filed a lawsuit against Blue Cross Blue Shield of Michigan (BCBSM) alleging that its use of most favored nation clauses in its contracts with hospitals raise costs for competing health plans, reduce competition for the sale of health insurance, and discourage discounts. In addition, the Department investigated and, in March 2010, expressed its intent to sue to enjoin BCBSM's proposed acquisition of Physicians Health Plan of Mid-Michigan from Sparrow Health System, which the parties abandoned after the Department's announcement. Over the years the two agencies have developed a process for determining which agency will handle a particular matter, generally on the basis of which agency has the most current experience in the particular markets involved. This process enables both agencies to make the most effective use of enforcement resources and avoids duplicative investigatory requests on private parties. The Department sought and obtained clearance to investigate the matter involving Idaho orthopedic surgeons' boycotts of payers under the agencies' process, and filed a lawsuit on May 28, 2010 to stop practices that would have denied medical care to patients, and would have forced those patients' insurers to increase fees for orthopedic services.

6. In his oral testimony, Chairman Leibowitz stated that "Under Christine Varney, the Department of Justice position has evolved considerably, and it now agree that pay for delay settlements are presumptively anticompetitive." Do you agree with Chairman Leibowitz's characterization of the Department's position? If this is the new position of the Division, what prompted the change from the previous Administration?

Answer:

Over the last few years, the Department has been asked to provide its views on specific cases involving pay-for-delay settlements, and more recently has been invited to provide guidance on the proper legal standard for analyzing such settlements under the antitrust laws.

In 2007, the Supreme Court invited the Solicitor General to express the views of the United States in *Joblove v. Barr Labs., Inc.* (*In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006) ("*Tamoxifen*"), with respect to the standard that the Second Circuit applied to the settlement agreement in that case. In its brief before the Supreme Court, the Department argued that the Second Circuit "applied an insufficiently stringent standard in scrutinizing the settlement at issue here," but also noted that the case before the court did not "appear to present an appropriate opportunity for this Court to establish the correct

standard for distinguishing legitimate patent settlements." S. Ct. No. 06-830, Brief for the United States as Amicus Curiae, at 8.

The Department received a request for the views of the Department from Senator Jon Kyl on the antitrust issues involved in pay-for-delay settlements, and in a reply letter, dated February 12, 2008, the Department emphasized that "there is a potential for such settlements to be anticompetitive." Although this letter stated that the Department did not believe per se liability under the antitrust laws is the appropriate standard for addressing pay-for-delay settlements, the letter did not define the most appropriate legal standard beyond noting that "rule of reason analysis is better suited to instances when the economic impact of the agreement is less certain."

On April 6, 2009, the Court of Appeals for the Second Circuit invited the Department to provide more guidance on the proper standard for analyzing such settlements. Specifically, the Court asked the Department to address "whether settlement of patent infringement lawsuits violate the federal antitrust laws when a potential generic drug manufacturer withdraws its challenge to the patent's validity, which if successful would allow it to market a generic version of a drug, and the brand-name patent holder, in return, offers the generic manufacturer substantial payments." In response to this request, the Department filed a brief on July 6, 2009, stating that:

> **"Private agreements that include reverse payments are properly evaluated under the antitrust rule of reason, which takes into account efficiency-related justifications as well as anticompetitive potential. The anticompetitive potential of reverse payments in the Hatch-Waxman context in exchange for the alleged infringer's agreement not to compete and to eschew any challenge to the patent is sufficiently clear that such agreements should be treated as presumptively unlawful under Section 1 of the Sherman Act. Defendants may rebut that presumption by providing a reasonable explanation of the payment, so that there is no reason to find that the settlement does not provide a degree of competition reasonably consistent with the parties' contemporaneous evaluations of their prospects of litigation success."**

7. The Antitrust Modernization Commission recommended that the FTC and DOJ "systematically collect and record information regarding the costs and burdens imposed on merging parties by the Hart-Scott-Rodino Act process." What information does DOJ already collect regarding the pre-merger clearance process? The Commission recommended this as a voluntary procedure, but is it something that Congress should be requiring of the agencies?

Answer:

The Division has devoted significant attention to both reducing the burdens on merging parties and streamlining our own merger review practices through the Merger Review Process Initiative (details available at www.justice.gov/atr/public/220237.htm.) The

Department is always open to negotiating the compliance of its document requests and works with parties to find ways to produce the information needed while reducing burdens.

In addition, the Division and the FTC are striving to improve our own HSR Form. The Division worked closely with the FTC on the proposed changes to the HSR Form, which were published for public comment in a Notice of Proposed Rulemaking on August 13, 2010. The proposed changes are aimed at getting the agencies more useful information in our initial review of transactions, while eliminating information requirements for which the burden to filing parties plainly exceeds the benefit to the agencies.

The Department does not systematically collect and record information regarding the costs and burdens imposed on merging parties or others by the Hart-Scott-Rodino Act, information that is available only to the merging parties and that may itself be burdensome to produce or subject to legal privileges.

8. The Antitrust Modernization Commission recommended that the "agencies should issue 'closing statements,' when appropriate, to explain the reasons for taking no enforcement action, in order to enhance public understanding of the agencies' merger enforcement policy." How many closing statements has DOJ issued in the last two years? How does that number compare to the preceding two years? Does DOJ plan to issue more closing statements in the future?

Answer:

The Antitrust Division's issuance of a closing statement under certain circumstances is an important tool for increasing transparency, and I am committed to issuing closing statements when appropriate. The Antitrust Division issued two closing statements in calendar year 2010, one in 2009, three in 2008, and three in 2007. The Department of Justice, on appropriate occasion may issue a public statement describing the reasons for closing an antitrust investigation. In determining whether issuing a closing statement is appropriate, the Department considers: whether the antitrust analysis is complex; whether best practice recommendations call for increased dissemination of rationales for enforcement and non-enforcement; whether public dissemination of enforcement and non-enforcement rationales benefit businesses attempting to comply with complex antitrust standards and consumers through a better understanding of the antitrust laws; and, whether transparency of antitrust analysis helps international enforcers understand U.S. standards for antitrust enforcement, encourages international convergence on enforcement standards, and serves to prevent noncompetition issues from inappropriately influencing antitrust enforcement.

The Department will only consider issuing a statement if the investigation has previously been publicly confirmed by the Department. The Department also considers whether the matter has received substantial publicity and interest from the public.

Guidance on the Antitrust Division's policy regarding closing statements is available at ***www.usdoj.gov/atr/public/guidelines/201888.htm.***

9. The Antitrust Modernization Commission recommended that the "Federal Trade Commission and the Antitrust Division of the Department of Justice should increase their use of retrospective studies of merger enforcement decisions to assist in determining the efficacy of merger policy." How many retrospective studies has DOJ conducted in the last two years? How does that number compare to the preceding two years? Does DOJ plan to conduct more retrospective studies in the future? If so, do you require greater resources from Congress for this task?

Answer:

The Department has not conducted any formal retrospective studies of previous merger enforcement decisions. As an initial matter, the Department does not have statutory authority to request information for purposes other than investigating potential violations of the antitrust laws. We believe our resources are best utilized in pursuing violations of the law. At the same time, however, the Department informally reviews market developments and past antitrust actions on an ongoing basis so that we understand the competitive dynamics in particular markets and to ensure that antitrust enforcement is having the desired impact on the marketplace. Also, when undertaking a new investigation or enforcement action in the same market or a related market as previous matters, the Department has an opportunity to assess competitive conditions as they developed subsequent to previous transactions. Furthermore, Department staff keeps up to date on market trends and monitors conditions that would be relevant to our enforcement efforts.

10. The Antitrust Modernization Commission observed that "Statutory immunities from the antitrust laws should be disfavored." Does the Antitrust Division agree that Congress, in general, should refrain from granting new antitrust exemptions?

Answer:

The Division believes that vigorous enforcement of the nation's antitrust laws is the most effective and best way to protect competition in our markets. Increased competition leads to lower prices and better products for American consumers. New statutory immunities from the antitrust laws have the potential to seriously undermine competition and harm consumers in affected markets. The Division therefore believes that Congress should be extremely cautious when considering new statutory immunities from the antitrust laws. In the vast majority of cases, competition and consumers are best served by continued application of the antitrust laws, including in the context of industry-specific regulation.

11. What does the Antitrust Division do to provide assistance to foreign countries, like China, that are forming their own antitrust laws? The Antitrust Modernization Commission recommended that Congress authorize and appropriate monies directly to DOJ and the FTC for international bi-lateral antitrust technical assistance. Does the Antitrust Division want specific Congressional authorization for this activity? How would you use such an authorization?

Answer:

The Division is engaging actively with new antitrust regimes, including China and India. For example, over the past year, the Division, often jointly with the FTC, has had exchanges with the Chinese antitrust agencies on their proposed regulations and guidelines, arranged a training program for 80 Chinese judges, and participated as instructors in workshops on merger enforcement, cartels, and other topics.

In addition, last fall, the Division and FTC published a joint report on technical assistance following its successful public workshop on the issue in 2008, which is available at *www.justice.gov/atr/public/reports/250908.htm*. Among other things, the report concluded that the time spent with emerging antitrust authorities paves the way for continued cooperation after the formal technical assistance program has ended and that effective technical assistance efforts cannot be "one-off" teaching efforts or ad hoc cooperation—they must be part of a long-term relationship. To provide a greater level of strategic focus and direction for our technical cooperation efforts, the DOJ and FTC called for the development of memoranda of understanding (MOUs) with certain of our foreign antitrust partners as a means of framing the nature and extent of that cooperation. In November 2009, the Division and the FTC entered into such an MOU with the Russian Federal Anti-Monopoly Service. Pursuant to this arrangement, the Division and the FTC, just completed a successful trainiug program for judges in Moscow, and the MOU should serve as a springboard for future collaborative efforts.

The Department is not seeking any additional authorization for international technical assistance activities at this time. Most of the Department's antitrust technical assistance has been funded by USAID. For over fifteen years, the Antitrust Division and the FTC have enjoyed a close, cooperative relationship with USAID that recognizes the value of training in the area of competition policy. The Department has also been able to provide technical assistance as a result of funding from the Trade Development Agency, the Department of Commerce's Commercial Law Development Program, and the State Department. The Department has also used small amounts of its own funds in special situations, such as for providing technical assistance in countries without an active USAID program.

12. Are there any areas of procedural harmonization between the United States and other countries that you are be pursuing? For example, is it possible to harmonize the merger clearance forms that various jurisdictions use? Would this require any action by Congress?

Answer:

Enhancing procedural fairness and transparency is and will remain an important priority of mine. As I have stated, it is of no benefit for parties to be surprised by the scope of an agency's concerns and therefore unable to engage in a meaningful dialogue in response. Given the importance of this issue, last fall I called for a global dialogue on procedural fairness issues. Since that time, I have had the privilege, as the chair of one of OECD's working parties, to have led two international roundtable discussions on procedural fairness and transparency issues. These issues were also a focal point of discussion at last February's APEC meeting of competition experts. I am pleased at the number of competition agencies that broadly agree on the importance of increased transparency and that are reviewing their own practices in this regard. In addition, the ICN's Merger Working Group's Notification and Procedures Subgroup has done excellent work in developing a set of Recommended Practices for Merger Notification and Review Procedures and continues to work toward promoting conformity with these best practices. These efforts promote a harmonization around a set of best practices.

The Antitrust Division, along with the FTC, has over the years explored the practical issues involved in harmonizing premerger forms, also working with some other jurisdictions and attorneys who often work on mergers that require premerger notification to be filed in multiple jurisdictions. These discussions and our own analysis thus far have led us to conclude that a common international premerger form likely would yield limited benefits. First, we found little actual incidence of duplicative information in jurisdictions because much of the information sought is country-specific. For example, the U.S. agencies seek product, revenue and overlap information for operations conducted only within the United States. Also, there are a number of practical differences that would make harmonization difficult. Because a jurisdiction that has found its form to be efficient and effective would understandably be reluctant to change the information that it requires, harmonization efforts would more likely lead to jurisdictions retaining their current information requirements while requiring additional information that other jurisdictions require. Thus, combining information requirements across jurisdictions would not likely streamline the review process.

In addition to the Division's efforts within the ICN, the Division and the FTC are striving to improve our own HSR Form. The Division worked closely with the FTC on the proposed changes to the HSR Form, which were recently published for public comment in a Notice of Proposed Rulemaking. The proposed changes are aimed at getting the agencies more useful information in our initial review of transactions, while eliminating information requirements for which the burden to filing parties plainly exceeds the benefit to the agencies.

13. To what extent do the Department of Justice and the Federal Trade Commission coordinate their responses when speaking to foreign competition authorities? Do you make efforts to speak as one voice? Do you coordinate with other entities in the federal government that have responsibility for dealing with foreign governments, such as the Department of State, Department of Treasury, Department of Commerce, and the U.S. Trade Representative? If not, why not?

Answer:

It is important that the United States speak with one voice on international antitrust matters. The Department of Justice and the FTC make every effort to coordinate their international efforts. For example, the agencies submit joint papers on substantive enforcement and policy issues to multilateral organizations, such as OECD and ICN. Similarly, the agencies closely coordinate when commenting on non-U.S. agencies' draft competition laws, regulations, guidelines, or policies. In addition, and as noted above, the Department's technical assistance efforts are often done jointly with the FTC. Moreover, the Department of Justice, as part of the Executive Branch, coordinates with other agencies of the U.S. government, such as the Department of State, the Office of the United States Trade Representative, and the Department of Commerce, as appropriate, to ensure that the Administration speaks with one voice. For example, much of the recent technical assistance that the Department of Justice and the FTC have provided to China has been part of a project funded by the U.S. Trade Development Agency, and in close coordination with USTR, Commerce, and State. Additionally, the Department participates in the Administration's initiatives in China, including the U.S.-China Strategic and Economic Dialogue and the Investment Forum, which are led by State and/or Treasury.

14. The new health care law encourages the creation of Accountable Care Organizations that allow groups of doctors, hospitals, other specialists to work out more efficient ways of providing care to patients. What role will the Antitrust Division have in providing guidance to these ACOs on what types of coordination are lawful?

Answer:

Antitrust has—and will continue to have—an essential role to play in health care. If health care reform is to harness the power of competitive markets to produce more and more efficient systems, then we must be up to the challenge of ensuring that our health care markets are as competitive as possible. The Affordable Care Act's development of Accountable Care Organizations (ACOs) is a good example of how providers might work together to deliver more efficient, high-quality care without inhibiting competition, so long as their collaborations are properly constructed. For example, the ACO encourages competing physicians and other providers to coordinate care for a defined population through redesigning care protocols, utilizing health IT, investing in infrastructure, and

meeting quality targets. If the ACO meets quality-of-care and cost targets established by the Department of Health and Human Services (HHS), it can receive a percentage of the savings achieved through incentive payments. Properly constructed, ACOs have the potential to improve health care delivery and drive down costs. Thus, as reform moves forward, the Justice Department is working closely with HHS and providers to ensure that providers pursue beneficial integrated ACOs that do not violate the antitrust laws. Notably, the Department's Antitrust Division has detailed to HHS an attorney with extensive expertise in health care markets to work closely with that agency as it implements the Affordable Care Act and develops various integrated health care delivery models to improve quality and reduce the costs of health care.

The Department is working closely with the FTC, HHS and the Centers for Medicare and Medicaid Services, and other government agencies to see if there are additional, or better, ways to reach out to clinical-integration stakeholders and convey the important message that antitrust is not an impediment to legitimate clinical integration and should not be a concern to those contemplating such efforts. We are also looking to see if we can improve, streamline, and make more transparent our review of integrated provider networks so that new integrated delivery models that will improve quality and reduce costs can be formed. In addition, the Department is paying close attention to ongoing changes in the health care industry, and will carefully consider whether such changes provide opportunities for effective competition advocacy and for collaborative business practices that increase efficiency and benefit customers. As the health care reform process moves forward, the Department will listen carefully to the questions, concerns, and requests of the provider communities as they consider potential new business models, and will consider suggestions from interested parties about the best means for working with provider communities, health care payers, and others to achieve the goals of health care reform.

15. The health care landscape has changed dramatically since 1996 when DOJ and the FTC issued their health care guidelines. Why have those guidelines not been revised since then? Do you anticipate revising them shortly?

Answer:

The Department recognizes that the health care industry has changed substantially since 1996. In addition to what I mentioned in the response to the last question, the Department has been following these changes and will carefully follow emerging developments in the health care industry under the Affordable Care Act. In light of these developments, both past and prospective, the Antitrust Division is working with the FTC to consider what additional guidance may be helpful. The Department and the FTC are working collaboratively to get a better understanding of the types of integrated delivery models that providers are contemplating, any potential antitrust concerns they might have, and how to best provide them with the guidance they need. Central to this, it is important that health care providers and other stakeholders in the health care industry understand that antitrust is not an impediment to the formation of innovative delivery systems that will

improve the quality and reduce the cost of health care for Americans. In this regard, we will consider how we can improve, streamline, and make more transparent our review of integrated provider networks so that providers have user-friendly guidance for forming such networks in accordance with rigorous competition principles.

16. What happens when a customer calls the DOJ to complain about a particular merger that is actually being reviewed by the FTC? Is there a system in place to ensure that customer complaints get to the correct reviewing agency?

Answer:

The Antitrust Division has procedures in place to ensure that customer complaints are considered by the appropriate agency. For consumer complaints or concerns that deal with matters for which one of the agencies has sought and received clearance, complainants are referred to the investigating agency. For complaints or concerns dealing with matters not under investigation, the Division will refer the consumer to the Federal Trade Commission when it is reasonably certain the FTC would have the most current experience in the particular markets involved.

17. The comment period for the Horizontal Mergers Guidelines closed in early June. Do you have a date that you believe the revisions will be finalized and what was the general feedback you received?

Answer:

The Department and the FTC issued their revised Horizontal Merger Guidelines on August 19, 2010. The antitrust agencies endeavored to make this revision process as open and transparent as possible. At the outset of the process, the agencies called for and received public comments on whether and how to revise the Guidelines. The agencies then held a series of public workshops around the country to discuss potential revisions. Once the agencies developed a draft of the new guidelines, they submitted that draft for public comment. The agencies received a number of public comments on this draft, which they took into account in producing the final revised Guidelines. The 2010 Guidelines are up-to-date and transparent and accurately reflect current agency merger review practice. They should prove to be a valuable tool for the business community, lawyers, and courts, by increasing the likelihood of accurate and consistent outcomes in merger analysis and challenges.

18. With respect to merger clearance:

a. the chart that was presented to the Committee showed that in FY 2009, there were 716 Hart-Scott-Rodino (HSR) reportable mergers. Of those 716, one or both

agencies requested clearance 92 times. However, on the chart, it only shows that 8 of the clearance disputes were resolved. What happened in the other 84 cases?

b. A footnote in the clearance data you provided the Committee mentions that the data does not reflect times when the parties pulled and refiled their HSR form. Do you have any numbers that reflect the number of times that the parties pulled and refiled in order to avoid a clearance fight?

Answers:

a. **The column in the chart referring to "Clearance Resolution" was intended to indicate resolutions of overlapping clearance requests. The vast majority of requests for clearance are sought by only one agency and granted by the other. The chart indicates that one or both agencies requested clearance 92 times. In 84 of these matters, only one agency requested clearance, so clearance was not in issue. Both agencies sought clearance in the remaining 8, leading to a clearance discussion. As the chart indicates, relatively few overlapping clearance requests go past seven days into the 30-day period.**

b. **In our experience, parties pull and refile in order to give the investigatiug agency additional time to resolve competitive issues arising from the transaction, after one agency has received clearance. I am not aware of a matter in which the parties pulled and refilled to avoid a clearance fight.**

Questions for the Record for Chairman Jon Leibowitz
Subcommittee on Courts and Competition Policy
Oversight Hearing on the Federal Trade Commission's Bureau of Competition and the U.S. Department of Justice's Antitrust Division
Tuesday, July 27, 2010

1. **Do you expect the Federal Trade Commission (FTC or Commission) to offer any formal guidance on the limits of Section 5 of the Federal Trade Commission Act in the near future? Given that almost two years have passed since the last workshop, do you anticipate soliciting more public feedback before making a public pronouncement on the bounds of Section 5?**

The Commission does not have jurisdiction to directly enforce the Sherman Act. Thus, the Commission challenges conduct that would violate the Sherman Act through its jurisdiction under Section 5 of the FTC Act to challenge "unfair methods of competition." In addition, the Supreme Court has confirmed that Section 5 authorizes the Commission "to define and proscribe an unfair competitive practice, even though the practice does not infringe either the letter or the spirit of the antitrust laws."[1] Thus, the Commission may challenge anticompetitive conduct that does not violate the Sherman Act under its "Section 5 stand-alone authority."

As you note, the Commission held a workshop in 2008 on Section 5 stand-alone authority in competition matters. That workshop generated an in-depth and wide-ranging record, so I do not foresee a need to solicit more public input at this time. Indeed, this year, the Commission plans to issue a report on the use of its Section 5 stand-alone authority in competition cases, and that report will provide additional guidance to companies seeking to conform their conduct to the law. Of course, guidance is available now, through Commission statements in connection with its consent orders reached under its Section 5 stand-alone competition authority.

The Commission has brought several cases under Section 5 in recent years against conduct that would not have violated the Sherman Act. For example, over the past twenty years the Commission has investigated at least seven situations in which one firm invited a competitor to join it in an illegal price-fixing agreement. These "invitations to collude" did not technically violate the Sherman Act, because the Sherman Act does not prohibit unsuccessful attempts to collude.

The Commission also has used this authority in high-tech industries in cases such as N-Data and Intel. These settlements provide further guidance on the application of

[1] FTC v. Sperry & Hutchinson Co., 405 U.S. 233, 239 (1972).

Section 5.[2] The proposed consent order with Intel, which was available for public comment until September 7, 2010, is accompanied by an Analysis to Aid Public Comment.[3] The Analysis further explains the Commission's view of the application of Section 5 to Intel's conduct.

2. How many consummated mergers has the FTC challenged in the last two years? How does this number compare to the previous two years? Is the FTC challenging more of these consummated mergers than before? If so, why? What criteria does the FTC use in deciding when to challenge already consummated mergers? Do your challenges of these already consummated mergers mean that the Commission feels that the Hart-Scott-Rodino process needs to be modified in some way?

In fiscal years 2009 and 2010 to date, out of a total of 38 merger enforcement actions, the Commission challenged eight consummated mergers.[4] In the two prior years, fiscal years 2007 and 2008, the Commission challenged two consummated mergers out of a total of 43 merger enforcement actions.

Whatever the number of challenges to consummated mergers in any given year, our approach to such deals is the same: we are always on the lookout for mergers that substantially lessen competition and harm consumers.

Consummated deals come to our attention in a number of ways; in fact, many investigations of consummated mergers begin with complaints from customers about price increases they believe are attributable to a recent merger. The Commission takes such complaints from the public seriously, even when the deal is relatively small, because widespread harm can occur as a result of even a relatively small deal. For instance in a recent enforcement action challenging The Dun & Bradstreet Corporation's February 2009 acquisition of Quality Education Data (QED), the Commission alleged that the deal hurt consumers by eliminating nearly all competition in the market for kindergarten through twelfth-grade educational marketing databases. At the time, Richard Feinstein, Director of the FTC's Bureau of Competition, noted that "despite its relatively low dollar value, this transaction dramatically decreased competition in the marketplace. When Dun & Bradstreet acquired QED, it bought its closest competitor and created a monopoly.

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[2] *FTC Challenges Patent Holder's Refusal to Meet Commitment to License Patents Covering 'Ethernet' Standard Used in Virtually All Personal Computers in U.S.*, news release dated January 26, 2008 and related documents and associated statements of the Commission, *available at* http://www.ftc.gov/opa/2008/01/ethernet.shtm; *FTC Settles Charges of Anticompetitive Conduct Against Intel*, news release dated August 4, 2010, and related documents, *available at* http://www.ftc.gov/opa/2010/08/intel.shtm.

[3] Analysis of Proposed Consent Order to Aid Public Comment, In the Matter of Intel Corporation, Docket No. 9341, *available at* http://www.ftc.gov/os/adjpro/d9341/100804intclanal.pdf.

[4] For a brief description of all merger enforcement actions since 1995, consult our Competition Enforcement database *available at* http://www.ftc.gov/bc/caselist/merger/total/expanded/total.pdf.

That's going to get the FTC's attention every time." On September 10, 2010, the Commission announced a settlement of its charges that requires Dun & Bradstreet to divest an updated K-12 database, the QED name, and certain associated intellectual property to restore the competition lost due to the merger.[5]

Of course, the agency continues its active program to identify all mergers – proposed and consummated – that are likely to substantially lessen competition and harm consumers. As you know, for this important task, the antitrust agencies rely primarily on premerger notification filings under the Hart-Scott-Rodino (HSR) Act. Premerger review, coupled with the filing of an action seeking a preliminary injunction in federal court in appropriate cases, prevents harm before it occurs and helps fulfill the mandate of the Clayton Act.

I believe that the current system strikes the right balance between requiring premerger filing for deals that are likely to raise competitive issues while avoiding unnecessary filing burdens on investors, who must file and then wait before completing a transaction if a filing is required. However, the Commission does believe that some minor changes in the specific information required may be useful. Under the current regulations, the agencies do not request additional information beyond the HSR Form in 95 percent of cases, but we'd like to continue to refine the process to balance our need for relevant information against the burden on those required to file an HSR notice. Recently, the FTC proposed changes to the premerger notification form[6] to make it easier for parties to prepare the filing while focusing on those categories of information the Agencies consider necessary for their initial review. The Commission will receive public comments on the proposed rule changes through October 18, 2010.[7]

3. As you are well aware, the FTC has gotten some unflattering press recently regarding the issuance of a subpoena to the CEO of Watson Pharmaceuticals.

a. What actually happened in this case? I understand from press reports that you have asked a former Commission staff member to conduct an internal inquiry. Can you share the results of that inquiry with the Committee?

b. Based on the FTC's response to the interrogatories, it appears that FTC staff was trying to inquire about the existence of any restraints on Watson's ability to give up its exclusivity with respect to a line of drugs. According to staff affidavits, it appears that FTC asked a series of

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[5] *Dun & Bradstreet Settles FTC Charges that 2009 Acquisition was Anticompetitive*, news release dated September 10, 2010, *available at* http://ftc.gov/opa/2010/09/mdr.shtm.

[6] *Commission Proposes Changes to Improve Premerger Notification Form*, news release dated August 13, 2010, *available at* http://www.ftc.gov/opa/2010/08/hsrcarilion.shtm.

[7] Federal Register Notice *available at* http://www.ftc.gov/os/2010/08/100812hsrfrn.pdf.

"hypothetical" questions to determine whether Watson was willing to relinquish that exclusivity. Was this the only way to obtain that information?

c. **Based on FTC staff affidavits, it appears that the FTC followed up with both Watson and the third party generic firm to see whether those negotiations bore fruit and were informed that they did not. Was the only reasonable assumption, based on those facts, that Watson had some sort of agreement not to relinquish its exclusivity? Might Watson have had other, legitimate, business reasons not to go through with a deal with Apotex?**

d. **In light of the way that this case proceeded, would you recommend to staff that they proceed with such hypothetical questions in the future?**

On July 22, 2010, the Commission filed papers with the court in support of its petition to enforce a subpoena issued to Paul M. Bisaro, CEO of Watson Pharmaceuticals. Our filings, which are attached for your convenience, fully explain our view of what happened in this case and directly refute the baseless claims made by Mr. Bisaro. I requested an internal review by an attorney in the Bureau of Competition, and his inquiry, consistent with our filings, found no misconduct. Recently, as you may be aware, the Magistrate, after reviewing the complete record, found that Mr. Bisaro had failed to prove his allegation of "improper purpose" by the Commission. The magistrate has granted our motion to require Mr. Bisaro to obey the subpoena and testify under oath, and Mr. Bisaro has now appealed that decision.

The Commission's subpoena seeking Mr. Bisaro's testimony has an entirely proper purpose: to determine whether an agreement between Watson and Cephalon has prevented Watson from relinquishing certain regulatory exclusivity rights. Such an agreement likely would be a per se antitrust violation and have enormous negative effects on consumers. It is possible that there are other reasons for Watson's decision to not relinquish whatever regulatory exclusivity rights it may have; unfortunately, the Commission has not been able to obtain a satisfactory explanation from Watson – which is one of the reasons that we are utilizing our investigatory authority and asking the Court to require Mr. Bisaro to testify on the record. The use of hypothetical questions is one of many standard investigative techniques and can be useful in certain circumstances. Accordingly, we will continue to use that technique as appropriate.

