Questions for the Record for Chairwoman Edith Ramirez
Senator Patrick Leahy
Chairman, Senate Judiciary Committee

Hearing before the Senate Committee on the Judiciary
Subcommittee on Antitrust, Competition Policy and Consumer Rights
"Oversight of the Enforcement of the Antitrust Laws"
April 16, 2013

1. **In 2012, the Government Accountability Office (GAO) issued a report concerning Federal oversight and self-regulation of Group Purchasing Organizations (GPOs). This area has long been of interest to the Judiciary Committee. After I raised concerns about the potential impact on patient costs of GPO contracting practices with the Justice Department in 2000, and the Department of Health and Human Services in 2001, the Antitrust Subcommittee held a series of hearings on GPO practices that culminated in a joint report by the Department of Justice and Federal Trade Commission in 2004. During the hearings, many expressed concern that fees paid by vendors to GPOs distort demand, resulting in higher prices for hospitals and consumers.**

   Although the Department of Justice and FTC have investigated complaints against various GPOs, since 2004 the Department has filed only one lawsuit against a GPO under the antitrust laws, and the FTC has filed none. The GAO's 2012 report observed: "While the oversight of GPOs is conducted through the exercise of investigatory authorities of HHS, DOJ, and FTC… this oversight does not address other key questions that have previously been raised about GPOs' activities. For example, inasmuch as the collection of contract administrative fees is permitted under the safe harbor provision to the Anti-Kickback statute and safe harbor regulation, this oversight cannot address whether or to what extent these fees create a financial incentive that is inconsistent with GPOs obtaining the lowest prices for their customers."

   Do you believe that the current legislative framework is sufficient to address the risk of undesirable conduct by GPOs that increases prices for consumers? Do you agree that the legal framework could be strengthened through other measures, such as revisiting the safe harbor for GPOs provided in the Anti-Kickback Statute?

   The FTC has authority to take action against GPOs if they were to engage in anticompetitive conduct in violation of the antitrust laws. For example, Commission staff have investigated allegations by medical device manufacturers that GPO contracting practices unreasonably foreclosed competition among rival manufacturers, which may discourage innovation and create a disincentive for GPOs to negotiate the lowest prices. The FTC will continue to review GPO conduct on a case-by-case basis as part of our mission to promote competition in health care markets and take action when the factual circumstances warrant it.

As your question acknowledges, some concerns raised by various parties regarding GPOs fall outside of the scope of the antitrust laws, including the role of the safe harbor in the Anti-Kickback statute. As you know, these concerns often center on the potential for "agency problems" and corporate governance issues, whereby GPO management may be enticed to enter into contracts that are not in the best interests of their members, as distinct from the antitrust issues that are the Commission's focus.

2. Last year, I asked then-Commissioner Ramirez and the Acting Assistant Attorney General for Antitrust, Joseph Wayland, whether "patent trolling" behavior by certain patent-assertion entities could constitute an antitrust violation. Mr. Wayland responded: "Any effort by a patent owner to harm competition by improperly extending the exclusionary scope of its patent . . . may violate the antitrust laws, and allegations of such actions merit investigation." I was pleased that your agencies recently held a joint workshop to further investigate this question. How do your agencies intend to follow up on the workshop?

The FTC and Department of Justice received almost 70 public comments in connection with our Patent Assertion Entities (PAE) workshop. We have been actively considering those comments and applying our learning from the workshop to evaluate potential next steps. If the FTC finds potentially anticompetitive conduct, we will investigate it using our authority under Section 5 of the FTC Act. In addition, PAE activity may be a suitable focus for Commission policy studies and competition advocacy. For example, patent system issues related to notice and remedies may promote PAE harms. The FTC will continue to recommend improvements to the system of patent notice and remedies, as well as other appropriate reform to the patent system, to address these issues going forward.

3. In your testimony, you stated that the FTC has heard reports of patent assertion entities making unsubstantiated claims relative to small businesses. Unfortunately, I continue to hear frequently about this problem from small businesses in Vermont and across the country. What steps can the FTC take to address this conduct through its consumer protection authority? Will you agree to monitor such activity and take appropriate action to address abusive behavior by patent trolls?

Yes, the FTC will continue to monitor PAE activity and, when appropriate, we will use our competition and consumer protection enforcement authority to prevent harmful practices by PAEs.

4. Earlier this year, the FTC concluded its investigation of Google's search engine practices. A majority of Commissioners found that certain practices used by Google

threatened competition and innovation, yet the FTC relied on voluntary commitments from Google to end those practices, instead of a consent order.

a. In your testimony, you expressed concern about the use of voluntary commitments to address anticompetitive violations. Can you please elaborate on that? What actions does the FTC intend to take to enforce Google's commitments?

The voluntary commitments made by Google should not be considered a precedent, but were a good outcome for consumers under the specific circumstances of that case.

Our policy long has been – and under my leadership, will continue to be – that when a majority of Commissioners finds reason to believe that a law we enforce has been violated and enforcement would be in the public interest, any remedy should be embodied in a formal consent order or adjudicated order.

In the Google matter, three of the Commissioners – myself included – were concerned that some of Google's conduct had the potential to restrict competition. A Commission majority did not, however, support an enforcement action on any of the allegations under investigation. Therefore, the Commission was not in a position to accept a formal consent agreement.