4. **With respect to merger enforcement:**

a. **Does the FTC have the ability to bring a combined preliminary injunction and merits case in federal district court under Section 7 of the Clayton Act like Department of Justice (DOJ) does? If so, has it ever used this approach?**

b. In an administrative proceeding, how many times has the administrative law judge ruled against FTC staff in a merger case? On appeal, how many times have the five Commissioners ruled against FTC staff?

The FTC is permitted, in a proper case, to seek both preliminary and permanent injunctive relief in federal district court. The Commission has not utilized this approach in the past, because such a strategy would ignore the structure that Congress created to review mergers initially at the Commission, and would limit the unique value that the Commission can bring to its cases-- its expertise and specialized experience in evaluating competition matters. Accordingly, the preferred approach of the agency has been to seek a preliminary injunction in federal court followed by an administrative proceeding on the merits. In administrative adjudication, the Commission has the opportunity to apply its expertise to consider the specific case before it and, as such cases accumulate over time, develop the law. (All of the Commission's decisions, of course, are subject to judicial review in the appellate courts).

An administrative law judge and/or the Commission has on occasion ruled against agency complaint counsel and dismissed a complaint. Specifically, over the past twenty-five years, out of 47 administrative merger complaints, the ALJ found no violation in five cases,[8] and the Commission found no violation in six cases.[9]

5. One of the justifications that you set forth for the different procedural rules that the FTC uses is that Congress set up the agency to be an expert on antitrust matters. Presumably, this expertise would include not just Commission staff, but also the Administrative Law Judges (ALJs) that hear Commission cases. How many ALJs does the FTC have to hear competition cases? Is this number sufficient for your purposes? What were the antitrust backgrounds of the ALJs prior to their employment by the FTC?

Currently, the agency has one administrative law judge who handles all of the agency's administrative litigation. One ALJ is sufficient for the current litigation workload. This ALJ had some antitrust experience when appointed and has developed additional expertise over the course of his tenure with the agency. Of course, the primary expert on the antitrust laws is the Commission itself. Each Commissioner focuses during his or her entire seven-year term on antitrust law and policy (along with consumer

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[8] B.F. Goodrich, Docket No. 9159 (Sept. 20, 1985), *rev'd* 110 F.T.C. 207 (1988); MidCon Corp., Docket No. 9198 (Feb. 2, 1987), *aff'd*,112 F.T.C. 93 (July 18, 1989); Adventist Health System/West, Docket No. 9234 (Aug. 2, 1990), *aff'd*, 117 F.T.C. 224 (April 1, 1994); Coca-Cola Bottling Co. of the Southwest, Docket No. 9215 (June 14, 1991), *rev'd*, 118 F.T.C. 452 (Aug. 31, 1994), *vacated and remanded on other grounds*, 85 F.3d 1139 (5th Cir. 1996) (*Comm'n dismissed complaint*, Sept. 6, 1996); Textron, Inc., Docket No. 9226 (Oct. 4, 1991), *settled by consent order*, 117 F.T.C. 597 (May 6, 1994).

[9] Weyerhauser Co., 106 F.T.C. 172 (Sept. 26, 1985); Echlin Manufacturing Co., 105 F.T.C. 10 (June 28, 1985); MidCon Corp., 112 F.T.C. 93 (July 18, 1989); Adventist Health System/West, 117 F.T.C. 224 (Apr. 1, 1994); Owens-Illinois Inc., 115 F.T.C. 179 (Feb. 26, 1992); R.R. Donnelley & Sons Co., 120 F.T.C. 36 (July 21, 1995).

protection law and policy); many of the Commissioners had substantial experience, sophistication and expertise regarding antitrust law, economics, and policy before serving on the Commission.

As the Committee knows, the very substantial body of existing antitrust law and the important role of complicated economic evidence combine to make antitrust adjudications a particularly challenging process. The difficulties are such that a person familiar with the law and experienced in handling the type of economic evidence offered in antitrust trials would be best suited for the role of ALJ for the Commission. Not every ALJ or aspirant to an ALJ appointment has such experience, and the current process for appointments specifically excludes such experience as a factor when considering applicants for the position. The Commission has recently supported a proposal that would allow consideration of such experience when hiring ALJs.[10] I believe that having ALJs with this kind of experience would help the FTC fulfill its role as a specialized, expert agency.

6. **Another method for achieving greater expertise would be to set up specialty antitrust courts in the federal judiciary. This way, both DOJ and the FTC could bring their cases before judges that were steeped in antitrust law and economics. This would also eliminate the procedural and substantive differences that have arisen between the two agencies. Would the FTC be supportive of such specialty courts? If not, why not?**

The Commission has not taken a position on the development of specialty courts that would handle the adjudication of antitrust lawsuits. It is a very interesting idea, but, at present I am not ready to support it. In fact, the FTC was created to be just such an expert body for competition law. Congress enacted Section 5 and gave its enforcement to the Commission, a body of competition experts with sufficient knowledge of antitrust law and competition policy to respond effectively to developments in economics and law and adjust to the changing realities of the market. Drawing on the foundation of policy studies, active ongoing economic research, and public workshops, the agency, with its exceptionally talented and experienced lawyers and economists, brings an expertise to its Part 3 proceedings that even a specialized antitrust court would struggle to match.

7. **The Antitrust Modernization Commission recommended that the FTC and DOJ "systematically collect and record information regarding the costs and burdens imposed on merging parties by the Hart-Scott-Rodino Act process." What information does the FTC already collect regarding the pre-merger clearance process? The Commission recommended this as a voluntary procedure, but is it something that Congress should be requiring of the agencies?**

[10] Prepared Statement of the Federal Trade Commission on Federal Trade Commission Reauthorization, before the Committee on Commerce, Science, and Transportation, United States Senate, 110th Cong., April 8, 2008, *available at* http://www.ftc.gov/os/testimony/P034101reauth.pdf.

When a HSR merger investigation concludes with an enforcement action, the Bureau of Competition collects a variety of data, such as the number of custodians, the volume and type of documents produced, and the size of any electronic productions. The Commission does not maintain or request information on the costs associated with the production incurred by the parties. Requiring such data would impose additional after-the-fact costs on the filing parties.

In 2006, during the pendency of the Antitrust Modernization Commission, former Chairman Deborah Majoras announced reforms to the merger review process that were intended to reduce the costs and burdens associated with the search for and production of data and documents responsive to a Second Request.[11] These reforms have already been implemented in merger investigations to reduce the burden on the parties while meeting the Commission's investigative needs. The Commission continues to look for ways to more quickly identify and obtain responsive data and documents, but I believe that any process reforms are best developed internally because any reforms must be sufficiently flexible to support a wide variety of merger reviews across a wide range of industries. The Commission can implement such flexible revisions readily through changes to our internal procedures without the need for legislative changes.

We have heard few, if any, complaints about HSR in recent years.

8. The Antitrust Modernization Commission recommended that the "agencies should issue 'closing statements,' when appropriate, to explain the reasons for taking no enforcement action, in order to enhance public understanding of the agencies' merger enforcement policy." How many closing statements has the Commission issued in the last two years? How does that number compare to the preceding two years? Does the FTC plan to issue more closing statements in the future?

We agree that closing statements can be very useful tools for understanding agency decisions. In fiscal years 2009 to 2010 to date, the Commission issued a closing statement to explain its reasons for ending its investigation of Google's acquisition of AdMob,[12] and an additional statement explaining its reasoning for not requiring additional relief in certain markets in the settlement of its investigation into Pfizer Inc.'s acquisition of Wyeth.[13] In December 2009, Richard Feinstein, Director of the Bureau of Competition, also issued a statement when closing a hospital merger investigation.[14] In

[11] *Available at* http://ftc.gov/os/2006/02/mergerreviewprocess.pdf.

[12] Statement of the Federal Trade Commission Concerning Google/AdMob, FTC File No. 101-0031(May 21, 2010), *available at* http://www.ftc.gov/os/closings/100521google-admobstmt.pdf.

[13] Statement of the Federal Trade Commission Concerning Pfizer/Wyeth, File No. 091-0053 (October 14, 2009) *available at* http://www.ftc.gov/os/caselist/0910053/091014pwyethstmt.pdf.

[14] Statement of Bureau of Competition Director Richard Feinstein on the FTC's Closure of its Investigation of Consummated Hospital Merger in Temple, Texas, FTC File No. 091-0084 (December 23, 2009), *available at* http://www.ftc.gov/os/closings/091223scottwhitestmt.pdf.

the prior two years, fiscal years 2007 and 2008, the Commission issued two closing statements. [15]

While the Commission does not issue statements when closing every competition investigation, it will continue to do so in appropriate circumstances to inform the public of our approach to particular competitive situation or to provide information about some of the factors that influenced our decision not to bring an enforcement action. Such statements can be particularly useful in dynamic, fast-paced markets, such as those involved in the two Google investigations. Closing statements also may be appropriate to help clarify the analysis of atypical situations; for example, the Commission issued a statement to discuss application of the failing firm defense, which was an important factor in the Temple, Texas hospital merger investigation.

9. The Antitrust Modernization Commission recommended that the "Federal Trade Commission and the Antitrust Division of the Department of Justice should increase their use of retrospective studies of merger enforcement decisions to assist in determining the efficacy of merger policy." How many retrospective studies has the Commission conducted in the last two years? How does that number compare to the preceding two years? Does the FTC plan to conduct more retrospective studies in the future? If so, do you require greater resources from Congress for this task?

In fiscal years 2009 and 2010 to date, Bureau of Economics ("BE") staff has conducted a number of different projects that might be considered retrospectives. Staff studied the effect of various mergers on market dynamics, such as post-merger prices, and produced six working papers detailing their findings.[16] In the prior two years, fiscal

[15] Statement of the Federal Trade Commission Concerning Google/DoubleClick, and Statements of Commissioner Leibowitz and Commissioner Harbour, December 20,2007, *available at* http://www.ftc.gov/os/caselist/0710170/071220statement.pdf ; http://www.ftc.gov/os/caselist/0710170/071220leib.pdf and http://www.ftc.gov/os/caselist/0710170/071220harbour.pdf; Statement of Chairman Majoras, Commissioner Kovacic, and Commissioner Rosch, and Statement of Commissioner Leibowitz and Commissioner Harbour, Concerning the Closing of the Investigation Into Transactions Involving Comcast, Time Warner Cable, and Adelphia Communications, January 21, 2006 *available at* *http://www.ftc.gov/os/closings/ftc/0510151twadelphiamajoras_kovacic_rosch.pdf and* http://www.ftc.gov/os/closings/ftc/0510151twadelphialeibowitz_harbour.pdf.

[16] Working Paper No. 300, Petroleum Mergers and Competition in the Northeast United States (April 2010), *available at* http://www.ftc.gov/be/workpapers/wp300.pdf ; Working Paper No. 297, The Evolution of the Baby Food Industry 2000-2008 (April 2009), *available at* http://www.ftc.gov/be/workpapers/wp297.pdf; Working Paper No. 296, The Success of Divestitures in Merger Enforcement: Evidence from the J&J-Pfizer Transaction (April 2009), *available at* http://www.ftc.gov/be/workpapers/wp296.pdf; Working Paper No. 295, The Effect of Hospital Mergers on Inpatient Prices: A Case Study of the New Hanover-Cape Fear Transaction (January 2009), *available at* http://www.ftc.gov/be/workpapers/wp295.pdf; Working Paper No. 294, Two Hospital Mergers on Chicago's North Shore: A Retrospective Study (January 2009), *available at* http://www.ftc.gov/be/workpapers/wp294.pdf; Working Paper No. 293, The Price Effects of Hospital Mergers: A Case Study of the Sutter-Summit Transaction, (November 2008), *available at* http://www.ftc.gov/be/workpapers/wp293.pdf.

years 2007 and 2008, a staff economist co-authored a paper studying price effects from mergers in five consumer products markets,[17] and BE hosted a conference to discuss developments in antitrust analysis in the grocery industry.[18] BE acts as the center of the Commission's efforts to conduct economic and empirical research to help inform our decisions. I strongly support these efforts.

10. What does the FTC do to provide assistance to foreign countries, like China, that are forming their own antitrust laws? The Antitrust Modernization Commission recommended that Congress authorize and appropriate monies directly to DOJ and the FTC for international bi-lateral antitrust technical assistance. Does the Commission want specific Congressional authorization for this activity? How would you use such an authorization?

The FTC, in cooperation with the Department of Justice, has provided technical assistance to foreign antitrust agencies since the early 1990s. Our lawyers and economists have helped countries with little experience with competition law and policy to set up and strengthen competition laws and enforcement institutions, for instance through training on basic investigative skills and techniques. Our technical assistance program has expanded to meet the demands of the increasing number of countries that have enacted antitrust laws. During the past year alone, we have conducted 54 missions, including programs in China, India, Russia, Mexico, and Vietnam.

The FTC's technical assistance program was originally funded by the U.S. Agency for International Development. In recent years the FTC has used its own funds as well, and some programs are funded by other U.S. agencies. In China, for example, the FTC and DOJ are sharing U.S. approaches to antitrust enforcement with their Chinese counterparts, using their own funds as well as funds administered by the U.S. Trade and Development Agency.

The SAFE WEB Act of 2006 amendments to the FTC Act, 15 U.S.C. § 46(l)(2), confirmed the FTC's authority to provide technical assistance to foreign competition agencies, and we believe that no further authorization is needed. In addition, the SAFE WEB ACT contained a provision that enables officials from foreign agencies to work on FTC investigations. We have implemented this authority by establishing an International Fellows program through which we have hosted 30 foreign officials, and we have also sent FTC staff abroad to work with their foreign counterparts. The FTC has requested that the SAFE WEB amendments to the FTC Act be made permanent.

11. To what extent do the Department of Justice and the Federal Trade Commission coordinate their responses when speaking to foreign competition

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[17] The Effect of Mergers on Consumer Prices: Evidence from Five Selected Case Studies, Orley Ashenfelter and Daniel Hosken (BE), NBER Working Paper No. 13859 (March 2008).

[18] A Conference on Grocery Store Antitrust: Historical Retrospective & Current Developments (May 2007), *materials available at* http://www.ftc.gov/be/grocery/index.shtm.

authorities? Do you make efforts to speak as one voice? Do you coordinate with other entities in the federal government that have responsibility for dealing with foreign governments, such as the Department of State, Department of Treasury, Department of Commerce, and the U.S. Trade Representative? If not, why not?

The FTC recognizes the importance of a coordinated and unified U.S. voice when speaking to foreign competition authorities. Accordingly, the FTC and Department of Justice routinely and effectively coordinate their responses in such situations. We often submit joint comments, written replies, and papers. When an issue affects the responsibilities of other U.S. agencies, including the Departments of State, Treasury, and Commerce, and the Office of the U.S. Trade Representative, the FTC and DOJ coordinate with those agencies as appropriate.

12. Are there any areas of procedural harmonization between the United States and other countries that you are pursuing? For example, is it possible to harmonize the merger clearance forms that various jurisdictions use? Would this require any action by Congress?

The FTC, along with DOJ, has made a priority of promoting convergence toward fair and transparent procedures. This is a long-term endeavor, given real differences among countries' underlying legal systems and traditions, but it has already resulted in real progress. Indeed, now that over 100 countries have a competition law, the FTC's promotion of international convergence toward sound antitrust policies and practices is critical to its competition mission. We have worked closely with the European Commission, which has adopted best practices in merger reviews that are closer to U.S. practices, and with Canada, which recently enacted reforms to its merger review procedures that are expressly designed to closely parallel those of the United States.

With respect to merger notification and review procedures, the FTC led the International Competition Network's project that culminated in the adoption of a detailed set of Recommended Practices for Merger Notification and Procedures. These have led many countries to revise their laws and agency practices to conform to those procedures. The FTC will continue to pursue opportunities for further convergence. However, there are challenges, such as the differences in systems around the world, each country's need for information tailored to its own markets, and the fact that most forms used by other jurisdictions require more information than the U.S. form. As a result, harmonization toward a notification form that will not result in imposing additional burdens on parties or agencies is not a realistic short-term objective. Nonetheless, the FTC remains closely attentive to how the Hart-Scott-Rodino premerger notification system interacts with those of other countries. It makes appropriate revisions to the form from time to time, as it is doing now. The FTC, with the concurrence of DOJ, has adequate authority under 15 U.S.C. § 18a(d)(2) to make needed changes to the premerger notification rules.

13. The new health care law encourages the creation of Accountable Care Organizations that allow groups of doctors, hospitals, other specialists to

work out more efficient ways of providing care to patients. What role will the Commission have in providing guidance to these ACOs on what types of coordination are lawful?

The FTC has begun to work with the Centers for Medicare and Medicaid Services (CMS), the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS), and the Antitrust and Civil Divisions of the Department of Justice with the aim of developing consistent approaches across the agencies regarding the approval of Accountable Care Organizations. In particular, the FTC, CMS, and OIG will be convening a public workshop this October to examine, among other things, antitrust issues relating to new models for delivering high-quality, cost-effective health care. Two purposes of the workshop are: (1) to ensure that misunderstandings about antitrust law do not deter potentially beneficial collaborations among competitors, and (2) to explain the importance of antitrust law in protecting consumers from unjustified and illegal price-fixing, group boycotts, or undue aggregations of market power, which undermine efforts to improve quality and control costs. The workshop is likely to focus on the circumstances under which collaboration among independent health care providers in an ACO (not including a merger) would permit an ACO to engage in joint price negotiations with private payers without running the risk of liability for illegal price fixing under the antitrust laws. In addition, it will focus on how to prevent ACOs from creating and exercising market power so as to drive up prices in private insurance markets.

14. The health care landscape has changed dramatically since 1996 when DOJ and the FTC issued their health care guidelines. Why have those guidelines not been revised since then? Do you anticipate revising them shortly?

The Health Care Statements reflect the framework that the agency uses to analyze all types of health care provider networks under general antitrust principles. These principles are sufficiently flexible to take into account the particular characteristics of health care markets and the rapid changes that are occurring in those markets. Many of the same principles can be found in the *Antitrust Guidelines for Collaborations Among Competitors,*[19] issued by the agencies in 2000.

The Commission and its staff have been active in a variety of other ways, both to further develop our knowledge and understanding of competition in health care markets, as well as to provide additional antitrust guidance, as appropriate, wherever possible. For example, in 2003, the Commission and the DOJ Antitrust Division held a lengthy series of joint hearings on a variety of health care issues. Those hearings culminated in issuance of the 2004 report *Improving Health Care: A Dose of Competition*, which discussed, among other issues, clinical integration.[20] In 2008, the Commission held a workshop on clinical integration, at which industry experts provided their insights

[19] *Available at* http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf.

[20] *Available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

regarding many aspects of clinical integration efforts.[21] The Commission staff has also issued advisory opinions on proposed clinical integration in various provider markets; all of the staff's advisory opinions in health care can be found at *Topic and Yearly Indices of Health Care Antitrust Advisory Opinions by Commission and Staff*.[22]

In addition, the Commission staff has for many years engaged in discussions regarding clinical integration with various stakeholders, including the American Medical Association, the American Hospital Association, and representatives of numerous groups contemplating clinical integration programs. I also have met with representatives of the American Medical Association and the American Hospital Association to hear their views. Just this past June I spoke to the AMA House of Delegates to reaffirm our commitment to work with physicians to improve health care quality.[23] All of these actions are part of our ongoing and continuing efforts to help ensure that competition fosters high quality, cost-effective care, and that antitrust law promotes, not impedes, efforts to efficiently organize the delivery of health care services.

15. What happens when a customer calls the FTC to complain about a particular merger that is actually being reviewed by DOJ? Is there a system in place to ensure that customer complaints get to the correct reviewing agency?

Customers and others can contact the FTC's Bureau of Competition at antitrust@ftc.gov or call the complaint line at (202) 326-3300 to register an antitrust complaint or discuss a situation that may raise competitive concerns. When a complaint relates to a matter already under investigation by DOJ, we refer the complainant directly to the Antitrust Division. If there is any evidence of a potential criminal violation, even in a matter under investigation by the FTC, that information is immediately forwarded to DOJ. This process is overseen by the Bureau of Competition clearance officer.

16. The comment period for the Horizontal Mergers Guidelines closed in early June. Do you have a date that you believe the revisions will be finalized and what was the general feedback you received?

The agencies issued revised Horizontal Merger Guidelines on August 19, 2010. Public comments to the proposed revisions can be found on the FTC's website at http://www.ftc.gov/os/comments/hmgrevisedguides/index.shtm.

17. With respect to merger clearance:

a. The chart that was presented to the Committee showed that in FY 2009, there were 716 Hart-Scott-Rodino (HSR) reportable mergers. Of those

[21] *See Clinical Integration in Health Care: a Check-Up* at http://www.ftc.gov/bc/healthcare/checkup.

[22] *Available at* http://www.ftc.gov/bc/adops/indexfin0310.pdf.

[23] *Available at* http://www.ftc.gov/speeches/leibowitz/100614amaspeech.pdf.

716, one or both agencies requested clearance 92 times. However, on the chart, it only shows that 8 of the clearance disputes were resolved. What happened in the other 84 cases?

b. A footnote in the clearance data you provided the Committee mentions that the data does not reflect times when the parties pulled and refiled their HSR form. Do you have any numbers that reflect the number of times that the parties pulled and refiled in order to avoid a clearance fight?

The 8 clearance requests represent the "contested" clearance requests where both agencies requested clearance, and these were resolved. The other 84 requests were not contested (that is, only one agency requested clearance), and they were resolved in the normal course of business.

The agency does not compile the information referred to in (b).

In addition, at the hearing, Representative Darrell Issa asked Chairman Leibowitz for his views on H.R. 5034, the "Comprehensive Alcohol Regulatory Effectiveness Act" (CARE Act). Chairman Leibowitz promised to consult with his colleagues and report back to the Subcommittee. Commission views follow:

The Commission recognizes that the sovereign states have many significant interests in alcohol within their borders, such as a state's interest in promoting public health and in restricting minors' access to alcoholic beverages. These are important interests, and the Commission appreciates the work done in this area by the states. However, the impact of the CARE Act must be viewed in light of the already existing balance of federal and state interests in this area. In reviewing this bill, we note that these state interests are already well-shielded from federal antitrust laws by both the state action doctrine enunciated in *Parker v. Brown*[24] and by the Twenty-first Amendment to the Constitution.

Broadly speaking, under the state action doctrine, federal antitrust jurisprudence gives each state wide berth to forego the benefits of competitive markets within their borders in order to further state interests if the state clearly articulates its intent to do so and actively supervises those engaging in the anticompetitive practices. Under the Twenty-first Amendment, no state law regulating the transportation or importation of alcohol is limited by the antitrust laws if the state can show that "the interests implicated by a state regulation are so closely related to the powers reserved by the Twenty-first Amendment that the regulation may prevail, notwithstanding that its requirements directly conflict with express federal policies."[25]

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[24] *See* Parker v. Brown, 317 U.S. 341 (1943); California Retail Liquor Dealers Ass'n v. Midcal Aluminum, 445 U.S. 97 (1980).

[25] *See* 324 Liquor Corp v.Duffy, 479 U.S. 335, 347 (1987); Midcal, 445 U.S. at 114.

Under both the state action doctrine and the caselaw interpreting the Twenty-first Amendment, the courts have attempted to harmonize and balance state and federal interests and powers. The impact of the proposed CARE Act on federal enforcement and on state laws is difficult to measure in the abstract, but it would apparently alter that balance in a number of ways. For example, the proposed Act would seem to make it more difficult to challenge a state alcohol law under federal antitrust law by shifting and raising the burden of proof for such a challenge, and by shielding any state law that has any effect on a number of specified state interests without weighing those interests against federal interests.

Federal interest in competitive markets is substantial, and, as all of us recognize, free and fair competition provides significant benefits to consumers and the economy. Given the undisputed benefits of competition to consumers in these markets, and the extensive authority a state already has to set aside competition in order to achieve its goals in regulating alcohol, we are concerned that further subordinating the benefits of competition to those goals might, on net, harm consumers.[26] Having said that, we do recognize that the states have a significant interest in alcohol regulation.

[26] For example, a FTC staff report found that state laws banning interstate direct shipping of wine to consumers had the effect of raising prices and decreasing selection. *Possible Anticompetitive Barriers to E-Commerce: Wine* 16-23 (July 2003), *available at* http://www.ftc.gov/os/2003/07/winereport2.pdf (finding consumers in McLean, Virginia buying online would save 5-13% for bottles priced at $20 or more, and would save 13-21% for bottles priced at $40 or more).

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
William E. Kovacic
J. Thomas Rosch
Edith Ramirez
Julie Brill

Statement Of The Federal Trade Commission Concerning Subpoena Issued To Paul M. Bisaro

Today the Commission filed court papers in support of its petition to enforce a subpoena issued to Paul M. Bisaro, CEO of Watson Pharmaceuticals, Inc. The Commission's subpoena enforcement action followed its unanimous letter ruling, dated April 2, 2010, denying Mr. Bisaro's petition to quash the Commission's subpoena seeking his testimony and rejecting his argument that the subpoena was issued for an improper purpose.

The Commission continues to stand behind its subpoena and its investigation. The investigation, which was initiated pursuant to a unanimously adopted Commission resolution, relates generally to a series of agreements entered among the branded drug company Cephalon and several generic drug companies to delay entry of generic versions of Provigil, a sleep disorder medication with nearly $1 billion in annual U.S. sales. As the Commission has alleged in a related enforcement action against Cephalon, these agreements cost consumers hundreds of millions of dollars a year. The Commission has substantial and legitimate concerns about these pay-for-delay agreements and their impact on consumers.

As today's court filing makes clear, the Commission issued the subpoena to Mr. Bisaro for an entirely proper purpose. The Commission sought to determine whether an agreement between Watson and Cephalon has prevented Watson from relinquishing certain regulatory exclusivity rights. Such an agreement likely would be a *per se* antitrust violation and have enormous negative effects on consumers. For this reason, the Commission sought the testimony of Mr. Bisaro. The subpoena was not issued "to pressure Watson to relinquish any exclusivity rights it may have, and thereby attempt to engineer generic entry into the [Provigil] market," as Mr. Bisaro argued in his petition to quash the subpoena. The Commission continues to believe that it is entitled to Mr. Bisaro's testimony in this matter.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION **Petitioner,**	)	
v.	)	Misc. No. 1:10-mc-00289 (CKK)(AK)
PAUL M. BISARO, **Respondent.**	)	

PETITIONER FTC'S MOTION FOR LEAVE TO SUPPLEMENT THE RECORD AND TO ENFORCE THE SUBPOENA *AD TESTIFICANDUM* FORTHWITH, AND MEMORANDUM IN SUPPORT

On July 13, 2010, this Court entered a Memorandum and Order finding that Respondent had made a "colorable claim" that the Federal Trade Commission ("FTC" or "Commission") had engaged in misconduct by seeking Respondent's oral sworn testimony in a law enforcement investigation issued pursuant to a resolution approved by the full Commission. Contrary to Respondent's assertions, the Commission's actions were carried out for legitimate law enforcement purposes in furtherance of the public interest – and, in one critical instance, with the consent of Respondent's counsel. Accordingly, we submit this Motion to Supplement the Record in order to provide the Court with a more complete factual background, and to ensure that this evidence is available on the public record and not just to Respondent. The Commission also moves this Court to enforce its Subpoena *Ad Testificandum* forthwith, as there is no remaining cause for delay.

For the reasons set forth below, we seek to supplement the record with (i) answers to Respondent's two interrogatories sworn to by Markus H. Meier, chief of the Health Care Division ("Interrog. Resp." attached as Exhibit A,); (ii) a Declaration by Richard A. Feinstein, Director of the Commission's Bureau of Competition and former chief of the Bureau's Health Care Division ("Feinstein Decl." attached as Exhibit B); and (iii) a Declaration by Saralisa C. Brau, Deputy Assistant Director of the Bureau's Health Care Division and the person responsible for day-to-day management of the investigation into potential anticompetitive conduct of Watson Pharmaceuticals, Inc. ("Watson") ("Brau Decl." attached as Exhibit C). Because the factual record amply demonstrates that the requirements for judicial enforcement have been satisfied, and for the reasons set forth in more detail below, the FTC also respectfully moves this Court to take all steps necessary to further the enforcement of the July 22, 2009, subpoena *ad testificandum* forthwith.

PRELIMINARY STATEMENT

The FTC acted appropriately at all times during the course of this investigation. Further, Respondent has made no objective "showing" of misconduct, and the "extraordinary circumstances" that might justify discovery within the context of summary subpoena enforcement proceedings are not present here. *Federal Trade Commission v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980). The Commission takes this opportunity to provide the Court with the full story. The proposed submissions – the FTC's Responses to Interrogatories, the Feinstein Declaration, and the Brau Declaration – demonstrate that: the law enforcement investigation giving rise to the subpoena at issue has been conducted in a proper and lawful manner that is fully consistent with the ordinary course of Commission practice; that the Commission did not try to broker any deal

between Watson and Apotex; that Watson's interactions with Apotex are directly relevant to determine whether Watson is bound by an agreement not to relinquish any potential exclusivity rights; that there were no improper disclosures of confidential information made at any time during the course of the investigation; and, finally, that Respondent has impeded an ongoing Commission investigation, potentially causing harm to the public interest.

As detailed below, and elaborated in the papers already on file with this Court, the requirements for judicial enforcement of the subpoena at issue have been fully satisfied. The FTC therefore respectfully requests that this Court, with a complete record now in hand, expeditiously resolve this matter pursuant to Local Civil Rule 72.3 so that the subpoena can be enforced at the earliest possible date. Respondent should be ordered to fulfill his legal obligation to cooperate with the lawful Commission investigation by sitting for an investigational hearing.

STATEMENT OF FACTS

The investigation giving rise to the subpoena in question, like all formal Commission investigations involving the use of compulsory process, required majority vote of the Commission. Feinstein Decl. at ¶ 3; 16 CFR § 2.7(a). On August 30, 2006, the Commission unanimously issued a Resolution authorizing the use of compulsory process in the present investigation.[1] The initial focus of the staff's investigation concerned a patent settlement agreement entered into between Cephalon, Inc. ("Cephalon") and various generic companies involving Cephalon's '516 patent. Interrog. Resp. at 3; Brau Decl. at ¶ 3; *see also* Dkt. No. 4 (Mem. of P. & A. in Supp. of Pet. of F.T.C. for an Order Enforcing Subpoena *Ad Testificandum*) at 4-5.

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[1] Resolution Authorizing Use of Compulsory Process in a NonPublic Investigation, File No. 0610182 (August 30, 2006). Pet. Exh. 2 (Dkt. No. 3 at 10).

It was not until January 2009, that the staff first learned of a subsequently-filed Cephalon patent – the '346 Patent. Interrog. Resp. at 3-4; Brau Decl. at ¶ 4. The agency's discovery that this second patent had been filed gave rise to a series of questions regarding the impact that such a patent might have on the competitive conditions in the market for generic modafinil – including, specifically, whether this second patent might be used to block generic entry. Interrog. Resp. at 4. At this point, the question arose as to whether Watson might have exclusivity rights with respect to a generic version of modafinil relating to the '346 Patent; and whether Watson had agreed with Cephalon not to relinquish or pursue those rights in exchange for a payment from Cephalon to Watson. Interrog. Resp. at 4; Brau Decl. at ¶ 4. Such an agreement would likely be a *per se* antitrust violation. *See, infra*, at 8. Thus, the Commission's investigation regarding potential anticompetitive conduct that might arise with relationship to the '346 patent began in January 2009, before any contact with Watson's counsel.

In the ordinary course of pursuing the investigation, Commission staff talked to the Food and Drug Administration (FDA) and to Apotex, Inc. ("Apotex")[2] to gather information needed to advance the Commission's understanding of the '346 Patent and its effects on the marketing of modafinil and any generic version of that drug, and to discover whether there was any possible agreement between Watson and Cephalon concerning potential exclusivity rights held by Watson. Interrog. Resp. at 4, 7. That staff action was fully consistent with normal and customary

[2] As detailed in the Interrogatory Responses, Apotex was an "obvious choice" to consult because it had filed an ANDA for a generic version of modafinil and was blocked from entering by Cephalon's modafinil settlements, it was already selling generic modafinil in Canada, and its Vice President of Global Intellectual Property, Shashank Upadye, is a published expert in the field. Interrog. Resp. at 7.

procedure followed in the ordinary course of Commission investigations. Feinstein Decl. at ¶ 10. At no time did staff improperly disclose any confidential information to the FDA, nor did staff improperly discuss any confidential FDA information with Watson or others. Interrog. Resp. at 5, 11; Feinstein Decl. at ¶¶ 2, 14.

More specifically, issuance of the '346 patent represented a novel situation to staff, Interrog. Resp. at 4, and a potentially new impediment to generic entry in the modafinil market. To the extent generic manufacturers obtained first-filer rights on this patent, and had entered into unlawful agreements with respect to those rights, it might allow them to block entry by other companies seeking to enter with a low-cost generic version of modafinil, causing further anticompetitive harm to consumers. Interrog. Resp. at 4; Brau Decl. at ¶ 4. That harm might be avoided if a generic company decided to relinquish any claim of exclusivity rights it might have on the '346 patent. But the FTC staff were concerned that Watson had lost the ability to do that. Indeed, Section 2.1 of the 2006 Settlement Agreement between Watson and Cephalon could be read to prohibit Watson from relinquishing any new exclusivity rights it might have obtained based on any filing with respect to the '346 patent. *See* Brau Decl. at ¶ 6.

In March 2009, Mr. Meier, the chief of the Commission's Health Care Division in its Bureau of Competition, contacted counsel for Watson, to probe whether Watson was willing to relinquish any exclusivity rights it might have. Interrog. Resp. at 9; Brau Decl. at ¶ 8. The basis for this inquiry was staff's belief that relinquishment could provide Watson with a potential business opportunity and, at the same time, potentially save consumers of Provigil millions of dollars a year by facilitating entry of generic modafinil. Brau Decl. at ¶ 7. If Watson was not interested in relinquishing, *i.e.*, was foregoing a potentially profitable opportunity against its

economic self-interest, the Commission would likely need to investigate further to assess whether that decision was based on an unlawful agreement with Cephalon or some other reason. Interrog. Resp. at 10; Brau Decl. at ¶ 9. Through a series of hypothetical questions, Mr. Meier sought to determine whether Watson would be interested in entering into a profit-maximizing agreement that would entail Watson licensing, relinquishing, or otherwise sharing whatever first-filer rights it might have. Interrog. Resp. at 9. Before the conversation ended, *Watson's counsel authorized Mr. Meier to contact Apotex regarding a possible deal between Watson and Apotex. Id.*

Not only did Mr. Sunshine, Watson's counsel, expressly assent to Mr. Meier calling Apotex and inviting Apotex to contact Watson, Mr. Sunshine even identified Watson's General Counsel, Mr. Buchen, as the person Apotex should call. Interrog. Resp. at 9-10; Brau Decl. at ¶ 8.[3] Contrary to Respondent's allegations that the FTC was engaged in improper deal brokering, the Commission was providing Watson with an opportunity to disprove its reasonable suspicion -- a suspicion based on language contained in the 2006 Settlement Agreement between Watson and Cephalon – that an illegal agreement to refuse to relinquish existed. Thus, with the express consent of Steven Sunshine, Mr. Meier and Ms. Brau thereafter contacted Apotex. Interrog. Resp. at 9-10. In that call, staff suggested that, if Apotex also thought any potential deal might be worth pursuing, it should contact Watson regarding a possible deal concerning generic modafinil. *Id.* At no time did staff improperly disclose any confidential Watson information to any third party, including Apotex. Interrog. Resp. at 5, 11; Feinstein Decl. at ¶¶ 2, 14.

[3] These facts are omitted from Mr. Sunshine's Declaration of July 30, 2009. Pet. Exh. 4 at 28-32.

Despite the opportunity presented to it, Watson declined to negotiate a deal to relinquish any exclusivity it may have, thereby leaving open the possibility that it had entered into an illegal agreement with Cephalon. The Commission continued to investigate whether Watson had agreed with Cephalon not to relinquish. Brau Decl. at ¶ 12

In short, notwithstanding efforts by the staff to determine whether such an agreement existed, Watson has, to this date, refused to give the Commission staff an unequivocal answer to one simple question: has Watson agreed with Cephalon not to relinquish any exclusivity rights that it might hold with respect to generic modafinil? Feinstein Decl. at ¶ 12; Brau Decl. at ¶¶ 14-19; *see also* Pet'rs Reply Mem. in Supp. of Pet. for an Order Enforcing Admin. Subpoena *Ad Testificandum* and Opp'n to Respondent's Mot. to Compel, at 2-7 [Dkt. No. 21]. The Commission seeks the sworn testimony of Mr. Bisaro for a proper purpose – to determine whether there has been anticompetitive collusion between Watson and Cephalon. Watson's potential exclusivity rights arising from the '346 patent, the written settlement agreement between Cephalon and Watson, Watson's actions vis-a-vis Apotex, and Watson's continued refusal to give unequivocal answers to critical questions throughout this investigation, all support an inference that Watson may have agreed with Cephalon not to relinquish any exclusivity rights it may have with respect to generic modafinil. Mr. Bisaro is the only Watson executive besides Watson's General Counsel, Mr. Buchen, who is likely to have knowledge of critical facts relevant to the Commission's investigation, including the critical question concerning whether Watson has an agreement with Cephalon prohibiting it from relinquishing any exclusivity rights. Mr. Buchen has declined to answer that question unequivocally, asserting the attorney-client privilege. Brau Decl. at ¶ 16; *see also* Dkt. No. 21, at 2-7.

LEGAL ARGUMENT

Watson has yet to provide the Commission with a clear and unequivocal answer to the question of whether it has agreed with Cephalon not to relinquish any exclusivity rights to generic modafinil. This is a critical question with clear competitive implications. Agreements not to relinquish exclusivity might be a *per se* violation of the antitrust laws. *See In re Cardizem*, 332 F.3d 896, 907-08 (6th Cir. 2003) (finding an agreement not to relinquish exclusivity rights to be a *per se* violation of the antitrust laws).[4]

The Commission is authorized to ask this question pursuant to a valid Commission resolution. *Supra* note 1. The subpoena at issue has gone through the full agency process in being issued. The subpoena was issued by a Commissioner acting under delegated authority of the full Commission. Feinstein Decl. at. ¶¶ 4, 5; 16 C.F.R. § 2.7(a). Respondent petitioned to quash the subpoena, and his petition was rejected by FTC Commissioner Pamela Jones Harbour, pursuant to authority delegated by the full Commission. Feinstein Decl. at ¶ 5. Respondent then

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[4] As the full Commission expressly noted in its Letter Opinion denying Petitioner's Motion to Quash the subpoena:

> Courts have expressed great skepticism of agreements in which a generic manufacturer who is eligible for the 180-day exclusivity agrees with the branded manufacturer not to relinquish or waive that exclusivity. *See, e.g. In re Ciprofloxacin*, 544 F.3d 1323, 1339 (Fed. Cir. 2008) (agreeing that "the only legitimate allegation by the plaintiffs was that the 180-day exclusivity period had been manipulated."); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 401 (2d Cir. 2005) ("[W]e think that an agreement to time the deployment of the exclusivity period to extend a patent monopoly power might well constitute anticompetitive action outside the scope of a valid patent."); *Andrx v. Elan*, 421 F.3d 1227, 1235 (11th Cir. 2005) (holding that delayed licensed plus putative agreement to refrain from ever marketing a generic barred any competitors from entering "would exceed the scope of exclusion intended by the '320 patent"); *FTC v. Cephalon, Inc.*, No. 2:08-cv-2141, mem. op. (E.D. Pa. Mar. 29, 2010) (declining to dismiss complaint alleging that agreement to settle patent litigation and affecting relinquishment of exclusivity rights is anticompetitive).

Pet. Exh. 7, at 2, n.1.

filed a petition for review, and the full Commission, by unanimous vote, rejected arguments and denied Respondent's Petition to Quash, a petition in which he raised largely the same arguments presented to this Court. Pet. Exh. 7; Feinstein Decl. at ¶ 5. The Commission now seeks to supplement the record in the interest of providing the full story to the Court and bringing this matter to a close.

In this case, as Respondent acknowledged in its Motion to Compel, "[t]he only question that needs to be resolved is factual – *i.e.*, what is the FTC's purpose in prosecuting the Subpoena." Dkt. No. 16, at 3. The Commission's answers to Respondent's Interrogatories and supplemental declarations show that the agency's purpose in prosecuting the Subpoena was proper. And, as the Commission's earlier briefing has demonstrated, and Respondent fails to adequately refute, all of the other requirements for prompt judicial enforcement have been satisfied.[5] With both sides of the story now in hand, and the resulting showing that the Commission has acted in accordance with the law and in pursuit of proper purpose, the FTC respectfully requests that the Court act swiftly to enforce the subpoena *ad testificandum*.

I. Fundamental Notions of Fairness Support Granting Leave To Supplement The Record.

Presently, the evidentiary record in this case relating to the misconduct issue consists almost entirely of one declaration submitted by Respondent's attorney that relies on qualifying words such as "indicated", "hypothetical scenarios", and "suggested" to insinuate misconduct in this case but that falls far short of stating any fact that would demonstrate actual misconduct by

[5] At the very least, any remaining questions are principally questions of law and can be decided based on the existing briefing; no further hearing is needed.

the FTC. Pet. Exh. 4, Sunshine Decl. at ¶¶ 15, 16, 22. Mr. Sunshine's characterization of events notwithstanding, the objective facts are themselves entirely consistent with good faith actions on the part of the Commission. The Commission had not previously adduced its own evidence, given its firmly-held position that any evidentiary response to Respondent's unsupported allegations was not needed, in light of this Circuit's governing precedent. *See FTC v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980).[6] Because the Commission is a law enforcement agency that Congress has charged with protecting the public interest, the existence of even this tentative

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[6] With respect, this Court applied the wrong legal standard in permitting discovery. Even if the Court is correct that the rule from *Carter* "cannot be squared" with *United States v. Powell*, 379 U.S. 48 (1964), Dkt. No. 31, at 9, *Carter* remains the governing law of the Circuit and must be applied. *Carter* was issued 16 years after *Powell* and the panel who decided *Carter* had the benefit of *Powell* in reaching its ruling (although the *Carter* decision does not expressly cite to *Powell*, it discusses *Donaldson v. United States*, 400 U.S. 517 (1971), a case which itself discusses *Powell*). Just as the courts of appeals leave to the Supreme Court "'the prerogative of overruling its ... decisions,'" *Rodgriguez de Quijas v. Shearson/American Express, Inc.*, 490 U.S. 477, 484 (1989), district judges, like panels of [the courts of appeals], are obligated to follow controlling circuit precedent until [the court of appeals] sitting en banc, or the Supreme Court, overrule it." *United States v. Torres*, 115 F.3d 1033, 1036 (D.C. Cir. 1997). Under the governing legal standard of this Circuit, therefore, Respondent is not entitled to discovery.

And, even apart from this threshold legal error, the limited "facts" presented by Respondent do not rise to the objective level necessary to support the extraordinary remedy of discovery in the context of summary enforcement proceedings and *a fortiorari*, are insufficient to thwart the prompt enforcement of the subpoena to which the Commission is demonstrably entitled. Thus, in *United States v. Fensterwald*, the single instance in which this Circuit has found "extraordinary circumstances" sufficient to warrant discovery, the ruling was based on objective facts, that the court expressly recognized to be "matters of public record," demonstrating the likelihood that the taxpayer was inappropriately targeted for a special audit outside of the course of normal agency proceedings. 553 F.2d 231, 233 (D.C. Cir. 1977). In contrast, the record here is bereft of any objective indicia of bad faith. The only showing is Respondent's characterization that is based on an incomplete and suppositional accounting of events by counsel, where the underlying events are themselves fully consistent with a lawful investigation carried out in the ordinary course of business. In light of its overriding interests in setting the record straight and given the importance of securing prompt enforcement of the subpoena, the Commission has not presently raised objections to the Magistrate's ruling in this case. The Commission, however, preserves the right to advance these arguments in the future if necessary.

finding by the Court potentially damages the public's confidence in the work the agency does. It is therefore important that the Commission have the opportunity to complete the record in this case to make clear that the Commission has properly conducted itself in all respects in this matter.

Notably, in partially granting Respondent limited discovery in this matter, the Court has directed the Commission to answer two interrogatories and has allowed Respondent ten days after receiving the answers to supplement the record. The Court's Order does not provide the Commission with an opportunity to respond. Unless the Commission is given an opportunity to supplement the record now, this means that the only evidentiary materials before the Court when it ultimately decides this matter may be those provided by the party that has the greatest interest in undermining the Commission's integrity. Fundamental notions of fairness and due process dictate that the Court be fully informed when making its decision. The Court should therefore grant the Commission's motion to supplement the record.

II. The Record, As Fairly Supplemented, Is Sufficient to Order Enforcement of the Subpoena *Ad Testificandum* Forthwith

The standards for judicial enforcement of administrative investigative process have long been settled in this Circuit. "[T]he court's role in a proceeding to enforce an administrative subpoena is a strictly limited one." *FTC v. Texaco, Inc.*, 555 F.2d 862, 871-72 (D.C. Cir. 1977) (*en banc*) (*citing Endicott Johnson Corp. v. Perkins*, 317 U.S. 501, 509 (1943); *accord, Oklahoma Press Publ'g Co. v. Walling*, 327 U.S. 186, 209 (1946); *United States v. Morton Salt Co.*, 338 U.S. 632, 643 (1950)). A district court must enforce agency process so long as the information sought is not "unduly burdensome" to produce (*Texaco*, 555 F.2d at 881), and is "reasonably relevant" (*id.* at 872-73 n.23 (quoting *Morton Salt*, 338 U.S. at 652), or, putting it

differently, "not plainly incompetent or irrelevant to any lawful purpose" of the agency. *Texaco*, 555 F.2d at 872 (quoting *Endicott Johnson*, 317 U.S. at 509). In making this determination, the agency's own appraisal of relevancy must be accepted so long as it is not "'obviously wrong.'" *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1089 (D.C. Cir. 1992) (citing *Carter*, 636 F.2d at 787-88 (quoting *Texaco*, 555 F.2d at 877 n.32)).

Respondent has previously argued that the "most important[]"of its reasons against enforcement of the subpoena is that enforcement would result in an abuse of this Court's process because "the FTC exceeded its statutory law-enforcement mission by seeking to broker a business deal between Watson and Apotex ... improperly using its privileged access to confidential information in the process, and apparently providing Watson's confidential information to Apotex." Resp'ts Mem. in Opp'n, Dkt. No. 12, at 3. As Respondent has also acknowledged, in his Motion to Compel, this argument turns on a factual question. Dkt. No. 16, at 3. The Court now has the evidence in hand necessary to resolve this factual question. There is no record support that the FTC has exceeded its authority or otherwise acted improperly – beyond the insinuations contained within the declaration of Respondent's counsel. And there is now ample evidence to the contrary.

With the Commission's submissions now before the Court, the record demonstrates that the FTC's purpose in prosecuting the subpoena was legitimate. The Commission seeks to ascertain whether or not Watson is party to any potentially anticompetitive agreement with Cephalon that would prohibit it from relinquishing potential exclusivity rights in the generic modafinil market.

The agency timely began to investigate any potential anticompetitive effects resulting from the filing of the '346 patent as soon as it first learned of the filing of the patent, *before* any conversations with Watson's counsel. Interrog. Resp. at 3; Brau Decl. at ¶ 4. There was, and continues to be, good reason for the agency to seek this information. *See Modern Home Institute, Inc. v. Hartford Acc. & Indem. Co.*513 F.2d 102, 111 (2nd Cir. 1975) ("Actions against the apparent individual economic self-interest of the alleged conspirators may raise an inference of interdependent action."). Respondent remains one of only two people who can address the agency's concerns, Brau Decl. at ¶ 19, and of the two, as Watson's President and CEO, Mr. Bisaro is well positioned to testify as to whether any business arrangement to relinquish exclusivity rights is likely to be in Watson's economic self-interest. Brau Decl. at ¶ 19. As the full Commission noted in denying Mr. Bisaro's Petition to Quash the Subpoena: "While Watson has provided the Commission information relating to the '346 Patent, [Respondent] has not shown that his testimony will shed no light on matters that fall within the scope of the Commission's investigatory concerns. As a key executive of Watson, [Respondent's] testimony may well be useful in elaborating on the information or explaining relevant circumstances." Pet. Exh. 7 at 6.

Throughout the course of this investigation, Watson has done nothing to allay the Commission's concerns that it has reached an illegal anticompetitive agreement with Cephalon; indeed, its actions (and inactions) indicate that it has. It should not be forgotten that the motion to compel discovery represents another method for Respondent to use in impeding a legitimate law enforcement proceeding. Respondent continues to avoid answering a central question to the Commission's investigation – namely, whether Watson's settlement agreement with a rival

manufacturer, Cephalon, limits Watson's ability to relinquish any exclusivity rights it may have with respect to marketing of the drug modafinil.

The Commission has shown that an investigational hearing of Respondent is necessary, because, to date, none of the sworn testimony contains a definitive disavowal of the existence of an agreement between Watson and Cepahlon that would prevent Watson from relinquishing exclusivity. Respondent has failed to rebut the Commission's showing that the investigative hearing is necessary. Moreover, Respondent does not dispute that Watson has repeatedly failed to answer, under oath, critical questions about the settlement agreement; it does not dispute that Respondent knows relevant facts to the investigation; and it does not assert that the investigational hearing would be unduly burdensome.

In furtherance of the interests of judicial economy and the public interest, and for the reasons previously articulated to this Court, the FTC respectfully requests that the Court recommend that Mr. Bisaro be directed to comply in full with the subpoena *ad testificandum*.

CONCLUSION

For the foregoing reasons, the Commission respectfully requests that this Court grant its Motion for Leave to Supplement the Record and Petition to Enforce the Subpoena Forthwith.

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Statement of Compliance

Pursuant to L.Cv. R. 7(m), on July 20, 2010, Petitioner's counsel conferred with counsel for Respondent regarding Petitioner's Motion for Leave to Supplement the Record, and counsel for Respondent opposes the motion. There is no obligation, under the local rules, to confer with respect to Petitioner's dispositive motion to Enforce the Subpoena *Ad Testificandum* Forthwith.

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CERTIFICATE OF SERVICE

I hereby certify that on July 22, 2010, a true and correct copy of the foregoing Motion for Leave to Supplement the Record and to Enforce the Subpoena *Ad Testificandum* Forthwith, together with: Exhibit A: FTC's Responses to First Set of Interrogatories of Respondent Paul M. Bisaro sworn to by Markus H. Meier; Exhibit B: Declaration of Richard A. Feinstein; Exhibit C: Declaration of Saralisa C. Brau; and a Proposed Order, were filed electronically in the United State District Court for the District of Columbia using the CM/ECF system.

Notice of this filing will be sent by email to all parties by operation of the Court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing.

Dated: July 22, 2010

/s/ Michael D. Bergman
Michael D. Bergman
Attorney for the Petitioner
Federal Trade Commission

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Federal Trade Commission,	)	
Petitioner,	)	
v.	)	**No. 01: 10-mc-00289-CKK-AK**
Paul M. Bisaro,	)	
Respondent.	)	

FEDERAL TRADE COMMISSION'S RESPONSES TO FIRST SET OF INTERROGATORIES OF RESPONDENT PAUL M. BISARO

Petitioner Federal Trade Commission ("FTC" or "Commission") hereby submits the following Responses to the First Set of Interrogatories of Respondent Paul M. Bisaro dated May 21, 2010.

GENERAL OBJECTIONS

1. By answering these interrogatories, the Commission does not waive the previous objections it made to these interrogatories in its June 21, 2010 Objections to First Set of Interrogatories of Respondent Paul M. Bisaro, nor does it waive its right to appeal, or otherwise assign error, to the Court's Order of July 13, 2010, directing it to engage in discovery in this matter.

2. To the extent Respondent's interrogatories seek the production of documents under Rule 34 or otherwise, the Commission objects on the ground that such discovery is beyond the scope of Rule 33 and beyond the scope of the Court's Order of July 13, 2010.

3. The FTC has responded to this interrogatory request to the best of its present ability. The FTC reserves its rights to supplement, revise, correct, or clarify any of the responses set forth herein, if necessary or appropriate.

In addition to these objections, the Commission further objects to Respondent's interrogatories as indicated below.

RESPONSES TO INTERROGATORIES

Interrogatory 1

Describe any communications the FTC had with the FDA relating to any potential marketing exclusivity for generic modafinil arising out of the ANDA Amendment during the period December 19, 2007, through July 22, 2009. For each communication:

a. Identify the date of the communication;

b. Identify the name and title of the individual(s) involved in the communication;

c. Identify the means through which the communication was made;

d. Identify who initiated the communication;

e. Identify the reason for the communication;

f. Identify the topic(s) discussed during the communication; and

g. State whether, during the course of the communication, or as a result of the communication, the FTC communicated to the FDA any confidential information provided to the FTC by Watson.

Response to Interrogatory 1

The FTC objects to Respondent's interrogatories to the extent they seek confidential information that the FTC obtained pursuant to inter-agency communications with the Food and Drug Administration and that is exempt from disclosure by statutes and regulations, including but not limited to 21 C. F. R. § § 20.64(a), 20.61, 20.62, and 314.430(b) (2010). Expressly reserving and without waiving the general objections and this specific objection, the FTC states as follows:

Before January 2009, the FTC's modafinil investigation had focused on a particular patent – U.S. Reissue Patent No. 37,516 (the "'516 patent") – and the potential barriers to competition arising from Cephalon's 2005-2006 patent litigation settlement agreements with Watson and the four first filers for the '516 patent. The initial phase of the modafinil investigation resulted in the FTC filing a complaint against Cephalon in February 2008.[1] The investigation remained open, however, though not active, with respect to the generic companies, including Watson, while the Commission pursued litigation against Cephalon in federal court in the Eastern District of Pennsylvania.

In January 2009, the FTC learned for the first time from the FDA that Cephalon had listed a second patent relating to Provigil, U.S. Patent No. 7,297,346 (the "'346 patent"), in the FDA's Orange Book. While the U.S. Patent and Trademark Office's issuance of the '346 patent to Cephalon in November 2007 and Cephalon's filing of it with the FDA in December 2007 were matters of public record, FTC staff had not been aware of these developments. The FTC also learned, in January 2009, that Watson/Carlsbad had filed an ANDA Amendment with the

[1] *FTC v. Cepahlon, Inc.*, No. 2:08-cv-2141-MSG (E.D. Pa. filed Feb. 13, 2008).

FDA on the same day that Cephalon listed the '346 patent. Together, these events created the possibility – one that did not exist for the '516 patent and was not a focus during the initial phase of the FTC's investigation – that Watson could be a "first filer" for the '346 patent, and therefore might block generic modafinil market entry for other companies. This new information caused the FTC staff to resume the modafinil investigation because it raised a host of questions about whether the '346 patent created any new impediments to generic entry and whether those impediments were the result of an unlawful agreement between Cephalon and Watson.

This new phase of the investigation was prompted by a conversation between the FTC and FDA on January 29, 2009. On that date, in response to the FTC's inquiries about the regulatory status of modafinil, Elizabeth Dickinson, Associate Chief Counsel in the FDA's Office of Chief Counsel, called Saralisa Brau, Deputy Assistant Director in the Health Care Division of the FTC. The two agencies routinely share information concerning the regulatory status of certain drug products, pursuant to a written inter-agency agreement, to advance the FTC's law enforcement and consumer protection missions. The modafinil investigation was no exception. The topics discussed during the call were: (1) Cephalon's later-issued '346 patent relating to Provigil; (2) Cephalon's listing of the '346 patent with the FDA; and (3) the identity of the generic company or companies that had submitted amended ANDAs containing a Paragraph IV certification as to the '346 patent and who might be eligible to claim 180-day marketing exclusivity as a "first filer."

In February 2009, the FTC requested a meeting with FDA to discuss how the '346 patent might potentially affect the FTC's ongoing modafinil investigation. Ms. Brau of the FTC had approximately three communications with Ms. Dickinson of the FDA to set up the meeting. Ms.