In a public letter to then-Chairman Leibowitz, Google responded to the concerns of some Commissioners with voluntary commitments. We expect Google to honor its commitments. Google has stated publicly that material violations of its commitments would be actionable under the FTC Act, and Google will submit periodic compliance reports to the Commission. We will use this and other information to monitor Google's activities.

b. In discussing potential remedies, some commentators noted the challenges involved in overseeing a technologically complex business practice that is constantly being updated, such as a search engine algorithm. How is the Commission responding to the challenges of enforcement in an online world?

As the Commission has demonstrated throughout its almost 100-year history, antitrust analysis is sufficiently flexible to accommodate the complexities of technological change in dynamic markets. To support our highly fact-based approach to antitrust enforcement, the Commission and its staff constantly strive to enhance our understanding of rapidly evolving technology markets. Staff's expertise deepens case-by-case, just as in other important markets. In addition, in 2010 the agency created a Chief Technologist position, which thus far has been filled by two notable academics with significant real-world experience. We also hire technical experts to work on staff or as consultants when needed.

c. In your testimony, you said that the FTC concluded that certain changes made by Google to its search engine algorithm were "pro-competitive" because they were "designed to improve the overall search experience for the user," even though they had the effect of negatively impacting rivals. Would your analysis have come out differently if the FTC had focused on the harm experienced by Google's other "users"; namely, the advertisers who pay to post ads on its site? How did the FTC determine its framework of analysis in assessing the procompetitive justifications of Google's conduct?

Our analysis focused on the impact of Google's conduct on both consumers and advertisers because they are so closely intertwined. While Google focuses its search product on the search needs and buying preferences of consumers, it does so in order to attract advertisers. As discussed in the Commission's statement, we carefully considered the potential long-term effects of Google's conduct on so-called "vertical" websites, which might be viewed as current or potential rivals in markets for search and search advertising.

d. In light of the recent reports of action by your European counterpart authorities, is the FTC taking any further action in these matters?

We have worked closely with the EC's Directorate General for Competition ("DG Comp") for many years, and our staffs cooperated extensively throughout the Google investigation as well. We do not anticipate any further FTC action on the Google search matter.

Questions for the Record for Chairwoman Edith Ramirez
Senator Chuck Grassley
Senate Judiciary Committee

Hearing before the Senate Committee on the Judiciary
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1. As you know, I've been concerned about settlement agreements between brand name and generic drug manufacturers that result in a payment to the generic manufacturer and a delay in market entry of the generic drug. These "pay for delay" or "reverse payment" agreements result in consumers having to pay higher costs for their drugs. Senator Klobuchar and I have introduced a bill, the Preserve Access to Affordable Generics Act, that would help put a stop to these anti-competitive agreements and ensure that lower priced generic drugs enter the market as soon as possible. Former Chairman Jon Leibowitz was very supportive of our efforts to address this anti-competitive practice.

a. Do you agree that these "pay for delay" agreements harm consumers?

Yes, pay-for-delay agreements pose a substantial threat to consumers. Agreements in which generic drug companies are paid to delay market entry of their products deprive consumers of the ability to choose lower cost medications – often for many years – and impose considerable costs on consumers and the government. FTC economists analyzed data from settlements reported to the FTC during 2004-2009 and calculated, using conservative assumptions, that pay-for-delay patent litigation settlements cost drug purchasers roughly $3.5 billion a year.[1]

b. Do you agree that these kinds of agreements are still a problem?

I do, and it seems the agreements are a growing problem. FTC staff analyzed settlements filed pursuant to the provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The results show a steady increase in the number of agreements containing both a restriction on market entry by the generic drug manufacturer and compensation from the branded drug firm to the generic drug company, from zero in FY 2004 to forty in FY 2012.[2]

[1] Federal Trade Commission Staff, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions* (January 2010), at 8-10.
[2] Federal Trade Commission Staff, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act* (FY 2012), http://www.ftc.gov/os/2013/01/130117mmareport.pdf.

c. What is the FTC doing to prevent these kinds of agreements?

The FTC currently has two law enforcement actions challenging pay-for-delay agreements. *FTC v. Actavis* is currently pending before the U.S. Supreme Court, with a decision expected to issue by the end of June. In the *Cephalon* case, the U.S. District Court for the Eastern District of Pennsylvania is awaiting the Supreme Court decision in *Actavis* before moving forward. Additionally, FTC staff continue to review every agreement reported to the agency pursuant to the MMA and have opened additional non-public investigations.

d. Do you believe that the Klobuchar/Grassley legislation would help preserve generic drug competition and ensure that more affordable drugs get to consumers as expeditiously as possible?

I do, and I strongly support this legislation. By declaring that pay-for-delay arrangements are presumptively illegal and requiring clear and convincing evidence to overcome that presumption, the Klobuchar/Grassley bill should help to protect consumers by deterring drug companies from entering into anticompetitive patent settlements.

Questions for the Record for Chairwoman Edith Ramirez
Senator Amy Klobuchar
Senate Judiciary Committee

Hearing before the Senate Committee on the Judiciary
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1. In these tough budget times, we're asking every agency to do more with less. Can you explain to us the value that you think antitrust enforcement brings to consumers and the economy as a whole?

Vigorous competition is a fundamental organizing principle of the U.S. economy. During financially troubled times, conscientious antitrust enforcement remains a good investment for the American people because it helps to support and strengthen our economy. Competitive markets yield lower prices, improved quality, and other benefits for consumers, including both individuals and businesses. Competition also promotes innovation, providing incentives and opportunities for the development of new goods and services.

The Commission, with its highly professional and dedicated staff, strives to be a good steward of the resources entrusted to us. As one example of the value we deliver to consumers, in FY 2012 the FTC's efforts to prevent anticompetitive mergers saved consumers approximately thirteen times the amount of resources devoted to the agency's merger enforcement program.[3]

2. The Antitrust Division and the Federal Trade Commission share responsibility for government enforcement of the federal antitrust laws. Sometimes this leads to conflicts regarding which agency will review a merger, what is known as the "clearance process." In some cases, the agencies take a long time, sometimes nearly the entire length of the thirty day pre-merger waiting period, to decide which one will investigate a merger. This unnecessarily delays resolution of the merger investigation, and imposes unnecessary burdens on the merging parties.

a. What is your agency doing to resolve clearance disputes in a more effective way? Are you working with the Antitrust Division/FTC, as the Antitrust Modernization Commission suggested in 2007, to develop a new merger clearance agreement?

Clearance disputes are rare, and there is a process in place to resolve, in a timely and professional way, the few that arise. Staff at both agencies are alert to the

[3] Federal Trade Commission, Performance and Accountability Report, FY 2012, at 14, *available at* http://www.ftc.gov/opp/gpra/2012parreport.pdf.

time-sensitivity of clearance and HSR review. We are all working to minimize clearance disputes and associated delays, and the recent ABA Antitrust Section Transition Report released in February finds that "delays due to clearance battles have been reduced."[4] Nonetheless, we can always do better, and Assistant Attorney General Bill Baer and I have agreed that we will both make this issue a priority.

3. Recently, standard essential patents have been the subject of several cases filed at the International Trade Commission (ITC). We can all agree that standardization of technology and standard essential patents have been critical to the development of a competitive market for smartphones and tablets. But recently, concerns have been raised about the practice of bringing standard essential patents cases to the ITC seeking an exclusion order to prevent products with the patents from being imported into the U.S. Some worry that the ITC exclusion orders related to standard essential patents could gravely harm competition.

a. What sorts of negative effects might the use of exclusion orders regarding standard essential patents have on competition and consumer welfare in general?

I am concerned that a patentee might voluntarily commit to license its intellectual property on fair, reasonable, and non-discriminatory (FRAND) terms as part of the standard-setting process, and then escape that licensing obligation by seeking an exclusion order for infringement of the FRAND-encumbered standard essential patent (SEP). The threat of the exclusion order undercuts the procompetitive goals of the FRAND commitment and the standard-setting process. A potential licensee is likely to accept an unreasonable royalty demand if the alternative is an order that blocks its products from the market. Even a relatively small risk of that disruptive outcome can force an implementer to accept licensing terms that far exceed what it would have paid to license the patent before the standard was adopted.

More broadly, unexpectedly high costs undermine the competitive value of the standard-setting process. And the uncertainty associated with the threat of an injunction can have the long-term impact of discouraging firms from investing to implement the standard, or to invest in standard-compliant products more generally.

[4] American Bar Association, Section of Antitrust Law, *Presidential Transition Report: The State of Antitrust Enforcement 2012* (Feb. 2013), at 12, *available at* http://www.americanbar.org/content/dam/aba/administrative/antitrust_law/at_comments_presidential_201302.authcheckdam.pdf.

b. Is there any justification for the use of exclusion orders in the context of standard essential patents?

While injunctive relief in most cases should be unavailable for infringement of a SEP covered by a FRAND commitment, this should not be a blanket rule in all cases. One likely exception would cover foreign manufacturers with an insufficient presence in the United States to support federal court jurisdiction. In that instance, a patent holder could not obtain damages for infringement of a valid patent in a U.S. district court, and an ITC exclusion order might be warranted.

Questions for the Record for Chairwoman Edith Ramirez
Senator Michael S. Lee
Senate Judiciary Committee

Hearing before the Senate Committee on the Judiciary
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1. In 2008, the Department of Justice released a report on Section 2 of the Sherman Act. The report was later withdrawn. That report provided the business community with guidance on applicable principles in Section 2 enforcement actions.

a. Do you agree with the 2008 report's findings and conclusions?

b. If not, with which specific findings and conclusions do you disagree?

c. Do you agree that it would be helpful for the business community to have formal guidance on the enforcement agencies' approach to Section 2 enforcement?

d. Will you commit to work with Mr. Baer to develop and publish formal guidance on Section 2 enforcement?

The Commission did not join or endorse the Section 2 Report when it was released by the Department of Justice, and various Commissioners issued statements explaining their concerns. I was not a Commissioner at the time, but I share the concerns of the Commissioners who declined to endorse the Report.