Brau contacted Ms. Dickinson in early February 2009 and they exchanged emails concerning meeting logistics on February 18, 2009, and February 19, 2009. The meeting took place on February 24, 2009. The following people attended:

FTC	FDA
Brad Albert, Deputy Assistant Director, Health Care Division	Rick Blumberg, Deputy Chief Counsel of Litigation, Office of Chief Counsel
Saralisa Brau, Deputy Assistant Director, Health Care Division	Kim Dettelbach, Associate Chief Counsel, Office of Chief Counsel
Michael Kades, Attorney Advisor to then-Commissioner (now Chairman) Leibowitz	Elizabeth Dickinson, Associate Chief Counsel, Office of Chief Counsel
Markus Meier, Assistant Director, Health Care Division	Dave Read, Regulatory Counsel, Center for Drug Evaluation and Research/Office of Generic Drugs

The topics discussed were: (1) the FTC's complaint filed in *FTC v. Cephalon, Inc.*, No. 1:08-cv-00244 (D.D.C. complaint filed Feb. 13, 2008) (later transferred to E.D. Pa.); and (2) the FDA's interpretation and analysis of relevant statutes concerning whether *second* filers on the earlier-listed '516 patent would be blocked from entering the market by any *first* filer(s) eligible to claim 180-day marketing exclusivity on the later-listed '346 patent.

At no time during this meeting or in the course of any communications with the FDA did the FTC reveal to the FDA any confidential information provided to the FTC by Watson.

Interrogatory 2

Describe any communications between the FTC and any third-party (excluding Watson and the FDA) including, but not limited to Apotex, relating to any potential marketing exclusivity for generic modafinil arising out of the ANDA Amendment during the period December 19, 2007, through July 22, 2009. For each communication:

- **a. Identify the date of the communication;**
- **b. Identify the name and title of the individual(s) involved in the communication;**
- **c. Identify the means through which the communication was made;**
- **d. Identify who initiated the communication;**
- **e. Identify the reason for the communication;**
- **f. Identify the topic(s) discussed during the communication;**
- **g. State whether, during the course of the communication, or as a result of the communication, the FTC communicated to any third-party any confidential information provided to the FTC by Watson; and**
- **h. State whether, during the course of the communication, or as a result of the communication, the FTC communicated to any third-party any confidential information provided to the FTC by the FDA.**

Response to Interrogatory 2

The FTC objects to Interrogatory 2 to the extent it seeks privileged information exchanged between Apotex and the FTC pursuant to a common interest privilege as co-plaintiffs in litigation in federal district court in the Eastern District of Pennsylvania challenging

Cephalon's modafinil patent litigation settlement agreements.[2] Expressly reserving and without waiving the general objections and this specific objection, the FTC states as follows:

The FTC had periodic communications with Apotex as part of its modafinil law enforcement investigation from February through May 2009. The FTC did not have communications with any other third party concerning the topics identified in Interrogatory 2, except that FTC staff did have communications relating to these issues with Watson's counsel, Steven C. Sunshine of Skadden, Arps, Slate, Meagher & Flom LLP, from March through May 2009.[3]

FTC staff first contacted Apotex in February 2009 as part of its efforts to understand the implications of the information it had learned about the later-listed '346 patent from the FDA in January and February 2009. Apotex was an obvious choice to contact to explore these issues: it had filed an ANDA for a generic version of modafinil and was blocked from entering by Cephalon's modafinil settlements; it was already selling a generic version of Provigil in Canada; and its Vice President of Global Intellectual Property, Shashank Upadhye, had written a book entitled *Generic Pharmaceutical Patent and FDA Law* (Thompson West Publishing, 2010 ed.), and could likely provide expertise relevant to the questions of interest to the FTC. In particular, the later-listed '346 patent and its potential effect on generic entry presented a novel issue for

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[2]*See FTC v. Cepahlon, Inc.*, No. 2:08-cv-2141-MSG (E.D. Pa. filed Feb. 13, 2008); *Apotex, Inc. v. Cephalon, Inc., et al.*, No. 2:06-cv-02768-MSG (E.D. Pa. filed June 26, 2006).

[3]*See* Brau Decl. ¶¶ 5, 7, 8, 10, attached as Exhibit C to Petitioner FTC's Motion for Leave to Supplement the Record and to Enforce the Subpoena *Ad Testificandum* Forthwith.

FTC staff, and by contacting Mr. Upadhye, staff hoped to gain insights into the applicable legal framework.

Staff was primarily interested in two threshold questions in February 2009. First, FTC staff sought to understand the regulatory significance of the '346 patent, and specifically whether any first filer(s) to the '346 patent could potentially block any second filers to the earlier-listed '516 patent from entering the market. This issue was relevant to the FTC's ongoing investigation because if any exclusivity Watson might have with respect to the '346 patent did *not* block entry of other generic filers, then any agreement Watson might have with Cepahlon was unlikely to harm competition. Second, FTC staff sought to understand practically how a generic company would be aware of a later-issued patent so that it would be in the position to file an ANDA amendment on precisely the same day that the brand company listed such later-issued patent with the FDA. Put simply, FTC staff was trying to assess whether a generic company was likely to have such information independently or whether such information was likely available to the generic only as a result of collusion with the brand company to create an additional barrier to impede potential generic entry. The answers to these questions would influence the future of the ongoing investigation.

From February 2, 2009, through March 3, 2009, Markus H. Meier, Assistant Director in the Health Care Division of the FTC and Saralisa C. Brau, Deputy Assistant Director in the Health Care Division of the FTC, had approximately four communications with Shashank Upadhye, Vice President, Global Intellectual Property, Apotex, Inc. Mr. Meier and Ms. Brau called Mr. Upadhye on February 2, 2009, February 24, 2009, and March 3, 2009. Mr. Upadhye sent an email to Mr. Meier on February 3, 2009.

The topics discussed during these communications were: (1) Cephalon's listing of the '346 patent; (2) whether Apotex had submitted to the FDA an amended ANDA containing a Paragraph IV certification as to the '346 patent; (3) Apotex's analysis of whether any first filer(s) eligible for marketing exclusivity on the later-listed '346 patent would block Apotex's ability to launch generic Provigil; (4) what it would take Apotex to launch a generic version of Provigil in the U.S., assuming it was interested in doing so; and (5) how a generic company could know the date on which a brand would list a later-issued patent with the FDA so that it could try to be a first filer by submitting its amended ANDA with the FDA on the same day.

In addition to the four earlier contacts with Mr. Upadhye, on March 13, 2009, Mr. Meier and Ms. Brau called Mr. Upadhye regarding the possibility of a business arrangement between Watson and Apotex. This call to Mr. Upadhye was a direct result of a conversation that took place earlier that day with Watson's counsel, Mr. Sunshine. From March 2, 2009, through March 13, 2009, Mr. Meier and Ms. Brau had initiated a number of telephone calls to Mr. Sunshine to discuss developments in the modafinil investigation.[4] During these conversations with Mr. Sunshine, FTC staff posited hypothetical scenarios to determine if Watson could profit from relinquishment of any modafinil marketing exclusivity for which it might be eligible, including scenarios where Watson relinquished any such exclusivity to potential new entrants into the market. In the context of these discussions, and in response to a question from Mr. Meier, Mr. Sunshine affirmed that Watson would be interested in hearing from a third party, Apotex, about a business proposal relating to relinquishment, and Mr. Sunshine then identified Watson's General Counsel, David Buchen, as the appropriate contact person.

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[4]*See* Brau Decl. ¶¶ 5, 7, 8.

After receiving Mr. Sunshine's explicit approval to put Apotex in touch with Watson concerning potential relinquishment, FTC staff then called Mr. Upadhye on March 13, 2009, to inform Apotex of Watson's interest and that if Apotex were likewise interested, he should contact Mr. Buchen at Watson. The FTC did not "broker a deal" between Watson and Apotex. In fact, after informing Apotex of Watson's interest, with the express assent of Watson's counsel, Mr. Sunshine, the FTC played no further role in any discussions between the two companies. The FTC did not attempt at any time to propose terms or otherwise direct the course of the discussions between Apotex and Watson.

From approximately March 18 through May 6, 2009, Mr. Meier and Ms. Brau initiated periodic follow-up calls to Mr. Upadhye of Apotex to inquire about the status of the discussions with Watson. These calls occurred on approximately March 18, March 30, April 7, April 22, and May 6, 2009. The reason for the calls was simple: if, on the one hand, Watson were to relinquish its potential exclusivity, the FTC's ongoing investigation about whether Watson had agreed with Cephalon *not* to relinquish its exclusivity would have been resolved, leaving nothing further to investigate. If, on the other hand, Watson chose not to relinquish its potential exclusivity, the FTC would need to assess whether the reason for the decision was attributable to an unlawful agreement with Cephalon not to relinquish. On May 6, 2009, Mr. Upadhye told Mr. Meier and Ms. Brau that discussions with Watson had stalled and that Watson did not appear interested in pursuing a business arrangement with Apotex.

At no time during the course of any communications with Apotex did the FTC reveal to Apotex any confidential information provided to the FTC by Watson. Although staff cannot specifically recall if Watson's name came up in any telephone conversation with Mr. Upadhye

before March 13, 2009, Watson's name did come up after March 13, 2009, once the FTC had received Mr. Sunshine's explicit approval to put Apotex in touch with Watson concerning potential relinquishment. FTC staff did not improperly reveal any confidential FDA information to Apotex.

Respectfully submitted,

As to Objections:

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Dated: July 21, 2010

VERIFICATION

I, Markus H. Meier, declare:

1. I am the Assistant Director of the Health Care Division in the Bureau of Competition of the Federal Trade Commission and make this verification on and for its behalf. As Assistant Director of the Health Care Division, I have overall supervisory responsibility for the Commission's investigation of Watson.
2. I have read the foregoing Petitioner Federal Trade Commission's Responses to First Set of Interrogatories of Respondent Paul M. Bisaro.
3. All of the information contained in the foregoing is either based on my personal knowledge or facts I have learned in my official capacity.
4. I am informed and believe that the matters stated therein are true and correct and hereby certify that the foregoing answers are true to the best of the Federal Trade Commission's present knowledge, information, and belief.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 21st day of July, 2010.

Markus H. Meier
Assistant Director
Bureau of Competition
Federal Trade Commission

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION **Petitioner,**	)	
v.	)	Misc. No. 1:10-mc-00289 (CKK)(AK)
PAUL M. BISARO, **Respondent.**	)	

DECLARATION OF RICHARD A. FEINSTEIN

Pursuant to 28 U.S.C. § 1746, Richard A. Feinstein declares as follows:

1. I am the Director of the Federal Trade Commission's Bureau of Competition where I am responsible, among many other things, for supervising all investigations and law enforcement actions that are undertaken by that Bureau. I have held this position since May 2009.

2. I offer this Declaration in order to clear up any misconceptions that may exist regarding the Commission's processes and procedures and to emphasize that, contrary to allegations and insinuations that have been made by Respondent in this matter, nothing improper has occurred in the Commission's investigation of Watson.

Commission Processes Preclude Inappropriate Investigations

3. At the outset it is important to note that the Commission's organizational structure and processes are designed to make sure that all investigations are undertaken in the public interest and to preclude the possibility of any investigation being undertaken for an improper purpose. The Commission is a law enforcement agency headed by five Commissioners who are appointed

by the President for seven-year staggered terms. No more than three Commissioners may be members of the same political party. All major Commission actions – including the opening of investigations that require compulsory process (like the subpoena at issue in this case)– require a majority vote of the Commission.

4. Although I and my immediate staff comprise the "Front Office" of the Bureau of Competition and are ultimately responsible for the conduct of Commission investigations, we have no authority to open (and close) preliminary law enforcement investigations without the approval of the Commissioners. After an investigation has advanced to the point where staff thinks sufficient evidence exists to support a law enforcement action, it must seek and obtain specific authority from the Commission to proceed either administratively or in federal court. Even after the Commission opens an investigation, staff has no authority to issue subpoenas or civil investigative demands on their own. Each subpoena must be submitted to a Commissioner for review and can only be issued by a Commissioner. 16 C.F.R. § 2.7(a). After a subpoena is issued, Commission rules allow a party to petition the Commission to quash compulsory process. Rulings on such petitions are decided by a single Commissioner (not necessarily the one who issues the subpoena in the first instance), and the party may thereafter seek review by the entire Commission.

5. In the present case, the subpoena to Mr. Bisaro was issued by Commissioner Leibowitz. Mr. Bisaro exercised his right to petition to quash the subpoena and he raised essentially the same arguments that he has advanced in this proceeding. Former Commissioner Pamela Jones Harbour considered these arguments and rejected them. Mr. Bisaro then appealed to the full Commission, which, after considering his arguments, unanimously rejected them as well in a detailed letter ruling. A true and correct copy of that letter ruling is attached hereto as Exhibit 1.

Disclosures By Staff in Commission Investigations

6. Almost all Commission investigations are non-public. This means that it is the Commission's policy not to make public announcements either confirming or denying the existence of any pending investigation except under very limited circumstances. However, it is appropriate, and often necessary, that in the course of seeking out information, staff may make limited disclosures about the subject matter and nature of a Commission investigation, or staff may use hypotheticals to gain insights into the views of marketplace participants. In fact, Mr. Sunshine's declaration reflects this process (at paragraph 15) where he notes that Mr. Meier "posited certain hypothetical regulatory scenarios" to him during a conversation.

7. Thus, in conducting FTC investigations, staff routinely contacts people and entities that are knowledgeable about the companies, industries, products, and markets that are the focus of an inquiry. Such contacts frequently include not only other government agencies that deal with the companies or industries, but also customers, competitors, and suppliers of the investigative targets. During these conversations staff asks questions that are designed to elicit information while protecting the confidential nature of the investigation. When staff inquires about a specific topic, it is difficult if not impossible to avoid all reference to the relevant facts of the investigation. Accordingly, it is not surprising that people who are interviewed by the staff during an investigation may draw their own inferences from the interview.

8. For example, in the merger context, the Commission has a policy of not disclosing the identity of firms that have filed pre-merger notification reports with the Commission and the Department of Justice. No matter how circumspect staff is in its questioning, however, once staff asks questions about the state of competition between Firm A and Firm B, people to whom such questions are directed may reasonably infer that an inquiry involving Firm A and Firm B is

underway. Such inferences cannot be avoided by the Commission staff, and are an ordinary consequence of the investigative process.

9. In such circumstances, one natural consequence is that third parties with whom the Commission staff has been in contact may communicate with the merging parties and inquire about matters of mutual interest. Indeed, most Commission challenges to problematic mergers are settled when the merging parties agree to divest overlapping assets to a third party. It is not unusual for that third party to be a person who has been interviewed by the Commission staff during the course of the Commission's investigation; and in some cases the staff will – with the consent or acquiescence of the parties and without disclosing any confidential information about the pending merger – contact firms that might be potential acquirers of assets and encourage them to contact the merging parties. In such situations, the staff appropriately facilitates communications between business entities who then take the opportunity to negotiate a private transaction that may alleviate a potential antitrust concern. The fact that a party who has been interviewed by the Commission staff contacts the subject of the investigation and ultimately negotiates (or attempts to negotiate) a business deal does not mean that staff made any improper disclosure during its interview.

The Commission's Investigation of Watson

10. I have read the pleadings and the court's record in the present proceeding as well as the Answers to Mr. Bisaro's Interrogatories that Mr. Meier has prepared. Based on this review, I see no evidence that Mr. Meier or anyone else in the Commission has engaged in improper – or even out-of-the-ordinary – conduct with respect to any aspect of the investigation.

11. At its core, the Commission's investigation seeks an answer to one simple question: Assuming Watson has exclusivity rights in connection with the '346 Patent, has Watson (a

generic pharmaceutical manufacturer) agreed with Cephalon (a brand name manufacturer with patent rights) not to relinquish those rights to a third party in violation of the antitrust law? In other words, is there an agreement between Cephalon and Watson to restrain trade in generic modafinil?

12. Despite the staff's repeated efforts, Watson never provided the Commission with a straight-up, sworn, answer to the question of whether it had an agreement with Cephalon that it not relinquish. This left the staff with only two possible ways to get an answer to this question. Either it could observe whether Watson acted in a way that precluded the possibility of such an agreement (i.e., Watson could enter into an agreement relinquishing those rights to a third party); or staff could continue to pursue a full investigation to try to determine directly whether an illegal agreement existed.

13. Contrary to the insinuation in Paragraph 15 of Mr. Sunshine's Declaration, there is nothing improper, or even extraordinary, about Mr. Meier "suggest[ing] that Watson should relinquish exclusivity." Such a "suggestion" was nothing more than a statement of the obvious: if Watson relinquished exclusivity, it would prove that it had no agreement with Cephalon prohibiting relinquishment – thereby leaving nothing for the Commission to investigate. Absent such relinquishment (and in light of other facts), the staff could reasonably infer that an agreement not to waive exclusivity might exist, and that it therefore needed to investigate the matter further. Thus, a statement by Mr. Meier that Watson's failure to waive exclusivity might lead the "Front Office" – i.e., the Bureau Director's Office – to continue the investigation reflects a common-sense assessment of the likely investigative decision of the Bureau.

14. Finally, I note that in his answers to the interrogatories, Mr. Meier has declared that 1) Mr. Sunshine gave Mr. Meier permission to talk to Apotex about Watson (a fact that Mr.

Sunshine omitted from his declaration); 2) prior to Mr. Sunshine giving that permission, Mr. Meier does not recall discussing Watson with Apotex; and 3) Mr. Meier did not improperly disclose any confidential information to Apotex. Mr. Meier is a senior FTC attorney who has spent 18 of his 20-year legal career at the FTC's Bureau of Competition. Before he became a lawyer, he was a security officer in the U.S. Army with a Top Secret clearance charged with protecting nuclear secrets. Thus, Mr. Meier knows how to handle confidential information without disclosing it.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on the 21st day of July, 2010.

Richard A. Feinstein, Director
Bureau of Competition
Federal Trade Commission
Washington, DC 20580

Exhibit 1 to Feinstein Declaration

Office of the Secretary

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

April 2, 2010

Watson Pharmaceuticals, Inc.
c/o Steven C. Sunshine, Esq.
Skadden, Arps, Slate, Meagher & Flom LLP
1440 New York Avenue NW
Washington, DC 20005

RE: Request for Review of Ruling Denying Petition to Quash Subpoena *Ad Testificandum* Dated July 22, 2009, File No. 091-0182

Dear Mr. Sunshine:

This letter responds to your November 27, 2009 Request for Review ("Request"), by the full Commission, of the November 13, 2009 ruling by Commissioner Pamela Jones Harbour, denying the Petition to Quash the Subpoena *Ad Testificandum*, dated July 22, 2009, and issued to Paul M. Bisaro ("Petition"). Mr. Bisaro is the President and Chief Executive Officer of Watson Pharmaceuticals, Inc. ("Watson"), and the Commission seeks his testimony in connection with an investigation of whether certain pharmaceutical companies, including Watson, have entered into any agreements to forego relinquishing any eligibility or rights they may have to market the generic drug modafinil – *i.e.*, whether these companies, including Watson, have entered into any agreements that potentially constitute an "unfair method of competition" in violation of the Federal Trade Commission Act. As you know, the market for modafinil (a/k/a Provigil) exceeds $800 million a year. So, if multiple generic companies enter the marketplace, consumers could save hundreds of millions of dollars per year.

The information the Commission may subpoena is broad in scope. As a general matter, "it is sufficient if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably necessary." *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950). Thus, in a petition to quash, the petitioner bears the burden to show that a subpoena is unreasonable, and where "'the agency inquiry is authorized by law and the materials sought are relevant to the inquiry, that burden is not easily met.'" *FTC v. Rockefeller*, 591 F.2d 182, 190 (2d Cir. 1979), *quoting SEC v. Brigadoon Scotch Distributing Co.*, 480 F.2d 1047, 1056 (2d Cir. 1973), *cert. denied*, 415 U.S. 915 (1974). Despite the Commission's broad authority, Watson refuses to produce Mr. Bisaro for an investigational hearing.

The Commission has more than a sufficient basis to seek Mr. Bisaro's testimony under *Morton Salt*. At issue in the Petition is whether the Commission can examine Mr. Bisaro to discover his knowledge about any agreement Watson may have that limits or restricts the exercise of any marketing rights or exclusivities it may have now or obtain in the future vis-à-vis modafinil. Such an agreement, if it exists, could be delaying generic entry to the detriment of consumers.[1] Despite the Petition's repeated assertions that Watson has reached no such agreement and that it has confirmed to the Commission that no such agreement exists, other facts raise questions about whether such an agreement exists. For example, in its response to the Commission's civil investigative demand ("CID"), Watson identified an agreement that it said "may relate to" its ability to relinquish any exclusivity rights relating to generic modafinil. Watson, however, has repeatedly refused to clarify – either through written responses or testimony – whether that agreement would prevent or otherwise limit its ability to relinquish. Further, although a company has approached Watson about relinquishing any potential exclusivity rights, Watson appears disinterested, and, according to one witness, would prefer to wait until 2012 to launch its own product. The extent to which this decision is inconsistent with Watson's economic interest is likely to shed light on whether Watson has entered into a potentially illegal agreement. Mr. Bisaro is a logical person to question on this issue that goes to the core of the Commission's investigation. Watson has identified him as one of only two people who has knowledge of relevant events, the Commission has already taken the testimony of the other person, and the critical question of whether Watson reached a potentially unlawful agreement remains unanswered.

Against this factual background and given the Commission's broad power to compel information in investigations conducted pursuant to its law enforcement efforts, we find that conducting an investigational hearing of Mr. Bisaro is proper. Accordingly, and as explained more fully below, we therefore deny the Request.

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[1] Courts have expressed great skepticism of agreements in which a generic manufacturer who is eligible for the 180-day exclusivity agrees with the branded manufacturer not to relinquish or waive that exclusivity. *See, e.g. In re Ciprofloxacin*, 544 F.3d 1323, 1339 (Fed. Cir. 2008) (agreeing that "the only legitimate allegation by the plaintiffs was that the 180-day exclusivity period had been manipulated."); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 401 (2d Cir. 2005) ("[W]e think that an agreement to time the deployment of the exclusivity period to extend a patent monopoly power might well constitute anticompetitive action outside the scope of a valid patent."); *Andrx v. Elan*, 421 F.3d 1227, 1235 (11th Cir. 2005) (holding that delayed licensed plus putative agreement to refrain from ever marketing a generic barred any competitors from entering "would exceed the scope of the patent"); *FTC v. Cephalon, Inc.*, No. 2:08-cv-2141, mem. op. (E.D. Pa. Mar. 29, 2010) (declining to dismiss complaint alleging that agreement to settle patent litigation and affecting relinquishment of exclusivity rights is anticompetitive).

Background

The Petition and Request relate to a Commission investigation,

> [t]o determine whether Cephalon, Inc., Teva Pharmaceuticals, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding modafinil products.[2]

Modafinil is a "wakefulness-enhancing" drug that Cephalon, Inc. ("Cephalon") has developed and marketed under the brand name Provigil.[3] Each of the other entities identified in the compulsory process resolution has developed and sought to market generic modafinil. The controversy giving rise to the Petition concerns the investigation of certain facts relating to Watson Pharmaceuticals, Inc. ("Watson") and its development partner, Carlsbad Technologies, Inc. ("Carlsbad") – in particular, obtaining the testimony of Paul Bisaro ("Petitioner"), Watson's President and Chief Executive Officer.

To that end, Commission staff is interested in any agreements between Cephalon and entities identified in the Commission's compulsory process resolution to settle patent litigation associated with modafinil. Cephalon sued most of the entities named in the resolution, alleging that they were infringing U.S. Reissued Patent No. 37,516 ("'516 Patent") relating to Provigil. These patent infringement allegations were based on each of the entities named in the resolution having filed Abbreviated New Drug Applications ("ANDA") with the Food and Drug Administration ("FDA") for generic modafinil, with a "Paragraph IV" certification that generic modafinil would not infringe the '516 Patent.[4] Each of the entities other than Watson/Carlsbad filed their ANDA on the same day, and before any other parties. As "first filers," these entities were eligible under applicable law for 180 days of joint marketing exclusivity at such time that the ANDA is approved. Watson/Carlsbad were not "first filers," but Cephalon also sued Carlsbad for patent infringement after Watson/Carlsbad filed their ANDA and Paragraph IV certification. Cephalon settled each of the suits between late 2005 and 2006, with the Carlsbad settlement occurring on August 2, 2006.[5] On February 13, 2008, the Commission filed a complaint against Cephalon, alleging that its settlement agreements, which provided compensation to the generic firms for foregoing generic entry, were anticompetitive, an abuse of

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[2] Resolution Authorizing Use of Compulsory Process in a Nonpublic Investigation, File No. 06110182 (Aug. 30, 2006).
[3] Petition at 3.
[4] ANDAs reflect a streamlined FDA approval process that enables manufacturers of generic drugs (*i.e.*, those that are the "bioequivalent" of branded drugs) to rely on the safety and efficacy studies relating to the branded drug. When a branded drug is covered by one or more patents, the company that seeks to market the generic drug prior to the expiration of any of those patents may proceed to seek FDA approval, but certify that the generic version does not infringe the patents on the brand-name drug, or that the patents are invalid. This certification is a "Paragraph IV" certification.
[5] Petition at 3-4.

monopoly power, and unlawful under Section 5 of the FTC Act. *FTC v. Cephalon, Inc.*, 08-cv-2141-MSG (E.D. Pa.).[6]

In December 2007, Cephalon listed a new patent with the FDA relating to modafinil: U.S. Patent No. 7,297,346 ("'346 Patent"). The subsequent listing of the '346 Patent required the existing ANDA applicants for modafinil to make a certification vis-à-vis the '346 Patent. Watson/Carlsbad filed a Paragraph IV certification on the same day that the FDA listed the new patent, identifying the Cephalon/Carlsbad settlement agreement as the basis for non-infringement of the '346 Patent. According to the Petition, if Watson were a "first filer" on the '346 Patent, it would be eligible for the 180-day marketing exclusivity for generic modafinil.[7]

Following these developments, Commission staff contacted Watson in March 2009 about its ANDA. Commission staff informed Watson that they were primarily interested in determining whether Watson had reached any agreement relating to relinquishment of any exclusivity rights it might have with respect to generic modafinil, and, if not, the basis for any decision not to waive such rights.[8] On May 19, 2009, the Commission issued a new CID to Watson and a subpoena *ad testificandum* to David A. Buchen, Watson's Senior Vice President, General Counsel, and Secretary. On May 22, 2009, the Commission issued a subpoena *ad testificandum* to Petitioner. The Commission also issued a CID and two subpoenas *ad testificandum* to Carlsbad executives.[9]

Controversies, discussed more below, ensued about the adequacy of Watson's CID responses, the necessity of investigational hearings for the Watson executives, and the schedule of the same. As a result of these discussions, Mr. Buchen ultimately appeared for a hearing. In contrast, Mr. Bisaro refused to appear and filed a petition to quash, which Commissioner Harbour denied on November 13, 2009. Pursuant to Commission Rule 2.6(f), 16 C.F.R. § 2.6(f), Mr. Bisaro has now asked the full Commission to review Commissioner Harbour's ruling.

Analysis of Petitioner's Legal Objections to Subpoena

The Supreme Court made clear that the Commission has a right to conduct an investigation "if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant." *U.S. v. Morton Salt Co.*, 338 U.S. 632, 652 (1950). This standard applies to administrative subpoenas issued by the Commission. *See, e.g., FTC v. Texaco, Inc.*, 555 F.2d 862, 872 (D.C. Cir. 1977) (en banc); *Adams v. FTC*, 296 F.2d 861, 866 (8th Cir. 1961), *cert. denied*, 369 U.S. 864 (1962). In the context of a Commission investigatory subpoena, "[t]he law on this issue is well-established: so long as an agency acts within its authority, requests information relevant to the lawful inquiry, and makes

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[6] The district court recently denied Cephalon's motion to dismiss the complaint. *FTC v. Cephalon, Inc.*, 08-cv-2141, mem. op. (E.D. Pa. Mar. 29, 2010).
[7] Petition at 6-7.
[8] Raptis Decl., at 2.
[9] Petition at 7-8.

reasonable demands, the court must uphold the validity of the administrative subpoena." *FTC v. Invention Submission Corp.*, 1991 WL 47104, *1 (D.D.C. 1991), *aff'd* 965 F.2d 1086 D.C. Cir 1992), *cert. denied*, 507 U.S. 910 (1993). Petitioner carries a heavy burden to show that the subpoena should not be enforced.

Petitioner does not challenge the Commission's authority to issue the subpoena. Nor does the Petition claim that the discovery sought is not "reasonably relevant" or too indefinite. Rather, Petitioner claims that the Commission is improperly using its compulsory process by being "unreasonable" in seeking his testimony. Petitioner raises five objections to the subpoena: (1) the resolution authorizing the compulsory process has already produced one lawsuit against Cephalon, and now cannot be used for the additional investigatory process directed to Watson; (2) the subpoena unreasonably demands information that the Commission already possesses; (3) the subpoena unreasonably seeks testimony from the "apex" of Watson's organization; (4) the subpoena was likely issued for an improper purpose; and (5) compelling Petitioner to travel to the Commission offices in Washington, DC to undergo an investigational hearing is unduly burdensome.[10]

Because we find that none of these arguments is persuasive, we deny the Petition and Request in their entirety. We address each of Petitioner's five specific challenges below.