The two agencies' extensive joint hearings that provided the foundation for the Report, along with the statements of the then-Commissioners, made an important contribution to the development of antitrust law. The hearings brought together experts with a wide range of views to discuss important doctrinal and policy questions related to single firm conduct. The record of these hearings (available on the FTC website) and several posted FTC staff working papers continue to provide guidance for businesses and their counsel on various types of conduct.

In addition, as Assistant Attorney General Bill Baer testified at the hearing, a series of U.S. Supreme Court and D.C. Circuit court opinions provide valuable guidance about how to apply Section 2. As courts continue to apply these analytical approaches to different sets of facts, the law will continue to evolve.

The antitrust laws should not be applied in ways that might impose liability on firms for achieving marketplace success as a result of their superior products, services, or business models. Likewise, we should not tolerate market power

achieved or maintained via conduct that does not reflect competition on the merits and impairs competition or the competitive process.

Striking the appropriate balance, based on specific factual circumstances and sound economic theory, will help to ensure that markets operate efficiently, that innovation is promoted, and that all firms are encouraged to compete on the merits. We can most effectively satisfy these goals by continuing on our present course: first, to develop sound and predictable principles through case-by-case enforcement; and second, to engage in advocacy (such as amicus briefs) to support competition on the merits and oppose conduct that poses a significant threat of harm to competition or the competitive process.

2. The Federal Trade Commission, particularly under the previous Chairman, has been in the practice of reaching settlements in cases brought under Section 5 of the FTC Act. These settlements are not subsequently reviewed by a court to establish a clear record of Section 5 enforcement boundaries. At the same time, the Commission has yet to provide definitive guidance as to how Section 5 can be used to enforce unfair methods of competition beyond the traditional scope of antitrust laws.

a. Do you plan to continue the practice of enforcing Section 5 by means of settlements outside of court review?

b. How do you think a practice of open-ended enforcement might be perceived in foreign jurisdictions where basic rule of law principles are often lacking?

c. What formal guidance will you provide the business community regarding Section 5 enforcement?

As with the Sherman Act and the Clayton Act, Section 5 of the FTC Act has been developed over time, case-by-case, in the manner of common law. These precedents provide the Commission and the business community with important guidance regarding the appropriate scope and use of the FTC's Section 5 authority.

For various reasons, including resource constraints, the Commission may – and often does – decide that it is in the public interest to settle a case, in exchange for a binding agreement to stop the allegedly harmful conduct. Parties before the agency, too, often prefer to settle cases for a variety of business reasons. Importantly, the possibility of settlement does not affect the rigor that we apply in choosing appropriate Section 5 enforcement actions, and the documents typically made public at the time of settlement provide significant guidance regarding the Commission's theory of harm.

3. At our Subcommittee's hearing last week, in response to a question regarding Section 5 of the FTC Act, you stated that you believe the Commission "has been using its Section 5 authority very rigorously and very judiciously," and that the agency is providing some measure of guidance through the pattern of its decisions.

a. If the Commission is applying Section 5 "cautiously" and wishes to provide useful enforcement guidance, why are you resistant to provide such guidance in a more comprehensive, published form upon which the business community and others can meaningfully rely?

Case-specific guidance, grounded in detailed facts and sound economic theory, is likely the most useful form of guidance for the business community and lawyers advising the business community. Due to the fact-based nature of antitrust cases, as well as our need to retain flexibility to use Section 5 to protect competition and consumers as markets and economic learning evolve, any non-case-specific guidance document would necessarily be far more general, and thus less useful.

However, we can always strive to be more transparent regarding our enforcement philosophy and case selection priorities. I will continue to engage in a dialogue with my fellow Commissioners and the business community in pursuit of that goal.

4. Some have expressed concern that the Commission's approach to Section 5 enforcement has left many in the business community confused and uncertain as the contours of that provision and the breadth of possible enforcement actions.

a. Do you believe that the Commission may use Section 5 to create convergence with U.S. antitrust doctrine and that of international jurisdictions?

b. Do you believe the Commission may use Section 5 to place additional emphasis within U.S. competition policy on consumer choice as a touchstone of antitrust law?

c. Do you believe the Commission may use Section 5 to bring actions that increasingly incorporate analysis and assumptions based on behavioral economics?

In my view, the Agency's work on international convergence should focus on the promotion of fair processes and transparency in all jurisdictions, along with efforts to develop and share rigorous analytical tools and common approaches to difficult antitrust issues. As we already have seen in recent years, continued international convergence generates substantial benefits for businesses and consumers. While convergence may tend to lead to similar outcomes, convergence neither contemplates nor requires identical rules of decision or identical outcomes. I do not intend to use Section 5 as a mechanism to create

international convergence with respect to substantive outcomes. The FTC will continue to enforce U.S. laws, applying U.S. legal standards.

In our application of Section 5, as in our application of the antitrust laws generally, we work to use, but not go beyond, state-of the-art economic techniques that are rigorous and well-accepted for identifying competitive effects and efficiencies. The range of recognized harms and benefits from mergers or other competitive conduct may of course include non-price effects, such as those related to product quality or innovation.

5. At our Subcommittee's hearing last week, you stated that you believe the standards used by the FTC and the DOJ for obtaining a preliminary injunction are "quite similar" and that "as a practical matter what each agency needs to do is go before a judge and show and provide evidence that backs up the charges that are being made." You further stated that you "believe it would be difficult to point to a specific situation where…a case would have led to a different outcome had it been handled by a different agency."

a. In its 2007 Report and Recommendations, the Antitrust Modernization Commission wrote that the "FTC's ability to continue a merger case in administrative litigation also may lead companies whose transactions are investigated by the FTC to feel greater pressure to settle a matter than if they had been investigated by the DOJ."

i. Should companies face greater pressure to settle if their mergers are reviewed by the FTC rather than the DOJ?

ii. Do you agree that even the perception of a more lenient standard for FTC cases than those brought by the DOJ could result in a practical difference for litigants who must weigh litigation risk?.

b. The 2007 Report further states that differences in the preliminary injunction standards faced by the FTC and the DOJ, whether real or perceived, "can undermine the public's confidence that the antitrust agencies are reviewing mergers efficiently and fairly and that it does not matter which agency reviews a given merger."

i. Do you agree that public confidence is important and can be affected by public perception of differing standards applied to identical issues?

ii. Do you agree that it would be problematic if the identity of the reviewing agency led to different outcomes due to the parties' perception that the FTC and the DOJ face different standards for obtaining a preliminary injunction?

iii. What measures do you believe appropriate to remedy any perceived or real inconsistency in the preliminary injunction standards faced by the agencies?

Although some in the antitrust community perceive that the FTC and Department of Justice Antitrust Division face different preliminary injunction standards to enjoin pending mergers, as Assistant Attorney General Baer and I both testified, this has not been our experience. While the wording may differ, there appears to be no evidence that the substantive standard varies, or that any perceived difference has influenced the outcome of any specific case.

Public confidence in the agency is important, and the FTC has sought to address the perception that any procedural differences between the two agencies could affect outcomes. Since the Antitrust Modernization Commission issued its 2007 report, the Commission has revised its administrative adjudicative process to, among other things, impose significantly shorter deadlines. As a result, while the litigation process may differ between the two agencies, the time frames from complaint to final resolution in merger matters are now, on average, about the same for a federal district court decision in an Antitrust Division matter and an FTC adjudicative decision. Furthermore, the same substantive Clayton Act Section 7 legal standards apply regardless of whether the adjudicator is the Commission or a federal district court.

c. In *FTC v. CCC Holdings*, the district court granted the FTC's request for a preliminary injunction. The judge noted that although the defendants' arguments might "ultimately win the day," under Section 13(b) the trial court needed only to determine that "the FTC had raised questions that are so 'serious, substantial, difficult and doubtful' that they are 'fair ground for thorough investigation, study, deliberation and determination by the FTC'" to conclude that a preliminary injunction should issue. Commentators have written that "[t]he importance of the CCC Holdings decision therefore is not merely academic, and the resulting agency divergence is not merely procedural. It may be outcome determinative in some cases."[5]

i. Do you believe the standard applied by the district court in *FTC v. CCC Holdings* was the same as the preliminary injunction standard applicable to the DOJ in a merger case?

ii. Do you agree that application of that lower standard may have had an impact on the outcome of the case, in the sense that the outcome may have been different if the DOJ standard had been applied?

[5] Peter Love & Ryan C. Thomas, *FTC v. CCC Holdings: Message Received*, GCP (April 2009), at 10.

d. In the *Whole Foods* litigation, the FTC argued on appeal before the D.C. Circuit: "This Court has recognized, in keeping with the intent of Congress in creating the Commission and in enacting Section 13(b), that the Commission is not required to 'prove' any aspect of its case in order to secure a preliminary injunction in aid of its own adjudicative and remedial powers; rather, it need only show 'serious, substantial' questions requiring plenary administrative consideration. The district court's contrary approach ignores the statutory scheme, and effectively usurps the adjudicative role of the Commission."[6]

i. Do you contend the standard the Commission advanced in the *Whole Foods* appeal was the same standard DOJ has to meet in order to obtain a preliminary injunction in a merger case?

e. *FTC v. Libbey, Inc.*, 211 F. Supp.2d 34 (D.D.C. 2002), is another case in which a court applied a lower preliminary injunction standard to an FTC merger challenge than would have been applied if DOJ had brought the case.

i. Do you agree that the standard applied in that instance may have had an impact on the outcome of the case?

Although various courts considering the appropriate standard have stated it in different ways, the core focus of the preliminary injunction standard for both agencies is the same: a strong evidentiary presentation by the agency, which a defendant fails to rebut. *See, e.g., FTC v. H.J. Heinz Co.*, 246 F.3d 708, 714 (D.C. Cir. 2001) (recognizing that government agencies bear a different preliminary injunction burden than private parties when enforcing federal laws). In addition, as the joint Horizontal Merger Guidelines indicate, the two agencies apply the same analytical framework to merger review. Any differences in merger challenge outcomes are a consequence of specific underlying facts and the strength of the evidence in individual cases. They do not result from a difference (real or perceived) in preliminary injunction standards, and they are not agency-dependent.

With regard to the specific cases you raise, I do not believe that the courts applied a more lenient preliminary injunction standard or that outcomes were affected as a result. For example, in *FTC v. CCC Holdings*, the court relied on *Heinz* for the relevant standard applicable to a FTC preliminary injunction, *i.e.*, that governmental plaintiffs like the FTC face a lower standard than private parties, and emphasized that "ultimate success" requires a showing that the effect of a merger "may be substantially to lessen competition, or tend to create a monopoly" – the same test that applies to the Antitrust Division. 605 F. Supp. 2d 26, 30 (D.D.C. 2009).