I.

We first address Petitioner's threshold argument that the subpoena is improper because the resolution authorizing the compulsory process has already culminated in one enforcement action.[11] Petitioner provides no legal support for this proposition. A Commission resolution authorizing compulsory process for an investigation does not, as a matter of law, expire automatically upon the filing of an enforcement action or because some litigation regarding related subjects may have commenced. *See, e.g., Linde Thomson Langworthy Kohn & Van Dyke, P.C. v. Resolution Trust Corp.*, 5 F.3d 1508 (D.C. Cir. 1993). To the contrary, multiple actions might be taken as a result of information obtained through compulsory process stemming from such a resolution. Moreover, as indicated above, the concerns that prompted the Commission's current investigation relating to the '346 Patent differ in scope from those that prompted its investigation of the "pay-for-delay" settlement agreements relating to the '516 Patent. However, both components of the investigation clearly fall within the broad parameters of the compulsory process resolution, *i.e.*, "[t]o determine whether ... Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec 45, as amended, by entering into agreements regarding modafinil products." As a result, we reject Petitioner's argument that because "the Commission resolution authorizing compulsory process in connection with the above-referenced matter has already culminated in a lawsuit," it "may not now be resurrected to burden Watson with additional process."[12]

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[10] Request at 3.
[11] Request at 3.
[12] Request at 3.

II.

We turn next to Petitioner's argument that the subpoena compelling his testimony is unreasonable because it demands information that, he contends, the Commission already possesses. While Watson has provided the Commission information relating to the '346 Patent, Petitioner has not shown that his testimony will shed no additional light on matters that fall within the scope of the Commission's investigatory concerns. As a key executive of Watson, Petitioner's testimony may well be useful in elaborating on the information or explaining relevant circumstances. Under the broad standard applicable to the investigatory process, Commission staff is entitled to question Petitioner to determine if he has any additional relevant information.

As indicated above, the investigation related to the '346 Patent focuses on two critical questions: (1) whether the company has entered into any agreements that restrict it from relinquishing any exclusivity it may have in connection with that patent, and (2) if not, why the company is not pursuing potentially lucrative arrangements with third parties concerning relinquishment. In connection with these issues, and as indicated above, the Commission issued CIDs to Watson and Carlsbad on May 19, 2009, and subpoenas *ad testificandum* to two executives at each company, including Petitioner. Petitioner contends that Watson "fully" responded to "each and every" inquiry in the CID directed to it, and that because Mr. Buchen confirmed the company's responses during his investigational hearing, Petitioner's testimony is unnecessary.[13] The record, however, leaves certain open questions.

On the first issue of interest, one of the CID specifications directed to Watson required the company to "[i]dentify and provide one copy of each agreement, whether written or oral, that prohibits, blocks, prevents, compromises, or limits in any way Watson or Carlsbad's ability to relinquish eligibility to claim 180-day Marketing Exclusivity for Generic Provigil," and to identify "[t]he portion(s) of the agreement that prohibit or limit Watson or Carlsbad's ability to relinquish."[14] In response, Watson identified its settlement agreement with Cephalon as the only agreement that "may relate" to its ability to relinquish, but failed to identify the portions that prohibit or limit its ability to relinquish.[15] In response to follow-up questions by staff designed to elicit complete answers, Watson simply stated that the settlement agreement "speaks for itself," and, citing attorney-client privilege, refused to provide any information about Watson's understanding of how that agreement might relate to marketing exclusivity.[16] As for Mr. Buchen's investigational hearing, he identified an indemnification provision in the Cephalon settlement agreement that "might relate to the investigation," but declined to answer questions about any other provisions, including whether the settlement agreement limits Watson's ability to relinquish exclusivity.[17] Against this backdrop, it is reasonable for the Commission to seek

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[13] Petition at 16.
[14] CID to Watson, FTC File No. 0610182 (issued May 19, 2009).
[15] Watson Responses to CID, FTC File No. 0610182 (June 10, 2009).
[16] Letter from Maria A. Raptis to Saralisa Brau (June 17, 2009).
[17] Buchen Transcript at 47, 50-51.

testimony from additional witnesses on these issues. Watson has identified Petitioner as the only other person other than Mr. Buchen who is knowledgeable about the issues and it is therefore logical to seek his testimony.

On the second issue of interest, one of the CID specifications required Watson to "[i]dentify each company with which Watson had contact relating to ... eligibility to claim 180-day Marketing Exclusivity for Generic Provigil; or the relinquishment thereof," and "[w]hether Watson entered into an agreement as a result of these discussions, and the reasons for Watson's decision."[18] In response, Watson identified a particular company with which it had discussions, stated that specific terms were not discussed and that no agreement or decision had been reached, but failed to provide any rationale.[19] In response to follow-up questions by staff designed to elicit complete answers, Watson again failed to provide the information sought, based on attorney-client privilege.[20] Yet at Mr. Buchen's investigational hearing, he provided at least two rationales for not pursuing relinquishment: (1) discussions with the company stopped after issuance of the Commission's process, and (2) his own business view that Watson would be in a better position to launch its own product.[21] Given this information, after Watson's initial response failed to explain its decision and its follow-up response failed to provide the requested information based on privilege, we again find that it is reasonable for the Commission to pose questions to Petitioner to determine what he knows.

We recognize that questions directed to Petitioner about whether Watson has an agreement that in some way limits its ability to relinquish any marketing exclusivity rights it has, as well as about the basis for any decision of Watson not to relinquish any such rights, *may* implicate privileged communications. However, that does not provide a basis upon which to quash the subpoena for his testimony in its entirety. Rather, the proper procedure is for (1) the investigational hearing to take place; (2) Petitioner to assert the privilege (as he believes it to be applicable); and (3) Commission staff to establish facts through questioning to determine whether Petitioner's assertion is proper.

III.

Petitioner also suggests that the subpoena directed to him is unreasonable because, as President and CEO of Watson, there is no reason to believe that he has personal knowledge of relevant information that cannot be obtained through other means.[22] Petitioner provides no case law indicating that the so-called "apex doctrine" applies in an administrative investigation. Even assuming, without deciding, that the principle might apply, we find that it does not provide an adequate basis to quash the subpoena here.

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[18] CID to Watson, FTC File No. 0610182 (issued May 19, 2009).
[19] Watson Responses to CID, FTC File No. 0610182 (June 10, 2009).
[20] Letter from Maria A. Raptis to Saralisa Brau (June 17, 2009).
[21] Buchen Transcript at 33, 67-68.
[22] Petition at 17-19; Request at 5.

As a preliminary matter, we note that high-ranking executives are, of course, not insulated from discovery. *Six West Retail Acquisition, Inc. v. Sony Theatre Mgmt. Corp.*, 203 F.R.D. 98, 102 (S.D.N.Y. 2001). Even when such an executive denies having personal knowledge of relevant issues, the examining party may test such a claim. *Id.*

In the current investigation, the Commission has already sought information through a CID to Watson, through a CID to Carlsbad, through an investigational hearing of Mr. Buchen, and through an investigational hearing of a Carlsbad executive. Petitioner is another logical, possible source of relevant information, since Mr. Buchen identified him as the only person with whom Mr. Buchen had discussions regarding potential relinquishment. In addition, Petitioner has personal knowledge of conversations that he had with Mr. Buchen, as well as other factual information that may not have been discovered yet and may not be privileged. Therefore, even under the stringent standards Petitioner suggests apply to administrative investigations, the investigational hearing requested here is warranted.

To summarize, we find no basis for Petitioner's assertion that the subpoena is "unreasonable" in requesting Mr. Bisaro's testimony. Accordingly, we reject Petitioner's arguments to the contrary.

IV.

Petitioner further contends that the subpoena is improper because it was issued for an improper purpose, *i.e.*, "to pressure Watson to relinquish any exclusivity rights it may have, and thereby attempt to engineer generic entry into the modafinil market."[23] In particular, Petitioner asserts that Commission staff threatened to continue its investigation of Watson if the company did not relinquish any exclusivity rights it has, and carried out that threat by issuing the process at issue in the Petition.

These allegations are baseless and do not support the Petition's assertion that the subpoena was issued for an improper purpose. The subpoena was issued pursuant to a valid and extant resolution "[t]o determine whether Cephalon, Inc., ... Carlsbad Technology, Inc., Watson Pharmaceuticals, or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding modafinil products." Pursuant to that resolution, the Commission is authorized to investigate whether Watson has entered into any agreements relating to relinquishment of any marketing exclusivity rights that it may have for generic modafinil, and, if not, whether it intends to relinquish such rights. In such an investigation, Commission staff may explore or suggest certain actions that might negate any anticompetitive concerns identified. We find that issuing a subpoena for the testimony of the President and CEO of Watson about any company agreements and discussions with third parties with regard to relinquishment – after first issuing CIDs to the company and receiving the testimony of another of its executives – is clearly a proper purpose.

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[23] Petition at 19.

V.

Finally, Petitioner contends that if his investigational hearing is to proceed, it is "unduly burdensome" for him to appear at FTC offices in Washington, D.C. as opposed to his place of residence.[24] Petitioner provides nothing more than a generalized assertion of burden, and does not explain how his travel to and participation in an investigational hearing in Washington, D.C. is unduly burdensome. On the current record, we therefore reject Petitioner's request that the investigational hearing proceed at a location other than the FTC's offices in Washington.

Conclusion and Order

For all of the foregoing reasons, **IT IS HEREBY ORDERED THAT** the Request be, and it hereby is, **DENIED**.

IT IS FURTHER ORDERED THAT Petitioner appear on April 15, 2010, for an investigational hearing in Washington, D.C., unless otherwise agreed to by Commission staff.

By direction of the Commission.

Donald S. Clark
Secretary

[24] Petition at 19; Request at 3.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION	)	
Petitioner,	)	
v.	)	Misc. No. 1:10-mc-00289 (CKK)(AK)
PAUL M. BISARO,	)	
Respondent.	)	

DECLARATION OF SARALISA C. BRAU

Pursuant to 28 U.S.C. § 1746, Saralisa C. Brau declares as follows:

1. I am a Deputy Assistant Director in the Health Care Division within the Bureau of Competition of the U.S. Federal Trade Commission ("FTC" or "Commission"). I have day-to-day supervisory responsibility over the Commission's modafinil investigation.

2. I submit this declaration in support of the Commission's Motion for Leave to Supplement the Record and to Enforce the Subpoena *Ad Testificandum* Forthwith. The facts set forth herein are based on my personal knowledge or information made known to me in the course of my official duties.

3. The Commission opened the modafinil investigation in 2006 to determine if Cephalon, Inc. ("Cephalon"), Watson Pharmaceuticals, Inc. ("Watson"), and certain other generic companies had entered into unlawful agreements to delay the introduction of generic versions of Provigil, Cephalon's branded modafinil product. The initial phase of the modafinil investigation focused on the generic companies' challenges to Cephalon's U.S. Resissued Patent

No. 37,516 ("the '516 patent") and Cephalon's 2005-2006 settlements of the '516 patent litigation, under which Watson and the other generic companies agreed they would not market generic modafinil until 2012. The initial phase of the Commission's modafinil investigation culminated in the filing of a federal court complaint against Cephalon (but not Watson or the other generics) in February 2008, which is currently being litigated in the Eastern District of Pennsylvania. *See FTC v. Cephalon, Inc.*, No. 2:08:-cv-2141-MSG, 2010 U.S. Dist. LEXIS 29905 (E.D. Pa. Mar. 29, 2010) (denying motion to dismiss). After filing the complaint, the Commission's modafinil investigation remained open, albeit inactive.

4. The most recent phase of the modafinil investigation began when, in January 2009, Commission staff first learned that Cephalon had filed a new patent in the Food and Drug Administration's ("FDA's") Orange Book covering Provigil, U.S. Patent No. 7,297,346 ("the '346 Patent"), and that Watson – on the same day – had filed a Paragraph IV certification against the '346 Patent claiming that the patent was either invalid or not infringed by Watson's generic product. Based on my understanding of applicable statutes and regulations, these events created the possibility that Watson might be a "first filer" with regard to the '346 Patent. As "first filers," generic companies are eligible for 180 days of marketing exclusivity at such time that the FDA grants final approval to their generic drug applications. That Watson might have potential marketing exclusivity arising from the '346 patent raised questions about whether Watson's agreement not to market generic modafinil until 2012 might act as an additional impediment to generic modafinil entry by other generic companies. In light of these new facts, FTC staff resumed the modafinil investigation.

5. Between March 2 and May 5, 2009, Markus H. Meier, the Assistant Director of the Health Care Division, and I initiated several telephone calls to Watson's counsel, Steven C. Sunshine of Skadden, Arps, Slate, Meagher & Flom LLP, to discuss the latest developments in the modafinil investigation. Those conversations, and what did and did not occur as a result of those conversations, raised troubling questions about whether Watson had entered into a potentially *per se* unlawful agreement with Cephalon not to relinquish any modafinil marketing exclusivity it might have. Beginning in May 2009, the Commission issued additional compulsory process, including the subpoena *ad testificandum* to Mr. Bisaro, to resolve those questions.

The Evidentiary Basis for the Investigation

6. The evidentiary basis for staff's concerns about an unlawful agreement between Watson and Cephalon not to relinquish Watson's potential exclusivity rights centered on two issues. First, in Section 2.1 of the 2006 Settlement and License Agreement between Cephalon and Watson's business development partner, Carlsbad Technologies, Inc., ("the Settlement Agreement"), Watson had agreed not to "make, use, offer to sell, or sell, *or actively induce or assist any other entity* to make, use, offer to sell, or sell any Generic Modafinil Product within the Territory . . . ."[1] To the extent that Watson's agreement not to "actively induce or assist any other entity," precluded it from relinquishing any exclusivity rights it might have, this provision could violate the antitrust laws as an agreement among potential competitors to block other

[1] Settlement Agreement § 2.1 (emphasis added). Although to the Commission's knowledge the parties have not disclosed publicly the complete terms of the Settlement Agreement, Cephalon included a redacted version (containing the language quoted above) as Exhibit 10.1 to its 10-Q, filed with the SEC on November 8, 2006.

generic competitors from entering the market. *See In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 907-08 (6th Cir. 2003) (condemning an agreement between a brand and generic company not to relinquish exclusivity rights as a *per se* violation of the antitrust laws). This provision of the Settlement Agreement had not been a focus of the initial phase of the investigation because Watson was not a first filer with regard to the '516 patent, and was therefore not eligible for marketing exclusivity. That changed, however, after FTC staff learned, in January 2009, that Watson was a first filer with potential exclusivity rights arising from the later-listed '346 patent.

7. Second, Watson appeared disinclined to pursue a potentially profitable business opportunity in which it could relinquish any modafinil exclusivity rights it might have in exchange for substantial compensation. In a telephone conversation with Mr. Sunshine in March 2009, Mr. Meier posited hypothetical scenarios to explore whether Watson might profit from relinquishment of any exclusivity rights it might have. Based on my understanding of the facts at the time, it appeared that relinquishment could be a more profitable option for Watson than waiting to launch its generic modafinil product under the terms of the Settlement Agreement.

8. On March 13, 2009, Mr. Meier asked Mr. Sunshine if Watson would be interested in talking with a third party, Apotex, Inc. ("Apotex") about a potential agreement to relinquish whatever marketing exclusivity rights Watson might have. Mr. Sunshine affirmed that Watson would be interested in talking to Apotex about the possibility of relinquishment, and identified David Buchen, Watson's General Counsel, as the person at Watson that Apotex should contact.

9. If Watson chose to relinquish its potential exclusivity, the FTC's ongoing investigation about whether Watson had agreed with Cephalon *not* to relinquish its exclusivity

would have been resolved, leaving nothing further to investigate. In contrast, if Watson chose not to relinquish its potential exclusivity, the FTC would need to assess whether Watson was acting independently or whether the reason for the decision was attributable to an unlawful agreement with Cephalon not to relinquish.

10. On May 5, 2009, Mr. Meier and I called Mr. Sunshine to determine whether there had been any further developments relating to Watson's potential relinquishment. On May 6, 2009, Mr. Meier and I placed a similar call to Apotex's Vice President of Global Intellectual Property, Shashank Upadhye. Mr. Upadhye told FTC staff that discussions with Watson had stalled and that Watson did not appear to be interested in pursuing a business arrangement with Apotex. Based on these conversations, by early May 2009, it appeared to FTC staff that Watson was not interested in potential relinquishment.

11. Watson's apparent decision to forego a potentially profitable business opportunity relating to relinquishment raised further questions to staff about why Watson was acting in a manner that appeared to be contrary to its own economic interest. These questions, combined with staff's concerns about Section 2.1 of the Settlement Agreement, required further investigation to assess whether the reason for the decision was attributable to an unlawful agreement with Cephalon not to relinquish.

Watson Repeatedly Fails to Answer the FTC's Questions

12. On May 19, 2009, the Commission issued narrowly targeted Civil Investigative Demands ("CIDs") to Watson (the "Watson CID") and its development partner, Carlsbad, to determine, *inter alia*, whether Watson is a party to any agreement that limits its ability to relinquish any marketing exclusivity rights it may have with respect to generic Provigil.

13. Specifically, Specification 3 of the Watson CID required it to identify "each agreement, written or oral, that prohibits, blocks, prevents, compromises, or limits in any way Watson or Carlsbad's ability to relinquish eligibility to claim 180-day Marketing Exclusivity for Generic Provigil," as well as "[t]he portion(s) of the agreement that prohibit or limit Watson's or Carlsbad's ability to relinquish." (Pet'r's Reply Mem. in Supp. of Pet. for an Order Enforcing Administrative Subpoena Ad Testificandum and Opp'n to Resp't's Mot. to Compel, Supplemental Pet. Ex. 2. (Doc. No. 20))

14. In its written response dated June 10, 2009, Watson identified the Settlement Agreement as the only agreement that "may relate" to its ability to relinquish, stating that "[a]ny relevant limitations or restrictions are contained therein." Watson, however, did not identify the relevant portions of the agreement as required by Specification 3 of the CID. (*Id.* at Ex. 2.) On June 11, 2009, Commission staff responded with a letter to Watson's counsel identifying the deficiency of Watson's initial CID response and again requesting that it identify the relevant portion of the Settlement Agreement as required by the CID. (*Id.* at Ex. 3.)

15. In a letter from counsel responding to Commission staff on June 17, 2009, Watson again refused to provide the requested information, stating that "[t]he Agreement speaks for itself," and claiming privilege for "Watson's analysis of . . . how the Agreement may relate to FDA marketing exclusivity." (*Id.* at Ex. 4.)

16. During the June 25, 2009 investigational hearing of David Buchen, Watson's General Counsel, Mr. Buchen identified an indemnification provision of the Settlement Agreement that "might relate to the investigation," but refused to answer when asked about any other provisions. (*Id.* at Ex. 5.) Mr. Buchen also refused to answer when asked whether the

Settlement Agreement limits Watson ability to relinquish any rights to marketing exclusivity it may have with respect to generic Provigil. (*Id.*)

17. The May 19, 2009 Watson CID also sought information relating to Watson's discussions with third parties regarding relinquishment. Specifically, Specification 4 required Watson to identify "each company with which Watson had contact relating to: ". . . eligibility to claim 180-day Marketing Exclusivity for Generic Provigil; or the relinquishment thereof," and "[w]hether Watson entered into an agreement as a result of these discussions, and the reasons for Watson's decision." (*Id.* at Ex. 2.)

18. On June 10, 2009, Watson identified Apotex in its written response as a firm with which it had discussed relinquishment, stating that "[n]o agreement or decision has been reached." Watson, however, did not provide the reasons as required by Specification 4 of the FTC's CID. (*Id.*) On June 11, 2009, Commission staff identified the deficiency of Watson's initial CID response in a letter to counsel, and requested again that Watson provide the reasons why no agreement was reached with Apotex. (*Id.* at Ex. 3.)

19. Again, Watson refused to provide the requested information. In a letter from counsel on June 17, 2009, Watson responded that the company's decision "is inextricably intertwined with legal matters; Watson's internal deliberations regarding this matter implicate legal advice and are protected from disclosure by the attorney-client privilege."(*Id.* at Ex. 4.) At his June 25, 2009 investigational hearing, however, Mr. Buchen identified for the first time two apparently non-privileged bases for not pursuing an agreement with Apotex. (*Id.* at Ex. 5.) Mr. Buchen also identified Mr. Bisaro as the only person at Watson with whom he had spoken regarding relevant discussions with a third party about a possible deal for generic Provigil. (*Id.*)

Mr. Bisaro, as President and CEO of Watson, is well positioned to testify, among other things, about whether a potential business arrangement with a third party to relinquish any modafinil exclusivity is likely to be in the company's economic interest.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: July 21, 2010

Saralisa C. Brau
Deputy Assistant Director
Bureau of Competition
Federal Trade Commission
Washington, DC 20580

FTC antitrust blitz

"Done deals" unraveled upon agency review of past mergers.

Jenna Greene

July 26, 2010

There's no such thing as a done deal. That's the message from federal antitrust enforcers, who in recent months have ramped up attacks against consummated mergers, aggressively breaking up already combined companies.

In the past two weeks alone, the Federal Trade Commission (FTC) announced two consent orders requiring companies to sell off assets from past mergers deemed anti-competitive. Court cases are pending as well. The FTC in May filed suit against The Dun & Bradstreet Corp., targeting its purchase of a competing education data provider 15 months after the fact, while the U.S. Department of Justice (DOJ) has challenged Dean Foods Co.'s acquisition of Foremost Farms last year. "If evidence of an anti-competitive effect emerges, we'll take a look at that," said Richard Feinstein, director of the FTC's Bureau of Competition. "Our track record makes that clear."

It's not new for the antitrust agencies on occasion to go after consummated deals. What's different is the number and variety of mergers under fire, from big deals like Fidelity National Financial Inc.'s $258 million purchase of LandAmerica Financial Group Inc.'s title insurance business to tiny transactions like Election Systems & Software Inc.'s $5 million deal to buy Premier Election Solutions Inc.

Since the start of fiscal year 2009, the FTC has challenged seven consummated mergers. By comparison, during the previous five years, the FTC averaged just one complaint per year.

As for the Justice Department, challenges to consummated deals have held steady — two so far in 2010, one in 2009, one in 2008, two in 2007. But there's been a spike in civil investigative demands — similar to

subpoenas — issued by the department, indicating heightened interest in the area. Seven such demands were issued in 2009, while five to date have issued in 2010, compared to two in 2008 and one in 2007.

The explanation, antitrust lawyers say, is not a change in policy, although the activity surrounding consummated deals roughly corresponds to the change in administration. Instead, they point to the economy. "There are a lot fewer Hart-Scott-Rodino reportable deals. It means the staff has more time to look at consummated deals," said Jones Day partner David Wales, who was acting director of the FTC's Bureau of Competition from 2008 to 2009.

REDUCTION IN MERGER FILINGS

The Hart-Scott-Rodino Act requires companies to notify DOJ or the FTC about large mergers — the current threshold is $63.4 million — prior to closing. Most of the time (though not always) antitrust issues are resolved during this review.

But the number of deals subject to Hart-Scott preclearance review has plummeted during the recession.

According to DOJ, in the 2009 fiscal year, a mere 713 such merger filings were filed — a 30-year low. That's a 60% drop from 2008, when there were 1,726 notifications. The decline is even starker compared to 2007, when there were 2,201 reportable deals.

Mergers have rebounded somewhat in 2010. With a little more than two months left in the fiscal year, about 890 deals to date have been granted so-called early termination — a green light to proceed — but it still puts 2010 on track to be one of the lowest in recent years. "It's unquestionably the case in the last couple of years that filings are down," Feinstein said. "That's given the merger shops some ability to devote a little more attention to transactions that are not reportable."

But just because the deals may be small doesn't mean the allegations are

trivial. For example, the FTC is currently awaiting a verdict in a case against Ovation Pharmaceuticals (now Lundbeck Inc.) in U.S. district court in Minnesota.

The agency challenged Ovation's 2006 purchase of the drug NeoProfen from Abbott Laboratories — a transaction that originally escaped review because it fell below the Hart-Scott reporting threshold. The drug is used to treat a serious and potentially deadly heart defect affecting about 30,000 premature babies a year. A year before buying NeoProfen, Ovation struck a deal with Merck & Co. for the rights to Indocin, which according to the FTC is the only other drug used to treat the heart condition.

Ovation then raised the price of Indocin from $36 a vial to $500 (an increase of nearly 1,300%) and set the price of NeoProfen at $483. The FTC has charged the company with violating Section 7 of the Clayton Act and Section 5 of the FTC Act. It wants the judge to force the company to divest NeoProfen, and also to disgorge all excessive profits — a rarely sought remedy reserved for the most serious violations.

FTC Chairman Jon Leibowitz in a December 2008 statement called the company "immoral" and accused it of "profiteering on the backs of critically ill premature babies."

Ovation's lawyer, Alfred Pfeiffer Jr., a partner in Latham & Watkins' San Francisco office, did not return a call seeking comment.

Cases like Ovation that fall below the reporting threshold "are generally started by people calling up to complain," said O'Melveny & Myers partner Richard Parker, a former director of the Bureau of Competition. He cautions clients whose deals fall below the Hart-Scott threshold that, post-merger, they "need to behave in a pro-consumer, pro-competitive fashion. Customers are watching, and they're not afraid to complain."

It's not always customers who tip off the feds. According to *The Capital Times* of Madison, Wis., the Justice Department got wind of Dean Foods'

acquisition of Foremost Farms from University of Wisconsin Law School professor Peter Carstensen, an antitrust expert, who read about it in the local newspaper.

In April 2009, Dean bought Foremost for $35 million, an acquisition that DOJ says gave the company 57% of milk sales in Wisconsin and parts of Michigan and Illinois and eliminated substantial competition in milk sales to schools, grocery stores and other retailers.

In January, DOJ sued Dean, alleging violations of Section 7 of the Clayton Act. A Wisconsin judge in April called the government's complaint "not well structured," but denied Dean's motion to dismiss. The case is now in discovery.

Paul Denis of Dechert represents Dean in the case. While declining to comment on the matter specifically, he's noticed the overall uptick in cases involving consummated deals. "The [Hart-Scott] filings are way down. They're going to do other things," he said. "If they find a case in a consummated deal, they'll bring it."

Even very small deals have recently come to the government's attention. For example, the Justice Department in March simultaneously announced a suit and proposed settlement with Election Systems & Software. The department and nine states objected to the company's 2009 purchase of voting equipment systems from Premier Election Solutions.

The dollar value of the transaction was small — a mere $5 million — but the impact was outsized. DOJ alleged the deal made Election Systems the provider of more than 70% of voting systems in the United States. The terms of the settlement call for Election Systems to divest all associated intellectual property as well as other Premier assets. Election Systems was represented by Joseph Krauss of Hogan Lovells, who did not respond to a request for comment.

"Some companies have a naïve view that, if you don't have to file a Hart-

Scott, you're home free, and that's just not right," said Cleary Gottlieb Steen & Hamilton partner George Cary, who was not involved in the case. "The government has always had the position that there's no such thing as a deal too small to worry about."

A SECOND LOOK

In a few rare cases, the transactions at issue have been above the Hart-Scott threshold. That was the case in one FTC action announced earlier this month.

On July 16, the FTC charged that Fidelity National Financial's 2008 acquisition of three LandAmerica subsidiaries for $258 million was anti-competitive. To settle FTC charges, Fidelity agreed to sell assets in the Portland, Ore., and Detroit metropolitan areas, and in four other Oregon counties.

Fidelity was represented by Paul, Weiss, Rifkind, Wharton & Garrison partner Joseph Simons, who declined comment.

What made the deal unusual was that, at the time of the purchase, LandAmerica had filed for a Chapter 11 reorganization in U.S. bankruptcy court in Virginia.

Wales, who was acting director of the Bureau of Competition when the FTC reviewed the deal, noted that, in a bankruptcy, the assets being purchased could expire if the antitrust review drags on. "The government has to weigh the value of holding up a deal versus allowing it to go through and dealing with issues later," he said.