[6] http://www.ftc.gov/os/caselist/0710114/080114ftcwholefoodsproofbrief.pdf at 27.

It is also important to recognize that the language used in *CCC Holdings* regarding the sufficiency of showing a likelihood of success by raising serious, substantial questions is a formulation adopted by many courts beginning in the late 1970s. See, *e.g.*, *FTC v. Beatrice Foods Co.*, 587 F.2d 1225, 1229 (D.C. Cir. 1978) (statement of Judges MacKinnon and Robb); *FTC v. Nat'l Tea Co.*, 603 F.2d 694, 698 (8th Cir. 1979); *FTC v. Warner Commc'ns Inc.*, 742 F.2d 1156, 1162 (9th Cir. 1984); *FTC v. Univ. Health*, 938 F.2d 1206, 1218 (11th Cir. 1991); *Heinz*, 246 F.3d at 714-15. In all of these cases, the FTC was required to make a persuasive evidentiary showing of a prima facie case that withstood the defendant's rebuttal. Where the FTC has not made such a showing, the agency's motion for a preliminary injunction has been denied. See, *e.g.*, *FTC v. Laboratory Corp. of Am.*, No. SACV 10-1873 AG, 2011 WL 3100372 (C.D. Cal. Mar. 11, 2011); *FTC v. Foster*, No. CIV 07-352 JBACT, 2007 WL 1793441 (D.N.M. May 29, 2007); *FTC v. ArchCoal Corp.*, 329 F. Supp. 2d 109 (D.D.C. 2004). With regard to the language you quote from the FTC's brief in the *Whole Foods* appeal, the FTC was merely clarifying that the court should not impose, in evaluating a preliminary injunction request, a requirement that the FTC prove the ultimate success of its case, which is the proper standard for a *permanent*, not a *preliminary*, injunction.

f. In February 2013, the Section of Antitrust Law of the American Bar Association issued a report entitled *Presidential Transition Report: The State of Antitrust Enforcement 2012*. The report commented that some circuits have relaxed the standard imposed on the FTC from the standard applicable to the DOJ. The Section noted that the standards applied in cases brought by the FTC differ from those in DOJ cases in other ways as well. The Section urged the FTC to adopt procedures "that will ensure that in merger cases it will seek injunctions only under the same equitable standard for a preliminary injunction as that applied to Division injunction cases." Absent such procedures, the report urged the Administration "to seek legislative changes to Section 13(b) of the Federal Trade Commission Act that will make it consistent with traditional equitable standards for injunctive relief."

i. Will you commit to adopt procedures to ensure that the Commission only seeks preliminary injunctions under the same equitable standards that apply to DOJ actions?

ii. Would you support legislation to clarify that the FTC and the DOJ must satisfy identical standards to obtain a preliminary injunction?

iii. If you remain convinced that the differing standards applied to FTC and DOJ actions are "quite similar" and as a practical matter lead to little if any difference in outcome, what would be the harm in

clarifying that the applicable standard is in fact the same or in establishing a unified standard?

In light of the fact that courts already apply what amounts to the same legal standard to preliminary injunction requests by both FTC and Antitrust Division, I do not believe the FTC needs to change its procedures. For the same reason, I do not believe there is any need for legislation altering the FTC standard.

6. At our Subcommittee's hearing last week, you expressed concern that an acceptance by the Commission of voluntary commitments, as opposed to a consent order, would create confusion over its settlement practices. You suggested that the Commission's acceptance of voluntary commitments by Google should not be considered precedent. Yet, other companies under investigation may believe they need not enter into binding consent decrees, instead asking to be treated by the Commission in the same manner as Google. In addition to an appearance of favoritism the Google agreement may create, I am concerned about informal and illegitimate regulatory creep when the Commission seeks to secure voluntary commitments from private companies. If a majority of commissioners finds a violation there should be a formal consent order. If a majority does not find a violation, the Commission has no authority to interfere in the market and should not pursue any enforcement action, whether voluntary or not.

a. Now that the Commission has in fact negotiated and accepted a voluntary commitment in lieu of consent order, what specifically do you plan to do to correct perceptions and assumptions about future enforcement actions?

b. If the Commission does not plan to follow the standard of settlement practices used in this case ever again, how will you respond to assertions that Google received special treatment from the Commission?

The voluntary commitments made by Google should not be considered a precedent, but were a good outcome for consumers under the specific circumstances of that case.

Our policy long has been – and under my leadership, will continue to be – that when a majority of Commissioners finds reason to believe a law we enforce has been violated, and enforcement would be in the public interest, any remedy should be embodied in a formal consent order or adjudicated order.

In the Google search matter, three of the Commissioners – myself included – were concerned that some of Google's conduct had the potential to restrict competition. A Commission majority did not, however, support an enforcement action on any of the allegations under investigation. Therefore, the Commission was not in a position to accept a formal consent agreement. Google received no special

treatment. Indeed, Google faced an extremely comprehensive inquiry as the Commission and its staff collected and analyzed a broad and complex set of facts under the reason to believe standard. Ultimately, in a letter to then-Chairman Leibowitz, Google responded to concerns about some of their business practices with voluntary commitments, a step that will likely benefit consumers.