In this case, the markets where competition was reduced made up only a small portion of the overall deal, which included 102 title insurance companies in 25 states. LandAmerica agreed to sell assets in Oregon to Northwest Title and those in Michigan to Data Trace. "I think it reflects on our ability to take a practical approach," Feinstein said.

Jenna Greene can be contacted at jgreene@alm.com.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
William E. Kovacic
J. Thomas Rosch
Edith Ramirez
Julie Brill

Statement Of The Federal Trade Commission
Concerning Subpoena Issued To Paul M. Bisaro

Today the Commission filed court papers in support of its petition to enforce a subpoena issued to Paul M. Bisaro, CEO of Watson Pharmaceuticals, Inc. The Commission's subpoena enforcement action followed its unanimous letter ruling, dated April 2, 2010, denying Mr. Bisaro's petition to quash the Commission's subpoena seeking his testimony and rejecting his argument that the subpoena was issued for an improper purpose.

The Commission continues to stand behind its subpoena and its investigation. The investigation, which was initiated pursuant to a unanimously adopted Commission resolution, relates generally to a series of agreements entered among the branded drug company Cephalon and several generic drug companies to delay entry of generic versions of Provigil, a sleep disorder medication with nearly $1 billion in annual U.S. sales. As the Commission has alleged in a related enforcement action against Cephalon, these agreements cost consumers hundreds of millions of dollars a year. The Commission has substantial and legitimate concerns about these pay-for-delay agreements and their impact on consumers.

As today's court filing makes clear, the Commission issued the subpoena to Mr. Bisaro for an entirely proper purpose. The Commission sought to determine whether an agreement between Watson and Cephalon has prevented Watson from relinquishing certain regulatory exclusivity rights. Such an agreement likely would be a *per se* antitrust violation and have enormous negative effects on consumers. For this reason, the Commission sought the testimony of Mr. Bisaro. The subpoena was not issued "to pressure Watson to relinquish any exclusivity rights it may have, and thereby attempt to engineer generic entry into the [Provigil] market," as Mr. Bisaro argued in his petition to quash the subpoena. The Commission continues to believe that it is entitled to Mr. Bisaro's testimony in this matter.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION **Petitioner**,	)	
v.	)	Misc. No. 1:10-mc-00289 (CKK)(AK)
PAUL M. BISARO, **Respondent.**	)	

PETITIONER FTC'S MOTION FOR LEAVE TO SUPPLEMENT THE RECORD AND TO ENFORCE THE SUBPOENA *AD TESTIFICANDUM* FORTHWITH, AND MEMORANDUM IN SUPPORT

On July 13, 2010, this Court entered a Memorandum and Order finding that Respondent had made a "colorable claim" that the Federal Trade Commission ("FTC" or "Commission") had engaged in misconduct by seeking Respondent's oral sworn testimony in a law enforcement investigation issued pursuant to a resolution approved by the full Commission. Contrary to Respondent's assertions, the Commission's actions were carried out for legitimate law enforcement purposes in furtherance of the public interest – and, in one critical instance, with the consent of Respondent's counsel. Accordingly, we submit this Motion to Supplement the Record in order to provide the Court with a more complete factual background, and to ensure that this evidence is available on the public record and not just to Respondent. The Commission also moves this Court to enforce its Subpoena *Ad Testificandum* forthwith, as there is no remaining cause for delay.

For the reasons set forth below, we seek to supplement the record with (i) answers to Respondent's two interrogatories sworn to by Markus H. Meier, chief of the Health Care Division ("Interrog. Resp." attached as Exhibit A,); (ii) a Declaration by Richard A. Feinstein, Director of the Commission's Bureau of Competition and former chief of the Bureau's Health Care Division ("Feinstein Decl." attached as Exhibit B); and (iii) a Declaration by Saralisa C. Brau, Deputy Assistant Director of the Bureau's Health Care Division and the person responsible for day-to-day management of the investigation into potential anticompetitive conduct of Watson Pharmaceuticals, Inc. ("Watson") ("Brau Decl." attached as Exhibit C). Because the factual record amply demonstrates that the requirements for judicial enforcement have been satisfied, and for the reasons set forth in more detail below, the FTC also respectfully moves this Court to take all steps necessary to further the enforcement of the July 22, 2009, subpoena *ad testificandum* forthwith.

PRELIMINARY STATEMENT

The FTC acted appropriately at all times during the course of this investigation. Further, Respondent has made no objective "showing" of misconduct, and the "extraordinary circumstances" that might justify discovery within the context of summary subpoena enforcement proceedings are not present here. *Federal Trade Commission v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980). The Commission takes this opportunity to provide the Court with the full story. The proposed submissions – the FTC's Responses to Interrogatories, the Feinstein Declaration, and the Brau Declaration – demonstrate that: the law enforcement investigation giving rise to the subpoena at issue has been conducted in a proper and lawful manner that is fully consistent with the ordinary course of Commission practice; that the Commission did not try to broker any deal

between Watson and Apotex; that Watson's interactions with Apotex are directly relevant to determine whether Watson is bound by an agreement not to relinquish any potential exclusivity rights; that there were no improper disclosures of confidential information made at any time during the course of the investigation; and, finally, that Respondent has impeded an ongoing Commission investigation, potentially causing harm to the public interest.

As detailed below, and elaborated in the papers already on file with this Court, the requirements for judicial enforcement of the subpoena at issue have been fully satisfied. The FTC therefore respectfully requests that this Court, with a complete record now in hand, expeditiously resolve this matter pursuant to Local Civil Rule 72.3 so that the subpoena can be enforced at the earliest possible date. Respondent should be ordered to fulfill his legal obligation to cooperate with the lawful Commission investigation by sitting for an investigational hearing.

STATEMENT OF FACTS

The investigation giving rise to the subpoena in question, like all formal Commission investigations involving the use of compulsory process, required majority vote of the Commission. Feinstein Decl. at ¶ 3; 16 CFR § 2.7(a). On August 30, 2006, the Commission unanimously issued a Resolution authorizing the use of compulsory process in the present investigation.[1] The initial focus of the staff's investigation concerned a patent settlement agreement entered into between Cephalon, Inc. ("Cephalon") and various generic companies involving Cephalon's '516 patent. Interrog. Resp. at 3; Brau Decl. at ¶ 3; *see also* Dkt. No. 4 (Mem. of P. & A. in Supp. of Pet. of F.T.C. for an Order Enforcing Subpoena *Ad Testificandum*) at 4-5.

[1] Resolution Authorizing Use of Compulsory Process in a NonPublic Investigation, File No. 0610182 (August 30, 2006). Pet. Exh. 2 (Dkt. No. 3 at 10).

It was not until January 2009, that the staff first learned of a subsequently-filed Cephalon patent – the '346 Patent. Interrog. Resp. at 3-4; Brau Decl. at ¶ 4. The agency's discovery that this second patent had been filed gave rise to a series of questions regarding the impact that such a patent might have on the competitive conditions in the market for generic modafinil – including, specifically, whether this second patent might be used to block generic entry. Interrog. Resp. at 4. At this point, the question arose as to whether Watson might have exclusivity rights with respect to a generic version of modafinil relating to the '346 Patent; and whether Watson had agreed with Cephalon not to relinquish or pursue those rights in exchange for a payment from Cephalon to Watson. Interrog. Resp. at 4; Brau Decl. at ¶ 4. Such an agreement would likely be a *per se* antitrust violation. *See, infra*, at 8. Thus, the Commission's investigation regarding potential anticompetitive conduct that might arise with relationship to the '346 patent began in January 2009, before any contact with Watson's counsel.

In the ordinary course of pursuing the investigation, Commission staff talked to the Food and Drug Administration (FDA) and to Apotex, Inc. ("Apotex")[2] to gather information needed to advance the Commission's understanding of the '346 Patent and its effects on the marketing of modafinil and any generic version of that drug, and to discover whether there was any possible agreement between Watson and Cephalon concerning potential exclusivity rights held by Watson. Interrog. Resp. at 4, 7. That staff action was fully consistent with normal and customary

[2] As detailed in the Interrogatory Responses, Apotex was an "obvious choice" to consult because it had filed an ANDA for a generic version of modafinil and was blocked from entering by Cephalon's modafinil settlements, it was already selling generic modafinil in Canada, and its Vice President of Global Intellectual Property, Shashank Upadye, is a published expert in the field. Interrog. Resp. at 7.

procedure followed in the ordinary course of Commission investigations. Feinstein Decl. at ¶ 10. At no time did staff improperly disclose any confidential information to the FDA, nor did staff improperly discuss any confidential FDA information with Watson or others. Interrog. Resp. at 5, 11; Feinstein Decl. at ¶¶ 2, 14.

More specifically, issuance of the '346 patent represented a novel situation to staff, Interrog. Resp. at 4, and a potentially new impediment to generic entry in the modafinil market. To the extent generic manufacturers obtained first-filer rights on this patent, and had entered into unlawful agreements with respect to those rights, it might allow them to block entry by other companies seeking to enter with a low-cost generic version of modafinil, causing further anticompetitive harm to consumers. Interrog. Resp. at 4; Brau Decl. at ¶ 4. That harm might be avoided if a generic company decided to relinquish any claim of exclusivity rights it might have on the '346 patent. But the FTC staff were concerned that Watson had lost the ability to do that. Indeed, Section 2.1 of the 2006 Settlement Agreement between Watson and Cephalon could be read to prohibit Watson from relinquishing any new exclusivity rights it might have obtained based on any filing with respect to the '346 patent. *See* Brau Decl. at ¶ 6.

In March 2009, Mr. Meier, the chief of the Commission's Health Care Division in its Bureau of Competition, contacted counsel for Watson, to probe whether Watson was willing to relinquish any exclusivity rights it might have. Interrog. Resp. at 9; Brau Decl. at ¶ 8. The basis for this inquiry was staff's belief that relinquishment could provide Watson with a potential business opportunity and, at the same time, potentially save consumers of Provigil millions of dollars a year by facilitating entry of generic modafinil. Brau Decl. at ¶ 7. If Watson was not interested in relinquishing, *i.e.*, was foregoing a potentially profitable opportunity against its

economic self-interest, the Commission would likely need to investigate further to assess whether that decision was based on an unlawful agreement with Cephalon or some other reason. Interrog. Resp. at 10; Brau Decl. at ¶ 9. Through a series of hypothetical questions, Mr. Meier sought to determine whether Watson would be interested in entering into a profit-maximizing agreement that would entail Watson licensing, relinquishing, or otherwise sharing whatever first-filer rights it might have. Interrog. Resp. at 9. Before the conversation ended, *Watson's counsel authorized Mr. Meier to contact Apotex regarding a possible deal between Watson and Apotex. Id.*

Not only did Mr. Sunshine, Watson's counsel, expressly assent to Mr. Meier calling Apotex and inviting Apotex to contact Watson, Mr. Sunshine even identified Watson's General Counsel, Mr. Buchen, as the person Apotex should call. Interrog. Resp. at 9-10; Brau Decl. at ¶ 8.[3] Contrary to Respondent's allegations that the FTC was engaged in improper deal brokering, the Commission was providing Watson with an opportunity to disprove its reasonable suspicion – a suspicion based on language contained in the 2006 Settlement Agreement between Watson and Cephalon – that an illegal agreement to refuse to relinquish existed. Thus, with the express consent of Steven Sunshine, Mr. Meier and Ms. Brau thereafter contacted Apotex. Interrog. Resp. at 9-10. In that call, staff suggested that, if Apotex also thought any potential deal might be worth pursuing, it should contact Watson regarding a possible deal concerning generic modafinil. *Id.* At no time did staff improperly disclose any confidential Watson information to any third party, including Apotex. Interrog. Resp. at 5, 11; Feinstein Decl. at ¶¶ 2, 14.

[3] These facts are omitted from Mr. Sunshine's Declaration of July 30, 2009. Pet. Exh. 4 at 28-32.

Despite the opportunity presented to it, Watson declined to negotiate a deal to relinquish any exclusivity it may have, thereby leaving open the possibility that it had entered into an illegal agreement with Cephalon. The Commission continued to investigate whether Watson had agreed with Cephalon not to relinquish. Brau Decl. at ¶ 12

In short, notwithstanding efforts by the staff to determine whether such an agreement existed, Watson has, to this date, refused to give the Commission staff an unequivocal answer to one simple question: has Watson agreed with Cephalon not to relinquish any exclusivity rights that it might hold with respect to generic modafinil? Feinstein Decl. at ¶ 12; Brau Decl. at ¶¶ 14-19; *see also* Pet'rs Reply Mem. in Supp. of Pet. for an Order Enforcing Admin. Subpoena *Ad Testificandum* and Opp'n to Respondent's Mot. to Compel, at 2-7 [Dkt. No. 21]. The Commission seeks the sworn testimony of Mr. Bisaro for a proper purpose – to determine whether there has been anticompetitive collusion between Watson and Cephalon. Watson's potential exclusivity rights arising from the '346 patent, the written settlement agreement between Cephalon and Watson, Watson's actions vis-a-vis Apotex, and Watson's continued refusal to give unequivocal answers to critical questions throughout this investigation, all support an inference that Watson may have agreed with Cephalon not to relinquish any exclusivity rights it may have with respect to generic modafinil. Mr. Bisaro is the only Watson executive besides Watson's General Counsel, Mr. Buchen, who is likely to have knowledge of critical facts relevant to the Commission's investigation, including the critical question concerning whether Watson has an agreement with Cephalon prohibiting it from relinquishing any exclusivity rights. Mr. Buchen has declined to answer that question unequivocally, asserting the attorney-client privilege. Brau Decl. at ¶ 16; *see also* Dkt. No. 21, at 2-7.

LEGAL ARGUMENT

Watson has yet to provide the Commission with a clear and unequivocal answer to the question of whether it has agreed with Cephalon not to relinquish any exclusivity rights to generic modafinil. This is a critical question with clear competitive implications. Agreements not to relinquish exclusivity might be a *per se* violation of the antitrust laws. *See In re Cardizem*, 332 F.3d 896, 907-08 (6th Cir. 2003) (finding an agreement not to relinquish exclusivity rights to be a *per se* violation of the antitrust laws).[4]

The Commission is authorized to ask this question pursuant to a valid Commission resolution. *Supra* note 1. The subpoena at issue has gone through the full agency process in being issued. The subpoena was issued by a Commissioner acting under delegated authority of the full Commission. Feinstein Decl. at. ¶¶ 4, 5; 16 C.F.R. § 2.7(a). Respondent petitioned to quash the subpoena, and his petition was rejected by FTC Commissioner Pamela Jones Harbour, pursuant to authority delegated by the full Commission. Feinstein Decl. at ¶ 5. Respondent then

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[4] As the full Commission expressly noted in its Letter Opinion denying Petitioner's Motion to Quash the subpoena:

> Courts have expressed great skepticism of agreements in which a generic manufacturer who is eligible for the 180-day exclusivity agrees with the branded manufacturer not to relinquish or waive that exclusivity. *See, e.g. In re Ciprofloxacin*, 544 F.3d 1323, 1339 (Fed. Cir. 2008) (agreeing that "the only legitimate allegation by the plaintiffs was that the 180-day exclusivity period had been manipulated."); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 401 (2d Cir. 2005) ("[W]e think that an agreement to time the deployment of the exclusivity period to extend a patent monopoly power might well constitute anticompetitive action outside the scope of a valid patent."); *Andrx v. Elan*, 421 F.3d 1227, 1235 (11th Cir. 2005) (holding that delayed licensed plus putative agreement to refrain from ever marketing a generic barred any competitors from entering "would exceed the scope of exclusion intended by the '320 patent"); *FTC v. Cephalon, Inc.*, No. 2:08-cv-2141, mem. op. (E.D. Pa. Mar. 29, 2010) (declining to dismiss complaint alleging that agreement to settle patent litigation and affecting relinquishment of exclusivity rights is anticompetitive).

Pet. Exh. 7, at 2, n.1.

filed a petition for review, and the full Commission, by unanimous vote, rejected arguments and denied Respondent's Petition to Quash, a petition in which he raised largely the same arguments presented to this Court. Pet. Exh. 7; Feinstein Decl. at ¶ 5. The Commission now seeks to supplement the record in the interest of providing the full story to the Court and bringing this matter to a close.

In this case, as Respondent acknowledged in its Motion to Compel, "[t]he only question that needs to be resolved is factual – *i.e.*, what is the FTC's purpose in prosecuting the Subpoena." Dkt. No. 16, at 3. The Commission's answers to Respondent's Interrogatories and supplemental declarations show that the agency's purpose in prosecuting the Subpoena was proper. And, as the Commission's earlier briefing has demonstrated, and Respondent fails to adequately refute, all of the other requirements for prompt judicial enforcement have been satisfied.[5] With both sides of the story now in hand, and the resulting showing that the Commission has acted in accordance with the law and in pursuit of proper purpose, the FTC respectfully requests that the Court act swiftly to enforce the subpoena *ad testificandum*.

I. Fundamental Notions of Fairness Support Granting Leave To Supplement The Record.

Presently, the evidentiary record in this case relating to the misconduct issue consists almost entirely of one declaration submitted by Respondent's attorney that relies on qualifying words such as "indicated", "hypothetical scenarios", and "suggested" to insinuate misconduct in this case but that falls far short of stating any fact that would demonstrate actual misconduct by

[5] At the very least, any remaining questions are principally questions of law and can be decided based on the existing briefing; no further hearing is needed.

the FTC. Pet. Exh. 4, Sunshine Decl. at ¶¶ 15, 16, 22. Mr. Sunshine's characterization of events notwithstanding, the objective facts are themselves entirely consistent with good faith actions on the part of the Commission. The Commission had not previously adduced its own evidence, given its firmly-held position that any evidentiary response to Respondent's unsupported allegations was not needed, in light of this Circuit's governing precedent. *See FTC v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980).[6] Because the Commission is a law enforcement agency that Congress has charged with protecting the public interest, the existence of even this tentative

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[6] With respect, this Court applied the wrong legal standard in permitting discovery. Even if the Court is correct that the rule from *Carter* "cannot be squared" with *United States v. Powell*, 379 U.S. 48 (1964), Dkt. No. 31, at 9, *Carter* remains the governing law of the Circuit and must be applied. *Carter* was issued 16 years after *Powell* and the panel who decided *Carter* had the benefit of *Powell* in reaching its ruling (although the *Carter* decision does not expressly cite to *Powell*, it discusses *Donaldson v. United States*, 400 U.S. 517 (1971), a case which itself discusses *Powell*). Just as the courts of appeals leave to the Supreme Court "'the prerogative of overuling its ... decisions,'" *Rodgriguez de Quijas v. Shearson/American Express, Inc.*, 490 U.S. 477, 484 (1989), district judges, like panels of [the courts of appeals], are obligated to follow controlling circuit precedent until [the court of appeals] sitting en banc, or the Supreme Court, overrule it." *United States v. Torres*, 115 F.3d 1033, 1036 (D.C. Cir. 1997). Under the governing legal standard of this Circuit, therefore, Respondent is not entitled to discovery.

And, even apart from this threshold legal error, the limited "facts" presented by Respondent do not rise to the objective level necessary to support the extraordinary remedy of discovery in the context of summary enforcement proceedings and *a fortiorari*, are insufficient to thwart the prompt enforcement of the subpoena to which the Commission is demonstrably entitled. Thus, in *United States v. Fensterwald*, the single instance in which this Circuit has found "extraordinary circumstances" sufficient to warrant discovery, the ruling was based on objective facts, that the court expressly recognized to be "matters of public record," demonstrating the likelihood that the taxpayer was inappropriately targeted for a special audit outside of the course of normal agency proceedings. 553 F.2d 231, 233 (D.C. Cir. 1977). In contrast, the record here is bereft of any objective indicia of bad faith. The only showing is Respondent's characterization that is based on an incomplete and suppositional accounting of events by counsel, where the underlying events are themselves fully consistent with a lawful investigation carried out in the ordinary course of business. In light of its overriding interests in setting the record straight and given the importance of securing prompt enforcement of the subpoena, the Commission has not presently raised objections to the Magistrate's ruling in this case. The Commission, however, preserves the right to advance these arguments in the future if necessary.

finding by the Court potentially damages the public's confidence in the work the agency does. It is therefore important that the Commission have the opportunity to complete the record in this case to make clear that the Commission has properly conducted itself in all respects in this matter.

Notably, in partially granting Respondent limited discovery in this matter, the Court has directed the Commission to answer two interrogatories and has allowed Respondent ten days after receiving the answers to supplement the record. The Court's Order does not provide the Commission with an opportunity to respond. Unless the Commission is given an opportunity to supplement the record now, this means that the only evidentiary materials before the Court when it ultimately decides this matter may be those provided by the party that has the greatest interest in undermining the Commission's integrity. Fundamental notions of fairness and due process dictate that the Court be fully informed when making its decision. The Court should therefore grant the Commission's motion to supplement the record.

II. The Record, As Fairly Supplemented, Is Sufficient to Order Enforcement of the Subpoena *Ad Testificandum* Forthwith

The standards for judicial enforcement of administrative investigative process have long been settled in this Circuit. "[T]he court's role in a proceeding to enforce an administrative subpoena is a strictly limited one." *FTC v. Texaco, Inc.*, 555 F.2d 862, 871-72 (D.C. Cir. 1977) (*en banc*) (*citing Endicott Johnson Corp. v. Perkins*, 317 U.S. 501, 509 (1943); *accord, Oklahoma Press Publ'g Co. v. Walling*, 327 U.S. 186, 209 (1946); *United States v. Morton Salt Co.*, 338 U.S. 632, 643 (1950)). A district court must enforce agency process so long as the information sought is not "unduly burdensome" to produce (*Texaco*, 555 F.2d at 881), and is "reasonably relevant" (*id.* at 872-73 n.23 (quoting *Morton Salt*, 338 U.S. at 652), or, putting it

differently, "not plainly incompetent or irrelevant to any lawful purpose" of the agency. *Texaco*, 555 F.2d at 872 (quoting *Endicott Johnson*, 317 U.S. at 509). In making this determination, the agency's own appraisal of relevancy must be accepted so long as it is not "'obviously wrong.'" *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1089 (D.C. Cir. 1992) (citing *Carter*, 636 F.2d at 787-88 (quoting *Texaco*, 555 F.2d at 877 n.32)).

Respondent has previously argued that the "most important[]"of its reasons against enforcement of the subpoena is that enforcement would result in an abuse of this Court's process because "the FTC exceeded its statutory law-enforcement mission by seeking to broker a business deal between Watson and Apotex ... improperly using its privileged access to confidential information in the process, and apparently providing Watson's confidential information to Apotex." Resp'ts Mem. in Opp'n, Dkt. No. 12, at 3. As Respondent has also acknowledged, in his Motion to Compel, this argument turns on a factual question. Dkt. No. 16, at 3. The Court now has the evidence in hand necessary to resolve this factual question. There is no record support that the FTC has exceeded its authority or otherwise acted improperly – beyond the insinuations contained within the declaration of Respondent's counsel. And there is now ample evidence to the contrary.

With the Commission's submissions now before the Court, the record demonstrates that the FTC's purpose in prosecuting the subpoena was legitimate. The Commission seeks to ascertain whether or not Watson is party to any potentially anticompetitive agreement with Cephalon that would prohibit it from relinquishing potential exclusivity rights in the generic modafinil market.

The agency timely began to investigate any potential anticompetitive effects resulting from the filing of the '346 patent as soon as it first learned of the filing of the patent, *before* any conversations with Watson's counsel. Interrog. Resp. at 3; Brau Decl. at ¶ 4. There was, and continues to be, good reason for the agency to seek this information. *See Modern Home Institute, Inc. v. Hartford Acc. & Indem. Co.* 513 F.2d 102, 111 (2nd Cir. 1975) ("Actions against the apparent individual economic self-interest of the alleged conspirators may raise an inference of interdependent action."). Respondent remains one of only two people who can address the agency's concerns, Brau Decl. at ¶ 19, and of the two, as Watson's President and CEO, Mr. Bisaro is well positioned to testify as to whether any business arrangement to relinquish exclusivity rights is likely to be in Watson's economic self-interest. Brau Decl. at ¶ 19. As the full Commission noted in denying Mr. Bisaro's Petition to Quash the Subpoena: "While Watson has provided the Commission information relating to the '346 Patent, [Respondent] has not shown that his testimony will shed no light on matters that fall within the scope of the Commission's investigatory concerns. As a key executive of Watson, [Respondent's] testimony may well be useful in elaborating on the information or explaining relevant circumstances." Pet. Exh. 7 at 6.

Throughout the course of this investigation, Watson has done nothing to allay the Commission's concerns that it has reached an illegal anticompetitive agreement with Cephalon; indeed, its actions (and inactions) indicate that it has. It should not be forgotten that the motion to compel discovery represents another method for Respondent to use in impeding a legitimate law enforcement proceeding. Respondent continues to avoid answering a central question to the Commission's investigation – namely, whether Watson's settlement agreement with a rival

manufacturer, Cephalon, limits Watson's ability to relinquish any exclusivity rights it may have with respect to marketing of the drug modafinil.

The Commission has shown that an investigational hearing of Respondent is necessary, because, to date, none of the sworn testimony contains a definitive disavowal of the existence of an agreement between Watson and Cepahlon that would prevent Watson from relinquishing exclusivity. Respondent has failed to rebut the Commission's showing that the investigative hearing is necessary. Moreover, Respondent does not dispute that Watson has repeatedly failed to answer, under oath, critical questions about the settlement agreement; it does not dispute that Respondent knows relevant facts to the investigation; and it does not assert that the investigational hearing would be unduly burdensome.

In furtherance of the interests of judicial economy and the public interest, and for the reasons previously articulated to this Court, the FTC respectfully requests that the Court recommend that Mr. Bisaro be directed to comply in full with the subpoena *ad testificandum*.

CONCLUSION

For the foregoing reasons, the Commission respectfully requests that this Court grant its Motion for Leave to Supplement the Record and Petition to Enforce the Subpoena Forthwith.

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Statement of Compliance

Pursuant to L.Cv. R. 7(m), on July 20, 2010, Petitioner's counsel conferred with counsel for Respondent regarding Petitioner's Motion for Leave to Supplement the Record, and counsel for Respondent opposes the motion. There is no obligation, under the local rules, to confer with respect to Petitioner's dispositive motion to Enforce the Subpoena *Ad Testificandum* Forthwith.

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CERTIFICATE OF SERVICE

I hereby certify that on July 22, 2010, a true and correct copy of the foregoing Motion for Leave to Supplement the Record and to Enforce the Subpoena *Ad Testificandum* Forthwith, together with: Exhibit A: FTC's Responses to First Set of Interrogatories of Respondent Paul M. Bisaro sworn to by Markus H. Meier; Exhibit B: Declaration of Richard A. Feinstein; Exhibit C: Declaration of Saralisa C. Brau; and a Proposed Order, were filed electronically in the United State District Court for the District of Columbia using the CM/ECF system.

Notice of this filing will be sent by email to all parties by operation of the Court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing.

Dated: July 22, 2010

/s/ Michael D. Bergman
Michael D. Bergman
Attorney for the Petitioner
Federal Trade Commission

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Federal Trade Commission,	)	
Petitioner,	)	
v.	)	**No. 01: 10-mc-00289-CKK-AK**
Paul M. Bisaro,	)	
Respondent.	)	

FEDERAL TRADE COMMISSION'S RESPONSES TO FIRST SET OF INTERROGATORIES OF RESPONDENT PAUL M. BISARO

Petitioner Federal Trade Commission ("FTC" or "Commission") hereby submits the following Responses to the First Set of Interrogatories of Respondent Paul M. Bisaro dated May 21, 2010.

GENERAL OBJECTIONS

1. By answering these interrogatories, the Commission does not waive the previous objections it made to these interrogatories in its June 21, 2010 Objections to First Set of Interrogatories of Respondent Paul M. Bisaro, nor does it waive its right to appeal, or otherwise assign error, to the Court's Order of July 13, 2010, directing it to engage in discovery in this matter.

2. To the extent Respondent's interrogatories seek the production of documents under Rule 34 or otherwise, the Commission objects on the ground that such discovery is beyond the scope of Rule 33 and beyond the scope of the Court's Order of July 13, 2010.

3. The FTC has responded to this interrogatory request to the best of its present ability. The FTC reserves its rights to supplement, revise, correct, or clarify any of the responses set forth herein, if necessary or appropriate.

In addition to these objections, the Commission further objects to Respondent's interrogatories as indicated below.

RESPONSES TO INTERROGATORIES

Interrogatory 1

Describe any communications the FTC had with the FDA relating to any potential marketing exclusivity for generic modafinil arising out of the ANDA Amendment during the period December 19, 2007, through July 22, 2009. For each communication:

a. Identify the date of the communication;

b. Identify the name and title of the individual(s) involved in the communication;

c. Identify the means through which the communication was made;

d. Identify who initiated the communication;

e. Identify the reason for the communication;

f. Identify the topic(s) discussed during the communication; and

g. State whether, during the course of the communication, or as a result of the communication, the FTC communicated to the FDA any confidential information provided to the FTC by Watson.

Response to Interrogatory 1

The FTC objects to Respondent's interrogatories to the extent they seek confidential information that the FTC obtained pursuant to inter-agency communications with the Food and Drug Administration and that is exempt from disclosure by statutes and regulations, including but not limited to 21 C. F. R. § § 20.64(a), 20.61, 20.62, and 314.430(b) (2010). Expressly reserving and without waiving the general objections and this specific objection, the FTC states as follows:

Before January 2009, the FTC's modafinil investigation had focused on a particular patent – U.S. Reissue Patent No. 37,516 (the "'516 patent") – and the potential barriers to competition arising from Cephalon's 2005-2006 patent litigation settlement agreements with Watson and the four first filers for the '516 patent. The initial phase of the modafinil investigation resulted in the FTC filing a complaint against Cephalon in February 2008.[1] The investigation remained open, however, though not active, with respect to the generic companies, including Watson, while the Commission pursued litigation against Cephalon in federal court in the Eastern District of Pennsylvania.

In January 2009, the FTC learned for the first time from the FDA that Cephalon had listed a second patent relating to Provigil, U.S. Patent No. 7,297,346 (the "'346 patent"), in the FDA's Orange Book. While the U.S. Patent and Trademark Office's issuance of the '346 patent to Cephalon in November 2007 and Cephalon's filing of it with the FDA in December 2007 were matters of public record, FTC staff had not been aware of these developments. The FTC also learned, in January 2009, that Watson/Carlsbad had filed an ANDA Amendment with the

[1] *FTC v. Cepahlon, Inc.*, No. 2:08-cv-2141-MSG (E.D. Pa. filed Feb. 13, 2008).

FDA on the same day that Cephalon listed the '346 patent. Together, these events created the possibility – one that did not exist for the '516 patent and was not a focus during the initial phase of the FTC's investigation – that Watson could be a "first filer" for the '346 patent, and therefore might block generic modafinil market entry for other companies. This new information caused the FTC staff to resume the modafinil investigation because it raised a host of questions about whether the '346 patent created any new impediments to generic entry and whether those impediments were the result of an unlawful agreement between Cephalon and Watson.

This new phase of the investigation was prompted by a conversation between the FTC and FDA on January 29, 2009. On that date, in response to the FTC's inquiries about the regulatory status of modafinil, Elizabeth Dickinson, Associate Chief Counsel in the FDA's Office of Chief Counsel, called Saralisa Brau, Deputy Assistant Director in the Health Care Division of the FTC. The two agencies routinely share information concerning the regulatory status of certain drug products, pursuant to a written inter-agency agreement, to advance the FTC's law enforcement and consumer protection missions. The modafinil investigation was no exception. The topics discussed during the call were: (1) Cephalon's later-issued '346 patent relating to Provigil; (2) Cephalon's listing of the '346 patent with the FDA; and (3) the identity of the generic company or companies that had submitted amended ANDAs containing a Paragraph IV certification as to the '346 patent and who might be eligible to claim 180-day marketing exclusivity as a "first filer."

In February 2009, the FTC requested a meeting with FDA to discuss how the '346 patent might potentially affect the FTC's ongoing modafinil investigation. Ms. Brau of the FTC had approximately three communications with Ms. Dickinson of the FDA to set up the meeting. Ms.

Brau contacted Ms. Dickinson in early February 2009 and they exchanged emails concerning meeting logistics on February 18, 2009, and February 19, 2009. The meeting took place on February 24, 2009. The following people attended:

FTC	FDA
Brad Albert, Deputy Assistant Director, Health Care Division	Rick Blumberg, Deputy Chief Counsel of Litigation, Office of Chief Counsel
Saralisa Brau, Deputy Assistant Director, Health Care Division	Kim Dettelbach, Associate Chief Counsel, Office of Chief Counsel
Michael Kades, Attorney Advisor to then-Commissioner (now Chairman) Leibowitz	Elizabeth Dickinson, Associate Chief Counsel, Office of Chief Counsel
Markus Meier, Assistant Director, Health Care Division	Dave Read, Regulatory Counsel, Center for Drug Evaluation and Research/Office of Generic Drugs

The topics discussed were: (1) the FTC's complaint filed in *FTC v. Cephalon, Inc.*, No. 1:08-cv-00244 (D.D.C. complaint filed Feb. 13, 2008) (later transferred to E.D. Pa.); and (2) the FDA's interpretation and analysis of relevant statutes concerning whether *second* filers on the earlier-listed '516 patent would be blocked from entering the market by any *first* filer(s) eligible to claim 180-day marketing exclusivity on the later-listed '346 patent.

At no time during this meeting or in the course of any communications with the FDA did the FTC reveal to the FDA any confidential information provided to the FTC by Watson.

Interrogatory 2

Describe any communications between the FTC and any third-party (excluding Watson and the FDA) including, but not limited to Apotex, relating to any potential marketing exclusivity for generic modafinil arising out of the ANDA Amendment during the period December 19, 2007, through July 22, 2009. For each communication:

- **a. Identify the date of the communication;**
- **b. Identify the name and title of the individual(s) involved in the communication;**
- **c. Identify the means through which the communication was made;**
- **d. Identify who initiated the communication;**
- **e. Identify the reason for the communication;**
- **f. Identify the topic(s) discussed during the communication;**
- **g. State whether, during the course of the communication, or as a result of the communication, the FTC communicated to any third-party any confidential information provided to the FTC by Watson; and**
- **h. State whether, during the course of the communication, or as a result of the communication, the FTC communicated to any third-party any confidential information provided to the FTC by the FDA.**

Response to Interrogatory 2

The FTC objects to Interrogatory 2 to the extent it seeks privileged information exchanged between Apotex and the FTC pursuant to a common interest privilege as co-plaintiffs in litigation in federal district court in the Eastern District of Pennsylvania challenging

Cephalon's modafinil patent litigation settlement agreements.[2] Expressly reserving and without waiving the general objections and this specific objection, the FTC states as follows:

The FTC had periodic communications with Apotex as part of its modafinil law enforcement investigation from February through May 2009. The FTC did not have communications with any other third party concerning the topics identified in Interrogatory 2, except that FTC staff did have communications relating to these issues with Watson's counsel, Steven C. Sunshine of Skadden, Arps, Slate, Meagher & Flom LLP, from March through May 2009.[3]

FTC staff first contacted Apotex in February 2009 as part of its efforts to understand the implications of the information it had learned about the later-listed '346 patent from the FDA in January and February 2009. Apotex was an obvious choice to contact to explore these issues: it had filed an ANDA for a generic version of modafinil and was blocked from entering by Cephalon's modafinil settlements; it was already selling a generic version of Provigil in Canada; and its Vice President of Global Intellectual Property, Shashank Upadhye, had written a book entitled *Generic Pharmaceutical Patent and FDA Law* (Thompson West Publishing, 2010 ed.), and could likely provide expertise relevant to the questions of interest to the FTC. In particular, the later-listed '346 patent and its potential effect on generic entry presented a novel issue for

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[2]*See FTC v. Cepahlon, Inc.*, No. 2:08-cv-2141-MSG (E.D. Pa. filed Feb. 13, 2008); *Apotex, Inc. v. Cephalon, Inc., et al.*, No. 2:06-cv-02768-MSG (E.D. Pa. filed June 26, 2006).

[3]*See* Brau Decl. ¶¶ 5, 7, 8, 10, attached as Exhibit C to Petitioner FTC's Motion for Leave to Supplement the Record and to Enforce the Subpoena *Ad Testificandum* Forthwith.

FTC staff, and by contacting Mr. Upadhye, staff hoped to gain insights into the applicable legal framework.

Staff was primarily interested in two threshold questions in February 2009. First, FTC staff sought to understand the regulatory significance of the '346 patent, and specifically whether any first filer(s) to the '346 patent could potentially block any second filers to the earlier-listed '516 patent from entering the market. This issue was relevant to the FTC's ongoing investigation because if any exclusivity Watson might have with respect to the '346 patent did *not* block entry of other generic filers, then any agreement Watson might have with Cepahlon was unlikely to harm competition. Second, FTC staff sought to understand practically how a generic company would be aware of a later-issued patent so that it would be in the position to file an ANDA amendment on precisely the same day that the brand company listed such later-issued patent with the FDA. Put simply, FTC staff was trying to assess whether a generic company was likely to have such information independently or whether such information was likely available to the generic only as a result of collusion with the brand company to create an additional barrier to impede potential generic entry. The answers to these questions would influence the future of the ongoing investigation.

From February 2, 2009, through March 3, 2009, Markus H. Meier, Assistant Director in the Health Care Division of the FTC and Saralisa C. Brau, Deputy Assistant Director in the Health Care Division of the FTC, had approximately four communications with Shashank Upadhye, Vice President, Global Intellectual Property, Apotex, Inc. Mr. Meier and Ms. Brau called Mr. Upadhye on February 2, 2009, February 24, 2009, and March 3, 2009. Mr. Upadhye sent an email to Mr. Meier on February 3, 2009.

The topics discussed during these communications were: (1) Cephalon's listing of the '346 patent; (2) whether Apotex had submitted to the FDA an amended ANDA containing a Paragraph IV certification as to the '346 patent; (3) Apotex's analysis of whether any first filer(s) eligible for marketing exclusivity on the later-listed '346 patent would block Apotex's ability to launch generic Provigil; (4) what it would take Apotex to launch a generic version of Provigil in the U.S., assuming it was interested in doing so; and (5) how a generic company could know the date on which a brand would list a later-issued patent with the FDA so that it could try to be a first filer by submitting its amended ANDA with the FDA on the same day.

In addition to the four earlier contacts with Mr. Upadhye, on March 13, 2009, Mr. Meier and Ms. Brau called Mr. Upadhye regarding the possibility of a business arrangement between Watson and Apotex. This call to Mr. Upadhye was a direct result of a conversation that took place earlier that day with Watson's counsel, Mr. Sunshine. From March 2, 2009, through March 13, 2009, Mr. Meier and Ms. Brau had initiated a number of telephone calls to Mr. Sunshine to discuss developments in the modafinil investigation.[4] During these conversations with Mr. Sunshine, FTC staff posited hypothetical scenarios to determine if Watson could profit from relinquishment of any modafinil marketing exclusivity for which it might be eligible, including scenarios where Watson relinquished any such exclusivity to potential new entrants into the market. In the context of these discussions, and in response to a question from Mr. Meier, Mr. Sunshine affirmed that Watson would be interested in hearing from a third party, Apotex, about a business proposal relating to relinquishment, and Mr. Sunshine then identified Watson's General Counsel, David Buchen, as the appropriate contact person.

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[4]*See* Brau Decl. ¶¶ 5, 7, 8.

After receiving Mr. Sunshine's explicit approval to put Apotex in touch with Watson concerning potential relinquishment, FTC staff then called Mr. Upadhye on March 13, 2009, to inform Apotex of Watson's interest and that if Apotex were likewise interested, he should contact Mr. Buchen at Watson. The FTC did not "broker a deal" between Watson and Apotex. In fact, after informing Apotex of Watson's interest, with the express assent of Watson's counsel, Mr. Sunshine, the FTC played no further role in any discussions between the two companies. The FTC did not attempt at any time to propose terms or otherwise direct the course of the discussions between Apotex and Watson.

From approximately March 18 through May 6, 2009, Mr. Meier and Ms. Brau initiated periodic follow-up calls to Mr. Upadhye of Apotex to inquire about the status of the discussions with Watson. These calls occurred on approximately March 18, March 30, April 7, April 22, and May 6, 2009. The reason for the calls was simple: if, on the one hand, Watson were to relinquish its potential exclusivity, the FTC's ongoing investigation about whether Watson had agreed with Cephalon *not* to relinquish its exclusivity would have been resolved, leaving nothing further to investigate. If, on the other hand, Watson chose not to relinquish its potential exclusivity, the FTC would need to assess whether the reason for the decision was attributable to an unlawful agreement with Cephalon not to relinquish. On May 6, 2009, Mr. Upadhye told Mr. Meier and Ms. Brau that discussions with Watson had stalled and that Watson did not appear interested in pursuing a business arrangement with Apotex.

At no time during the course of any communications with Apotex did the FTC reveal to Apotex any confidential information provided to the FTC by Watson. Although staff cannot specifically recall if Watson's name came up in any telephone conversation with Mr. Upadhye

before March 13, 2009, Watson's name did come up after March 13, 2009, once the FTC had received Mr. Sunshine's explicit approval to put Apotex in touch with Watson concerning potential relinquishment. FTC staff did not improperly reveal any confidential FDA information to Apotex.

Respectfully submitted,

As to Objections:

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Principal Deputy General Counsel
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Dated: July 21, 2010

VERIFICATION

I, Markus H. Meier, declare:

1. I am the Assistant Director of the Health Care Division in the Bureau of Competition of the Federal Trade Commission and make this verification on and for its behalf. As Assistant Director of the Health Care Division, I have overall supervisory responsibility for the Commission's investigation of Watson.
2. I have read the foregoing Petitioner Federal Trade Commission's Responses to First Set of Interrogatories of Respondent Paul M. Bisaro.
3. All of the information contained in the foregoing is either based on my personal knowledge or facts I have learned in my official capacity.
4. I am informed and believe that the matters stated therein are true and correct and hereby certify that the foregoing answers are true to the best of the Federal Trade Commission's present knowledge, information, and belief.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 21st day of July, 2010.

Markus H. Meier
Assistant Director
Bureau of Competition
Federal Trade Commission

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION **Petitioner,**	)	
v.	)	Misc. No. 1:10-mc-00289 (CKK)(AK)
PAUL M. BISARO,	)	
Respondent.	)	

DECLARATION OF RICHARD A. FEINSTEIN

Pursuant to 28 U.S.C. § 1746, Richard A. Feinstein declares as follows:

1. I am the Director of the Federal Trade Commission's Bureau of Competition where I am responsible, among many other things, for supervising all investigations and law enforcement actions that are undertaken by that Bureau. I have held this position since May 2009.

2. I offer this Declaration in order to clear up any misconceptions that may exist regarding the Commission's processes and procedures and to emphasize that, contrary to allegations and insinuations that have been made by Respondent in this matter, nothing improper has occurred in the Commission's investigation of Watson.

Commission Processes Preclude Inappropriate Investigations

3. At the outset it is important to note that the Commission's organizational structure and processes are designed to make sure that all investigations are undertaken in the public interest and to preclude the possibility of any investigation being undertaken for an improper purpose. The Commission is a law enforcement agency headed by five Commissioners who are appointed

by the President for seven-year staggered terms. No more than three Commissioners may be members of the same political party. All major Commission actions – including the opening of investigations that require compulsory process (like the subpoena at issue in this case)– require a majority vote of the Commission.

4. Although I and my immediate staff comprise the "Front Office" of the Bureau of Competition and are ultimately responsible for the conduct of Commission investigations, we have no authority to open (and close) preliminary law enforcement investigations without the approval of the Commissioners. After an investigation has advanced to the point where staff thinks sufficient evidence exists to support a law enforcement action, it must seek and obtain specific authority from the Commission to proceed either administratively or in federal court. Even after the Commission opens an investigation, staff has no authority to issue subpoenas or civil investigative demands on their own. Each subpoena must be submitted to a Commissioner for review and can only be issued by a Commissioner. 16 C.F.R. § 2.7(a). After a subpoena is issued, Commission rules allow a party to petition the Commission to quash compulsory process. Rulings on such petitions are decided by a single Commissioner (not necessarily the one who issues the subpoena in the first instance), and the party may thereafter seek review by the entire Commission.

5. In the present case, the subpoena to Mr. Bisaro was issued by Commissioner Leibowitz. Mr. Bisaro exercised his right to petition to quash the subpoena and he raised essentially the same arguments that he has advanced in this proceeding. Former Commissioner Pamela Jones Harbour considered these arguments and rejected them. Mr. Bisaro then appealed to the full Commission, which, after considering his arguments, unanimously rejected them as well in a detailed letter ruling. A true and correct copy of that letter ruling is attached hereto as Exhibit 1.

Disclosures By Staff in Commission Investigations

6. Almost all Commission investigations are non-public. This means that it is the Commission's policy not to make public announcements either confirming or denying the existence of any pending investigation except under very limited circumstances. However, it is appropriate, and often necessary, that in the course of seeking our information, staff may make limited disclosures about the subject matter and nature of a Commission investigation, or staff may use hypotheticals to gain insights into the views of marketplace participants. In fact, Mr. Sunshine's declaration reflects this process (at paragraph 15) where he notes that Mr. Meier "posited certain hypothetical regulatory scenarios" to him during a conversation.

7. Thus, in conducting FTC investigations, staff routinely contacts people and entities that are knowledgeable about the companies, industries, products, and markets that are the focus of an inquiry. Such contacts frequently include not only other government agencies that deal with the companies or industries, but also customers, competitors, and suppliers of the investigative targets. During these conversations staff asks questions that are designed to elicit information while protecting the confidential nature of the investigation. When staff inquires about a specific topic, it is difficult if not impossible to avoid all reference to the relevant facts of the investigation. Accordingly, it is not surprising that people who are interviewed by the staff during an investigation may draw their own inferences from the interview.

8. For example, in the merger context, the Commission has a policy of not disclosing the identity of firms that have filed pre-merger notification reports with the Commission and the Department of Justice. No matter how circumspect staff is in its questioning, however, once staff asks questions about the state of competition between Firm A and Firm B, people to whom such questions are directed may reasonably infer that an inquiry involving Firm A and Firm B is

underway. Such inferences cannot be avoided by the Commission staff, and are an ordinary consequence of the investigative process.

9. In such circumstances, one natural consequence is that third parties with whom the Commission staff has been in contact may communicate with the merging parties and inquire about matters of mutual interest. Indeed, most Commission challenges to problematic mergers are settled when the merging parties agree to divest overlapping assets to a third party. It is not unusual for that third party to be a person who has been interviewed by the Commission staff during the course of the Commission's investigation; and in some cases the staff will – with the consent or acquiescence of the parties and without disclosing any confidential information about the pending merger – contact firms that might be potential acquirers of assets and encourage them to contact the merging parties. In such situations, the staff appropriately facilitates communications between business entities who then take the opportunity to negotiate a private transaction that may alleviate a potential antitrust concern. The fact that a party who has been interviewed by the Commission staff contacts the subject of the investigation and ultimately negotiates (or attempts to negotiate) a business deal does not mean that staff made any improper disclosure during its interview.

The Commission's Investigation of Watson

10. I have read the pleadings and the court's record in the present proceeding as well as the Answers to Mr. Bisaro's Interrogatories that Mr. Meier has prepared. Based on this review, I see no evidence that Mr. Meier or anyone else in the Commission has engaged in improper – or even out-of-the-ordinary – conduct with respect to any aspect of the investigation.

11. At its core, the Commission's investigation seeks an answer to one simple question: Assuming Watson has exclusivity rights in connection with the '346 Patent, has Watson (a

generic pharmaceutical manufacturer) agreed with Cephalon (a brand name manufacturer with patent rights) not to relinquish those rights to a third party in violation of the antitrust law? In other words, is there an agreement between Cephalon and Watson to restrain trade in generic modafinil?

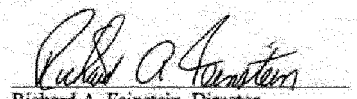
12. Despite the staff's repeated efforts, Watson never provided the Commission with a straight-up, sworn, answer to the question of whether it had an agreement with Cephalon that it not relinquish. This left the staff with only two possible ways to get an answer to this question. Either it could observe whether Watson acted in a way that precluded the possibility of such an agreement (i.e., Watson could enter into an agreement relinquishing those rights to a third party); or staff could continue to pursue a full investigation to try to determine directly whether an illegal agreement existed.

13. Contrary to the insinuation in Paragraph 15 of Mr. Sunshine's Declaration, there is nothing improper, or even extraordinary, about Mr. Meier "suggest[ing] that Watson should relinquish exclusivity." Such a "suggestion" was nothing more than a statement of the obvious: if Watson relinquished exclusivity, it would prove that it had no agreement with Cephalon prohibiting relinquishment – thereby leaving nothing for the Commission to investigate. Absent such relinquishment (and in light of other facts), the staff could reasonably infer that an agreement not to waive exclusivity might exist, and that it therefore needed to investigate the matter further. Thus, a statement by Mr. Meier that Watson's failure to waive exclusivity might lead the "Front Office" – i.e., the Bureau Director's Office – to continue the investigation reflects a common-sense assessment of the likely investigative decision of the Bureau.

14. Finally, I note that in his answers to the interrogatories, Mr. Meier has declared that 1) Mr. Sunshine gave Mr. Meier permission to talk to Apotex about Watson (a fact that Mr.

Sunshine omitted from his declaration), 2) prior to Mr. Sunshine giving that permission, Mr. Meier does not recall discussing Watson with Apotex; and 3) Mr. Meier did not improperly disclose any confidential information to Apotex. Mr. Meier is a senior FTC attorney who has spent 18 of his 20-year legal career at the FTC's Bureau of Competition. Before he became a lawyer, he was a security officer in the U.S. Army with a Top Secret clearance charged with protecting nuclear secrets. Thus, Mr. Meier knows how to handle confidential information without disclosing it.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on the 21st day of July, 2010.



Richard A. Feinstein, Director
Bureau of Competition
Federal Trade Commission
Washington, DC 20580

Exhibit 1 to Feinstein Declaration

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Secretary

April 2, 2010

Watson Pharmaceuticals, Inc.
c/o Steven C. Sunshine, Esq.
Skadden, Arps, Slate, Meagher & Flom LLP
1440 New York Avenue NW
Washington, DC 20005

RE: Request for Review of Ruling Denying Petition to Quash Subpoena *Ad Testificandum* Dated July 22, 2009, File No. 091-0182

Dear Mr. Sunshine:

This letter responds to your November 27, 2009 Request for Review ("Request"), by the full Commission, of the November 13, 2009 ruling by Commissioner Pamela Jones Harbour, denying the Petition to Quash the Subpoena *Ad Testificandum*, dated July 22, 2009, and issued to Paul M. Bisaro ("Petition"). Mr. Bisaro is the President and Chief Executive Officer of Watson Pharmaceuticals, Inc. ("Watson"), and the Commission seeks his testimony in connection with an investigation of whether certain pharmaceutical companies, including Watson, have entered into any agreements to forego relinquishing any eligibility or rights they may have to market the generic drug modafinil – *i.e.*, whether these companies, including Watson, have entered into any agreements that potentially constitute an "unfair method of competition" in violation of the Federal Trade Commission Act. As you know, the market for modafinil (a/k/a Provigil) exceeds $800 million a year. So, if multiple generic companies enter the marketplace, consumers could save hundreds of millions of dollars per year.

The information the Commission may subpoena is broad in scope. As a general matter, "it is sufficient if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably necessary." *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950). Thus, in a petition to quash, the petitioner bears the burden to show that a subpoena is unreasonable, and where "'the agency inquiry is authorized by law and the materials sought are relevant to the inquiry, that burden is not easily met.'" *FTC v. Rockefeller*, 591 F.2d 182, 190 (2d Cir. 1979), *quoting SEC v. Brigadoon Scotch Distributing Co.*, 480 F.2d 1047, 1056 (2d Cir. 1973), *cert. denied*, 415 U.S. 915 (1974). Despite the Commission's broad authority, Watson refuses to produce Mr. Bisaro for an investigational hearing.

The Commission has more than a sufficient basis to seek Mr. Bisaro's testimony under *Morton Salt*. At issue in the Petition is whether the Commission can examine Mr. Bisaro to discover his knowledge about any agreement Watson may have that limits or restricts the exercise of any marketing rights or exclusivities it may have now or obtain in the future vis-à-vis modafinil. Such an agreement, if it exists, could be delaying generic entry to the detriment of consumers.[1] Despite the Petition's repeated assertions that Watson has reached no such agreement and that it has confirmed to the Commission that no such agreement exists, other facts raise questions about whether such an agreement exists. For example, in its response to the Commission's civil investigative demand ("CID"), Watson identified an agreement that it said "may relate to" its ability to relinquish any exclusivity rights relating to generic modafinil. Watson, however, has repeatedly refused to clarify – either through written responses or testimony – whether that agreement would prevent or otherwise limit its ability to relinquish. Further, although a company has approached Watson about relinquishing any potential exclusivity rights, Watson appears disinterested, and, according to one witness, would prefer to wait until 2012 to launch its own product. The extent to which this decision is inconsistent with Watson's economic interest is likely to shed light on whether Watson has entered into a potentially illegal agreement. Mr. Bisaro is a logical person to question on this issue that goes to the core of the Commission's investigation. Watson has identified him as one of only two people who has knowledge of relevant events, the Commission has already taken the testimony of the other person, and the critical question of whether Watson reached a potentially unlawful agreement remains unanswered.

Against this factual background and given the Commission's broad power to compel information in investigations conducted pursuant to its law enforcement efforts, we find that conducting an investigational hearing of Mr. Bisaro is proper. Accordingly, and as explained more fully below, we therefore deny the Request.

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[1] Courts have expressed great skepticism of agreements in which a generic manufacturer who is eligible for the 180-day exclusivity agrees with the branded manufacturer not to relinquish or waive that exclusivity. *See, e.g. In re Ciprofloxacin*, 544 F.3d 1323, 1339 (Fed. Cir. 2008) (agreeing that "the only legitimate allegation by the plaintiffs was that the 180-day exclusivity period had been manipulated."); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 401 (2d Cir. 2005) ("[W]e think that an agreement to time the deployment of the exclusivity period to extend a patent monopoly power might well constitute anticompetitive action outside the scope of a valid patent."); *Andrx v. Elan*, 421 F.3d 1227, 1235 (11th Cir. 2005) (holding that delayed licensed plus putative agreement to refrain from ever marketing a generic barred any competitors from entering "would exceed the scope of the patent"); *FTC v. Cephalon, Inc.*, No. 2:08-cv-2141, mem. op. (E.D. Pa. Mar. 29, 2010) (declining to dismiss complaint alleging that agreement to settle patent litigation and affecting relinquishment of exclusivity rights is anticompetitive).

Background

The Petition and Request relate to a Commission investigation,

> [t]o determine whether Cephalon, Inc., Teva Pharmaceuticals, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding modafinil products.[2]

Modafinil is a "wakefulness-enhancing" drug that Cephalon, Inc. ("Cephalon") has developed and marketed under the brand name Provigil.[3] Each of the other entities identified in the compulsory process resolution has developed and sought to market generic modafinil. The controversy giving rise to the Petition concerns the investigation of certain facts relating to Watson Pharmaceuticals, Inc. ("Watson") and its development partner, Carlsbad Technologies, Inc. ("Carlsbad") – in particular, obtaining the testimony of Paul Bisaro ("Petitioner"), Watson's President and Chief Executive Officer.