7. At our Subcommittee's hearing last week, you seemed to agree with me that voluntary commitments are an illegitimate approach for the Commission to use in seeking to resolve antitrust violations.

a. Under your leadership, will the Commission move to correct this misstep and seek to embody Google's voluntary commitments in a formal consent order?

Whenever a Commission majority finds reason to believe that violation of the law has occurred, and an enforcement action is in the public interest, I will make every effort to pursue formal agency action. Formal action through an enforcement proceeding or a consent decree is the most effective way for the Commission to enforce the antitrust laws. As noted above, however, the Commission was not in a position to accept a formal consent in the Google matter.

We nonetheless expect Google to honor its commitments. Google has stated publicly that material violations of its commitments would be actionable under the FTC Act, and Google will submit periodic compliance reports to the Commission. We will use this and other information to monitor Google's activities, and will take appropriate action if Google does not abide by its commitments.

8. At our Subcommittee's hearing last week, you stated that if Google does not uphold and complete its voluntary commitments from the settlement, the Commission will take "appropriate action."

a. Given that there is no Commission precedent for dealing with this type of voluntary commitment, what specifically would that appropriate action entail?

b. Would such action require the Commission to undergo another complex and lengthy investigative proceeding, which could allow harmful business practices to continue undeterred until there is a formal settlement?

As part of its commitments, Google not only agreed to stop the troubling conduct, but also stated publicly that material violations of the commitments would be actionable under the FTC Act for a period of at least five years. The Commission will make every effort to hold Google to those commitments.

9. The Commission's closing statement in the Google matter concluded: "Challenging Google's product design decisions in this case would require the Commission – or court – to second-guess a firm's product design decisions where plausible procompetitive justifications have been offered, and where those justifications are supported by ample evidence." Similarly, Chairman Leibowitz's opening remarks stated: "Google's primary reason for changing the look and feel of its search results to highlight its own products was to improve the user experience."

a. This approach appears to differ from the standard set forth in the Microsoft case and the standard that you said the Commission used to evaluate Google's conduct. Under the Microsoft decision, the Commission, or a court, must examine whether "the anticompetitive effect of the challenged action outweighs [any proffered justification for the product design change]." United States v. Microsoft Corp, 253 F.3d 34, 67 (D.C. Cir. 2001). It would have required the Commission to apply a balancing test rather than concluding its analysis simply upon a finding that Google put forth a plausible business justification, as suggested by the Commission's closing statement and Chairman Leibowitz's remarks. Please explain this apparent inconsistency.

b. What standard will the Commission apply in the future to similar circumstances?

The Commission's Google investigation was guided by the precedent established in the D.C. Circuit's *Microsoft* decision, along with the existing, well-developed body of federal case law governing monopolization and product design. We carefully investigated whether Google's conduct harmed the competitive process. A majority of the Commission concluded, based on ample evidence, that Google's design changes were procompetitive because they improved the overall search experience for the user – even though the conduct also had some negative impact on competing search engines.

The Commission will continue to follow *Microsoft* and related case law when assessing allegations of harm from unilateral conduct. The Commission will carefully review and assess any actual or probable harm to competition and the competitive process, on the one hand, and the likely consumer benefits of the challenged conduct, on the other. In my view, a monopolist cannot escape antitrust liability simply by putting forward any plausible explanation for its exclusionary conduct.

10. Several states have ongoing investigations of Google's conduct.

a. Did the Commission coordinate its legal and factual analysis with these states?

b. Did the Commission attempt to work with these states to obtain a coordinated settlement?

The Commission frequently coordinates its investigations with state enforcers, sharing resources and information, and we did so during our investigation of Google's conduct. Among other things, state enforcement personnel attended investigational hearings with Google executives and participated in conference calls and meetings where complainants provided us with information. FTC staff also regularly briefed state personnel on the progress and direction of our investigation, and these discussions enhanced the Commission's review.

In many cases, our cooperation with state enforcers culminates in a coordinated settlement that resolves both Commission and states' concerns. In the end, however, each public enforcer must make its own enforcement and settlement decisions. As a matter of prosecutorial discretion, and in the interest of conserving scarce investigative resources, the Commission unanimously determined to close our investigation.

11. Google's practice of negotiating exclusionary syndication and distribution agreements was not addressed in the Commission's decision.

a. Did the Commission review this conduct?

b. If so, why was it not included in the Commission's final decision?

The Commission extensively investigated these issues, but in the end determined an enforcement action was not warranted. The Commission does not routinely comment publicly on decisions to close investigations. In this case, the Commission determined that a closing statement focused mainly on the search bias allegations would provide useful transparency and guidance to the public and the antitrust bar, due to the novel nature of the claims and the exceptionally high level of public interest.