To that end, Commission staff is interested in any agreements between Cephalon and entities identified in the Commission's compulsory process resolution to settle patent litigation associated with modafinil. Cephalon sued most of the entities named in the resolution, alleging that they were infringing U.S. Reissued Patent No. 37,516 ("'516 Patent") relating to Provigil. These patent infringement allegations were based on each of the entities named in the resolution having filed Abbreviated New Drug Applications ("ANDA") with the Food and Drug Administration ("FDA") for generic modafinil, with a "Paragraph IV" certification that generic modafinil would not infringe the '516 Patent.[4] Each of the entities other than Watson/Carlsbad filed their ANDA on the same day, and before any other parties. As "first filers," these entities were eligible under applicable law for 180 days of joint marketing exclusivity at such time that the ANDA is approved. Watson/Carlsbad were not "first filers," but Cephalon also sued Carlsbad for patent infringement after Watson/Carlsbad filed their ANDA and Paragraph IV certification. Cephalon settled each of the suits between late 2005 and 2006, with the Carlsbad settlement occurring on August 2, 2006.[5] On February 13, 2008, the Commission filed a complaint against Cephalon, alleging that its settlement agreements, which provided compensation to the generic firms for foregoing generic entry, were anticompetitive, an abuse of

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[2] Resolution Authorizing Use of Compulsory Process in a Nonpublic Investigation, File No. 06110182 (Aug. 30, 2006).
[3] Petition at 3.
[4] ANDAs reflect a streamlined FDA approval process that enables manufacturers of generic drugs (*i.e.*, those that are the "bioequivalent" of branded drugs) to rely on the safety and efficacy studies relating to the branded drug. When a branded drug is covered by one or more patents, the company that seeks to market the generic drug prior to the expiration of any of those patents may proceed to seek FDA approval, but certify that the generic version does not infringe the patents on the brand-name drug, or that the patents are invalid. This certification is a "Paragraph IV" certification.
[5] Petition at 3-4.

monopoly power, and unlawful under Section 5 of the FTC Act. *FTC v. Cephalon, Inc.*, 08-cv-2141-MSG (E.D. Pa.).[6]

In December 2007, Cephalon listed a new patent with the FDA relating to modafinil: U.S. Patent No. 7,297,346 ("'346 Patent"). The subsequent listing of the '346 Patent required the existing ANDA applicants for modafinil to make a certification vis-à-vis the '346 Patent. Watson/Carlsbad filed a Paragraph IV certification on the same day that the FDA listed the new patent, identifying the Cephalon/Carlsbad settlement agreement as the basis for non-infringement of the '346 Patent. According to the Petition, if Watson were a "first filer" on the '346 Patent, it would be eligible for the 180-day marketing exclusivity for generic modafinil.[7]

Following these developments, Commission staff contacted Watson in March 2009 about its ANDA. Commission staff informed Watson that they were primarily interested in determining whether Watson had reached any agreement relating to relinquishment of any exclusivity rights it might have with respect to generic modafinil, and, if not, the basis for any decision not to waive such rights.[8] On May 19, 2009, the Commission issued a new CID to Watson and a subpoena *ad testificandum* to David A. Buchen, Watson's Senior Vice President, General Counsel, and Secretary. On May 22, 2009, the Commission issued a subpoena *ad testificandum* to Petitioner. The Commission also issued a CID and two subpoenas *ad testificandum* to Carlsbad executives.[9]

Controversies, discussed more below, ensued about the adequacy of Watson's CID responses, the necessity of investigational hearings for the Watson executives, and the schedule of the same. As a result of these discussions, Mr. Buchen ultimately appeared for a hearing. In contrast, Mr. Bisaro refused to appear and filed a petition to quash, which Commissioner Harbour denied on November 13, 2009. Pursuant to Commission Rule 2.6(f), 16 C.F.R. § 2.6(f), Mr. Bisaro has now asked the full Commission to review Commissioner Harbour's ruling.

Analysis of Petitioner's Legal Objections to Subpoena

The Supreme Court made clear that the Commission has a right to conduct an investigation "if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant." *U.S. v. Morton Salt Co.*, 338 U.S. 632, 652 (1950). This standard applies to administrative subpoenas issued by the Commission. *See, e.g., FTC v. Texaco, Inc.*, 555 F.2d 862, 872 (D.C. Cir. 1977) (en banc); *Adams v. FTC*, 296 F.2d 861, 866 (8th Cir. 1961), *cert. denied*, 369 U.S. 864 (1962). In the context of a Commission investigatory subpoena, "[t]he law on this issue is well-established: so long as an agency acts within its authority, requests information relevant to the lawful inquiry, and makes

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[6] The district court recently denied Cephalon's motion to dismiss the complaint. *FTC v. Cephalon, Inc.*, 08-cv-2141, mem. op. (E.D. Pa. Mar. 29, 2010).
[7] Petition at 6-7.
[8] Raptis Decl., at 2.
[9] Petition at 7-8.

reasonable demands, the court must uphold the validity of the administrative subpoena." *FTC v. Invention Submission Corp.*, 1991 WL 47104, *1 (D.D.C. 1991), *aff'd* 965 F.2d 1086 D.C. Cir 1992), *cert. denied*, 507 U.S. 910 (1993). Petitioner carries a heavy burden to show that the subpoena should not be enforced.

Petitioner does not challenge the Commission's authority to issue the subpoena. Nor does the Petition claim that the discovery sought is not "reasonably relevant" or too indefinite. Rather, Petitioner claims that the Commission is improperly using its compulsory process by being "unreasonable" in seeking his testimony. Petitioner raises five objections to the subpoena: (1) the resolution authorizing the compulsory process has already produced one lawsuit against Cephalon, and now cannot be used for the additional investigatory process directed to Watson; (2) the subpoena unreasonably demands information that the Commission already possesses; (3) the subpoena unreasonably seeks testimony from the "apex" of Watson's organization; (4) the subpoena was likely issued for an improper purpose; and (5) compelling Petitioner to travel to the Commission offices in Washington, DC to undergo an investigational hearing is unduly burdensome.[10]

Because we find that none of these arguments is persuasive, we deny the Petition and Request in their entirety. We address each of Petitioner's five specific challenges below.

I.

We first address Petitioner's threshold argument that the subpoena is improper because the resolution authorizing the compulsory process has already culminated in one enforcement action.[11] Petitioner provides no legal support for this proposition. A Commission resolution authorizing compulsory process for an investigation does not, as a matter of law, expire automatically upon the filing of an enforcement action or because some litigation regarding related subjects may have commenced. *See, e.g., Linde Thomson Langworthy Kohn & Van Dyke, P.C. v. Resolution Trust Corp.*, 5 F.3d 1508 (D.C. Cir. 1993). To the contrary, multiple actions might be taken as a result of information obtained through compulsory process stemming from such a resolution. Moreover, as indicated above, the concerns that prompted the Commission's current investigation relating to the '346 Patent differ in scope from those that prompted its investigation of the "pay-for-delay" settlement agreements relating to the '516 Patent. However, both components of the investigation clearly fall within the broad parameters of the compulsory process resolution, *i.e.*, "[t]o determine whether ... Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec 45, as amended, by entering into agreements regarding modafinil products." As a result, we reject Petitioner's argument that because "the Commission resolution authorizing compulsory process in connection with the above-referenced matter has already culminated in a lawsuit," it "may not now be resurrected to burden Watson with additional process."[12]

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[10] Request at 3.
[11] Request at 3.
[12] Request at 3.

II.

We turn next to Petitioner's argument that the subpoena compelling his testimony is unreasonable because it demands information that, he contends, the Commission already possesses. While Watson has provided the Commission information relating to the '346 Patent, Petitioner has not shown that his testimony will shed no additional light on matters that fall within the scope of the Commission's investigatory concerns. As a key executive of Watson, Petitioner's testimony may well be useful in elaborating on the information or explaining relevant circumstances. Under the broad standard applicable to the investigatory process, Commission staff is entitled to question Petitioner to determine if he has any additional relevant information.

As indicated above, the investigation related to the '346 Patent focuses on two critical questions: (1) whether the company has entered into any agreements that restrict it from relinquishing any exclusivity it may have in connection with that patent, and (2) if not, why the company is not pursuing potentially lucrative arrangements with third parties concerning relinquishment. In connection with these issues, and as indicated above, the Commission issued CIDs to Watson and Carlsbad on May 19, 2009, and subpoenas *ad testificandum* to two executives at each company, including Petitioner. Petitioner contends that Watson "fully" responded to "each and every" inquiry in the CID directed to it, and that because Mr. Buchen confirmed the company's responses during his investigational hearing, Petitioner's testimony is unnecessary.[13] The record, however, leaves certain open questions.

On the first issue of interest, one of the CID specifications directed to Watson required the company to "[i]dentify and provide one copy of each agreement, whether written or oral, that prohibits, blocks, prevents, compromises, or limits in any way Watson or Carlsbad's ability to relinquish eligibility to claim 180-day Marketing Exclusivity for Generic Provigil," and to identify "[t]he portion(s) of the agreement that prohibit or limit Watson or Carlsbad's ability to relinquish."[14] In response, Watson identified its settlement agreement with Cephalon as the only agreement that "may relate" to its ability to relinquish, but failed to identify the portions that prohibit or limit its ability to relinquish.[15] In response to follow-up questions by staff designed to elicit complete answers, Watson simply stated that the settlement agreement "speaks for itself," and, citing attorney-client privilege, refused to provide any information about Watson's understanding of how that agreement might relate to marketing exclusivity.[16] As for Mr. Buchen's investigational hearing, he identified an indemnification provision in the Cephalon settlement agreement that "might relate to the investigation," but declined to answer questions about any other provisions, including whether the settlement agreement limits Watson's ability to relinquish exclusivity.[17] Against this backdrop, it is reasonable for the Commission to seek

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[13] Petition at 16.
[14] CID to Watson, FTC File No. 0610182 (issued May 19, 2009).
[15] Watson Responses to CID, FTC File No. 0610182 (June 10, 2009).
[16] Letter from Maria A. Raptis to Saralisa Brau (June 17, 2009).
[17] Buchen Transcript at 47, 50-51.

testimony from additional witnesses on these issues. Watson has identified Petitioner as the only other person other than Mr. Buchen who is knowledgeable about the issues and it is therefore logical to seek his testimony.

On the second issue of interest, one of the CID specifications required Watson to "[i]dentify each company with which Watson had contact relating to … eligibility to claim 180-day Marketing Exclusivity for Generic Provigil, or the relinquishment thereof," and "[w]hether Watson entered into an agreement as a result of these discussions, and the reasons for Watson's decision."[18] In response, Watson identified a particular company with which it had discussions, stated that specific terms were not discussed and that no agreement or decision had been reached, but failed to provide any rationale.[19] In response to follow-up questions by staff designed to elicit complete answers, Watson again failed to provide the information sought, based on attorney-client privilege.[20] Yet at Mr. Buchen's investigational hearing, he provided at least two rationales for not pursuing relinquishment: (1) discussions with the company stopped after issuance of the Commission's process, and (2) his own business view that Watson would be in a better position to launch its own product.[21] Given this information, after Watson's initial response failed to explain its decision and its follow-up response failed to provide the requested information based on privilege, we again find that it is reasonable for the Commission to pose questions to Petitioner to determine what he knows.

We recognize that questions directed to Petitioner about whether Watson has an agreement that in some way limits its ability to relinquish any marketing exclusivity rights it has, as well as about the basis for any decision of Watson not to relinquish any such rights, *may* implicate privileged communications. However, that does not provide a basis upon which to quash the subpoena for his testimony in its entirety. Rather, the proper procedure is for (1) the investigational hearing to take place; (2) Petitioner to assert the privilege (as he believes it to be applicable); and (3) Commission staff to establish facts through questioning to determine whether Petitioner's assertion is proper.

III.

Petitioner also suggests that the subpoena directed to him is unreasonable because, as President and CEO of Watson, there is no reason to believe that he has personal knowledge of relevant information that cannot be obtained through other means.[22] Petitioner provides no case law indicating that the so-called "apex doctrine" applies in an administrative investigation. Even assuming, without deciding, that the principle might apply, we find that it does not provide an adequate basis to quash the subpoena here.

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[18] CID to Watson, FTC File No. 0610182 (issued May 19, 2009).
[19] Watson Responses to CID, FTC File No. 0610182 (June 10, 2009).
[20] Letter from Maria A. Raptis to Saralisa Brau (June 17, 2009).
[21] Buchen Transcript at 33, 67-68.
[22] Petition at 17-19; Request at 3.

As a preliminary matter, we note that high-ranking executives are, of course, not insulated from discovery. *Six West Retail Acquisition, Inc. v. Sony Theatre Mgmt. Corp.*, 203 F.R.D. 98, 102 (S.D.N.Y. 2001). Even when such an executive denies having personal knowledge of relevant issues, the examining party may test such a claim. *Id.*

In the current investigation, the Commission has already sought information through a CID to Watson, through a CID to Carlsbad, through an investigational hearing of Mr. Buchen, and through an investigational hearing of a Carlsbad executive. Petitioner is another logical, possible source of relevant information, since Mr. Buchen identified him as the only person with whom Mr. Buchen had discussions regarding potential relinquishment. In addition, Petitioner has personal knowledge of conversations that he had with Mr. Buchen, as well as other factual information that may not have been discovered yet and may not be privileged. Therefore, even under the stringent standards Petitioner suggests apply to administrative investigations, the investigational hearing requested here is warranted.

To summarize, we find no basis for Petitioner's assertion that the subpoena is "unreasonable" in requesting Mr. Bisaro's testimony. Accordingly, we reject Petitioner's arguments to the contrary.

IV.

Petitioner further contends that the subpoena is improper because it was issued for an improper purpose, *i.e.*, "to pressure Watson to relinquish any exclusivity rights it may have, and thereby attempt to engineer generic entry into the modafinil market."[23] In particular, Petitioner asserts that Commission staff threatened to continue its investigation of Watson if the company did not relinquish any exclusivity rights it has, and carried out that threat by issuing the process at issue in the Petition.

These allegations are baseless and do not support the Petition's assertion that the subpoena was issued for an improper purpose. The subpoena was issued pursuant to a valid and extant resolution "[t]o determine whether Cephalon, Inc., ... Carlsbad Technology, Inc., Watson Pharmaceuticals, or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding modafinil products." Pursuant to that resolution, the Commission is authorized to investigate whether Watson has entered into any agreements relating to relinquishment of any marketing exclusivity rights that it may have for generic modafinil, and, if not, whether it intends to relinquish such rights. In such an investigation, Commission staff may explore or suggest certain actions that might negate any anticompetitive concerns identified. We find that issuing a subpoena for the testimony of the President and CEO of Watson about any company agreements and discussions with third parties with regard to relinquishment – after first issuing CIDs to the company and receiving the testimony of another of its executives – is clearly a proper purpose.

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[23] Petition at 19.

V.

Finally, Petitioner contends that if his investigational hearing is to proceed, it is "unduly burdensome" for him to appear at FTC offices in Washington, D.C. as opposed to his place of residence.[24] Petitioner provides nothing more than a generalized assertion of burden, and does not explain how his travel to and participation in an investigational hearing in Washington, D.C. is unduly burdensome. On the current record, we therefore reject Petitioner's request that the investigational hearing proceed at a location other than the FTC's offices in Washington.

Conclusion and Order

For all of the foregoing reasons, **IT IS HEREBY ORDERED THAT** the Request be, and it hereby is, **DENIED**.

IT IS FURTHER ORDERED THAT Petitioner appear on April 15, 2010, for an investigational hearing in Washington, D.C., unless otherwise agreed to by Commission staff.

By direction of the Commission.

Donald S. Clark

Donald S. Clark
Secretary

[24] Petition at 19; Request at 3.

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION	)	
Petitioner,	)	
v.	)	Misc. No. 1:10-mc-00289 (CKK)(AK)
PAUL M. BISARO,	)	
Respondent.	)	

DECLARATION OF SARALISA C. BRAU

Pursuant to 28 U.S.C. § 1746, Saralisa C. Brau declares as follows:

1. I am a Deputy Assistant Director in the Health Care Division within the Bureau of Competition of the U.S. Federal Trade Commission ("FTC" or "Commission"). I have day-to-day supervisory responsibility over the Commission's modafinil investigation.

2. I submit this declaration in support of the Commission's Motion for Leave to Supplement the Record and to Enforce the Subpoena *Ad Testificandum* Forthwith. The facts set forth herein are based on my personal knowledge or information made known to me in the course of my official duties.

3. The Commission opened the modafinil investigation in 2006 to determine if Cephalon, Inc. ("Cephalon"), Watson Pharmaceuticals, Inc. ("Watson"), and certain other generic companies had entered into unlawful agreements to delay the introduction of generic versions of Provigil, Cephalon's branded modafinil product. The initial phase of the modafinil investigation focused on the generic companies' challenges to Cephalon's U.S. Reissued Patent

No. 37,516 ("the '516 patent") and Cephalon's 2005-2006 settlements of the '516 patent litigation, under which Watson and the other generic companies agreed they would not market generic modafinil until 2012. The initial phase of the Commission's modafinil investigation culminated in the filing of a federal court complaint against Cephalon (but not Watson or the other generics) in February 2008, which is currently being litigated in the Eastern District of Pennsylvania. *See FTC v. Cephalon, Inc.*, No. 2:08:-cv-2141-MSG, 2010 U.S. Dist. LEXIS 29905 (E.D. Pa. Mar. 29, 2010) (denying motion to dismiss). After filing the complaint, the Commission's modafinil investigation remained open, albeit inactive.

4. The most recent phase of the modafinil investigation began when, in January 2009, Commission staff first learned that Cephalon had filed a new patent in the Food and Drug Administration's ("FDA's") Orange Book covering Provigil, U.S. Patent No. 7,297,346 ("the '346 Patent"), and that Watson – on the same day – had filed a Paragraph IV certification against the '346 Patent claiming that the patent was either invalid or not infringed by Watson's generic product. Based on my understanding of applicable statutes and regulations, these events created the possibility that Watson might be a "first filer" with regard to the '346 Patent. As "first filers," generic companies are eligible for 180 days of marketing exclusivity at such time that the FDA grants final approval to their generic drug applications. That Watson might have potential marketing exclusivity arising from the '346 patent raised questions about whether Watson's agreement not to market generic modafinil until 2012 might act as an additional impediment to generic modafinil entry by other generic companies. In light of these new facts, FTC staff resumed the modafinil investigation.

5. Between March 2 and May 5, 2009, Markus H. Meier, the Assistant Director of the Health Care Division, and I initiated several telephone calls to Watson's counsel, Steven C. Sunshine of Skadden, Arps, Slate, Meagher & Flom LLP, to discuss the latest developments in the modafinil investigation. Those conversations, and what did and did not occur as a result of those conversations, raised troubling questions about whether Watson had entered into a potentially *per se* unlawful agreement with Cephalon not to relinquish any modafinil marketing exclusivity it might have. Beginning in May 2009, the Commission issued additional compulsory process, including the subpoena *ad testificandum* to Mr. Bisaro, to resolve those questions.

The Evidentiary Basis for the Investigation

6. The evidentiary basis for staff's concerns about an unlawful agreement between Watson and Cephalon not to relinquish Watson's potential exclusivity rights centered on two issues. First, in Section 2.1 of the 2006 Settlement and License Agreement between Cephalon and Watson's business development partner, Carlsbad Technologies, Inc., ("the Settlement Agreement"), Watson had agreed not to "make, use, offer to sell, or sell, *or actively induce or assist any other entity* to make, use, offer to sell, or sell any Generic Modafinil Product within the Territory . . . ."[1] To the extent that Watson's agreement not to "actively induce or assist any other entity," precluded it from relinquishing any exclusivity rights it might have, this provision could violate the antitrust laws as an agreement among potential competitors to block other

[1] Settlement Agreement § 2.1 (emphasis added). Although to the Commission's knowledge the parties have not disclosed publicly the complete terms of the Settlement Agreement, Cephalon included a redacted version (containing the language quoted above) as Exhibit 10.1 to its 10-Q, filed with the SEC on November 8, 2006.

generic competitors from entering the market. *See In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 907-08 (6th Cir. 2003) (condemning an agreement between a brand and generic company not to relinquish exclusivity rights as a *per se* violation of the antitrust laws). This provision of the Settlement Agreement had not been a focus of the initial phase of the investigation because Watson was not a first filer with regard to the '516 patent, and was therefore not eligible for marketing exclusivity. That changed, however, after FTC staff learned, in January 2009, that Watson was a first filer with potential exclusivity rights arising from the later-listed '346 patent.

7. Second, Watson appeared disinclined to pursue a potentially profitable business opportunity in which it could relinquish any modafinil exclusivity rights it might have in exchange for substantial compensation. In a telephone conversation with Mr. Sunshine in March 2009, Mr. Meier posited hypothetical scenarios to explore whether Watson might profit from relinquishment of any exclusivity rights it might have. Based on my understanding of the facts at the time, it appeared that relinquishment could be a more profitable option for Watson than waiting to launch its generic modafinil product under the terms of the Settlement Agreement.

8. On March 13, 2009, Mr. Meier asked Mr. Sunshine if Watson would be interested in talking with a third party, Apotex, Inc. ("Apotex") about a potential agreement to relinquish whatever marketing exclusivity rights Watson might have. Mr. Sunshine affirmed that Watson would be interested in talking to Apotex about the possibility of relinquishment, and identified David Buchen, Watson's General Counsel, as the person at Watson that Apotex should contact.

9. If Watson chose to relinquish its potential exclusivity, the FTC's ongoing investigation about whether Watson had agreed with Cephalon *not* to relinquish its exclusivity

would have been resolved, leaving nothing further to investigate. In contrast, if Watson chose not to relinquish its potential exclusivity, the FTC would need to assess whether Watson was acting independently or whether the reason for the decision was attributable to an unlawful agreement with Cephalon not to relinquish.

10. On May 5, 2009, Mr. Meier and I called Mr. Sunshine to determine whether there had been any further developments relating to Watson's potential relinquishment. On May 6, 2009, Mr. Meier and I placed a similar call to Apotex's Vice President of Global Intellectual Property, Shashank Upadhye. Mr. Upadhye told FTC staff that discussions with Watson had stalled and that Watson did not appear to be interested in pursuing a business arrangement with Apotex. Based on these conversations, by early May 2009, it appeared to FTC staff that Watson was not interested in potential relinquishment.

11. Watson's apparent decision to forego a potentially profitable business opportunity relating to relinquishment raised further questions to staff about why Watson was acting in a manner that appeared to be contrary to its own economic interest. These questions, combined with staff's concerns about Section 2.1 of the Settlement Agreement, required further investigation to assess whether the reason for the decision was attributable to an unlawful agreement with Cephalon not to relinquish.

Watson Repeatedly Fails to Answer the FTC's Questions

12. On May 19, 2009, the Commission issued narrowly targeted Civil Investigative Demands ("CIDs") to Watson (the "Watson CID") and its development partner, Carlsbad, to determine, *inter alia*, whether Watson is a party to any agreement that limits its ability to relinquish any marketing exclusivity rights it may have with respect to generic Provigil.

13. Specifically, Specification 3 of the Watson CID required it to identify "each agreement, written or oral, that prohibits, blocks, prevents, compromises, or limits in any way Watson or Carlsbad's ability to relinquish eligibility to claim 180-day Marketing Exclusivity for Generic Provigil," as well as "[t]he portion(s) of the agreement that prohibit or limit Watson's or Carlsbad's ability to relinquish." (Pet'r's Reply Mem. in Supp. of Pet. for an Order Enforcing Administrative Subpoena Ad Testificandum and Opp'n to Resp't's Mot. to Compel, Supplemental Pet. Ex. 2. (Doc. No. 20))

14. In its written response dated June 10, 2009, Watson identified the Settlement Agreement as the only agreement that "may relate" to its ability to relinquish, stating that "[a]ny relevant limitations or restrictions are contained therein." Watson, however, did not identify the relevant portions of the agreement as required by Specification 3 of the CID. (*Id.* at Ex. 2.) On June 11, 2009, Commission staff responded with a letter to Watson's counsel identifying the deficiency of Watson's initial CID response and again requesting that it identify the relevant portion of the Settlement Agreement as required by the CID. (*Id.* at Ex. 3.)

15. In a letter from counsel responding to Commission staff on June 17, 2009, Watson again refused to provide the requested information, stating that "[t]he Agreement speaks for itself," and claiming privilege for "Watson's analysis of . . . how the Agreement may relate to FDA marketing exclusivity." (*Id.* at Ex. 4.)

16. During the June 25, 2009 investigational hearing of David Buchen, Watson's General Counsel, Mr. Buchen identified an indemnification provision of the Settlement Agreement that "might relate to the investigation," but refused to answer when asked about any other provisions. (*Id.* at Ex. 5.) Mr. Buchen also refused to answer when asked whether the

Settlement Agreement limits Watson ability to relinquish any rights to marketing exclusivity it may have with respect to generic Provigil. (*Id.*)

17. The May 19, 2009 Watson CID also sought information relating to Watson's discussions with third parties regarding relinquishment. Specifically, Specification 4 required Watson to identify "each company with which Watson had contact relating to: ". . . eligibility to claim 180-day Marketing Exclusivity for Generic Provigil; or the relinquishment thereof," and "[w]hether Watson entered into an agreement as a result of these discussions, and the reasons for Watson's decision." (*Id.* at Ex. 2.)

18. On June 10, 2009, Watson identified Apotex in its written response as a firm with which it had discussed relinquishment, stating that "[n]o agreement or decision has been reached." Watson, however, did not provide the reasons as required by Specification 4 of the FTC's CID. (*Id.*) On June 11, 2009, Commission staff identified the deficiency of Watson's initial CID response in a letter to counsel, and requested again that Watson provide the reasons why no agreement was reached with Apotex. (*Id.* at Ex. 3.)

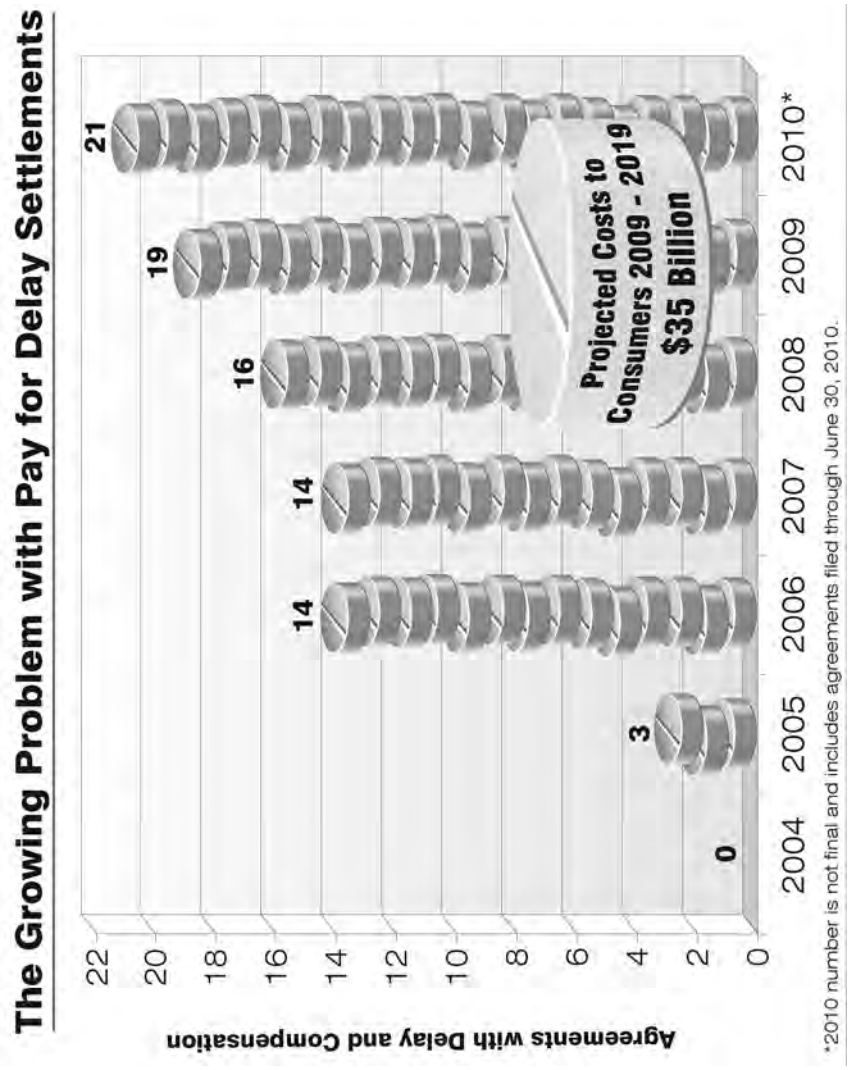
19. Again, Watson refused to provide the requested information. In a letter from counsel on June 17, 2009, Watson responded that the company's decision "is inextricably intertwined with legal matters; Watson's internal deliberations regarding this matter implicate legal advice and are protected from disclosure by the attorney-client privilege."(*Id.* at Ex. 4.) At his June 25, 2009 investigational hearing, however, Mr. Buchen identified for the first time two apparently non-privileged bases for not pursuing an agreement with Apotex. (*Id.* at Ex. 5.) Mr. Buchen also identified Mr. Bisaro as the only person at Watson with whom he had spoken regarding relevant discussions with a third party about a possible deal for generic Provigil. (*Id.*)

Mr. Bisaro, as President and CEO of Watson, is well positioned to testify, among other things, about whether a potential business arrangement with a third party to relinquish any modafinil exclusivity is likely to be in the company's economic interest.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: July 21, 2010

Saralisa C. Brau
Deputy Assistant Director
Bureau of Competition
Federal Trade Commission
Washington, DC 20580


The Growing Problem with Pay for Delay Settlements
Agreements with Delay and Compensation
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