12. The Commission and the Department of Justice share enforcement of the antitrust laws, both in mergers and conduct investigations. It is not always clear to the parties involved who will review a transaction or business practice. In June 2011, then-Chairman Leibowitz told the Senate Commerce Committee: "It is true that there are occasional clearance disputes over which agency is in the better position to investigate a matter . . . . The FTC and DOJ have a process in place to resolve clearance disputes, which helps resolve the issue quickly." Please provide the Subcommittee:

a. The precise process(es) for resolving these disputes;

b. Examples of the types of agreements that the Commission and the Department have reached in merger and non-merger clearance disputes, including how the parties determine which agency will review a subsequent transaction involving the same company or industry and the duration of such agreements; and

c. The number of such disputes since January 2009 and the average length of time such disputes lasted.

Due to the shared antitrust jurisdiction of the FTC and the Department of Justice Antitrust Division, all proposed merger and conduct investigations are formally submitted to the other agency as a "clearance request" through a shared database. Until the other agency approves or "clears" the request, no formal investigation may commence and no parties or third parties may be contacted. Most investigations are submitted and cleared within two business days. When both agencies make a request to investigate the same merger transaction or conduct, this is called a "contested matter."

I understand that since January 2009, there have been 90 instances in which both the Antitrust Division and the FTC were interested in reviewing the same Hart-Scott-Rodino notified transaction. In those instances, it took an average of five business days for the agencies to agree which agency should handle the investigation.

Most of the time, clearance contests are resolved through an informal exchange of information regarding each agency's expertise. This is done by the designated Clearance Officers at each agency, working with investigative staff, by e-mail or telephone. The Clearance Officers are career staff with knowledge of the agency's work. If the Clearance Officers cannot resolve a matter informally, each agency prepares a clearance "claim," a memorandum explaining why it has the better expertise, gained from past investigations, to investigate the particular matter.

If clearance cannot be resolved by the agencies' Clearance Officers, it is escalated to the Deputy Director of the Bureau of Competition at the FTC and the Director of Civil Enforcement at the Antitrust Division for resolution, and if still unresolved, to the heads of the agencies. This level of escalation is extremely rare.

We are all working to minimize clearance disputes and associated delays. The recent ABA Antitrust Section Transition Report released in February found that "delays due to clearance battles have been reduced." Nonetheless, we can always do better. Assistant Attorney General Bill Baer and I have spoken about this issue

recently, and we both agree that one of our priorities is to continue to minimize such disputes to ensure that the clearance process is both fair and efficient.

13. The Commission has issued two recent orders that address the meaning of commitments to license on fair, reasonable, and non-discriminatory (FRAND) terms. In *Bosch*, the Commission embraced an order and remedy that many believe represented progress on this issue. A month later, the Commission adopted a more complicated order and remedy in the Google matter, criticized by some as being weak and riddled with loopholes.

a. Why did the Commission seek such a complicated (and potentially weakened) remedy in the Google matter?

The FTC's *Bosch* and *Google* consent orders continue the Commission's longstanding commitment to safeguard the integrity of the standard-setting process. Standard setting can deliver substantial benefits to American consumers, promoting innovation, competition, and consumer choice. But standard setting by its nature also creates the risk of harm to the competitive process and to consumers. Because standard setting often displaces the normal competitive process with the collective decision-making of competitors, preserving the integrity of the standard-setting process is central to ensuring that standard setting works to the benefit of, rather than against, consumers.

Although the proposed Google order differs from the Bosch order, I respectfully disagree with those who believe that the relief is weak or unduly complicated. Consent orders remedy violations arising out of specific factual situations, reflecting the Commission's assessment of the market and the conduct involved, and each is by nature different. The Google order is not yet final, and is still under consideration by the Commission. However, in January, I voted to issue the proposed order because I believed it remedied Google's alleged anticompetitive conduct resulting from breaches by Google and its subsidiary Motorola of Motorola's commitments to license its standard essential patents (SEPs) on FRAND terms.

b. Please explain your view of the *Bosch* decision.

As alleged in the Complaint, before its acquisition by Robert Bosch GmbH ("Bosch"), SPX Services ("SPX") reneged on a licensing commitment made to two standard-setting bodies to license its SEPs on FRAND terms, by seeking injunctions against willing licensees of those SEPs. Together with a majority of the Commission, I had reason to believe that this conduct tended to impair competition in the market for automobile air conditioning servicing devices.

i. Are you concerned about using a merger review process to require relief on unrelated conduct as a condition for clearing the deal?

I would be concerned about using the FTC's merger review process to require relief that was not reasonably related to an underlying violation of law, but that was not the case in the Commission's agreement with *Bosch*. If a party decides to settle an adjudicative challenge, then the FTC will consider various settlement options, including the potential to settle merger and conduct challenges concurrently.

14. In the debate over standard essential patents and FRAND commitments, much discussion has focused on the willingness of potential licensees to engage in negotiations.

a. In your view, what does it mean to be a willing licensee?

In this context, a willing licensee is a potential licensee who is engaged in good-faith negotiation to obtain a FRAND license to a standard essential patent and is capable of complying with the terms of a license.

b. Is a licensee unwilling simply because it refuses to accept a stated demand as FRAND or demands that the party demonstrate that its portfolio is composed of valid and infringed patents that have some value apart from its inclusion in the standard?

A potential licensee is not unwilling simply because it refuses to accept a stated demand as FRAND. When negotiating FRAND royalties, both the potential licensor and the potential licensee have a duty to negotiate in good faith.

c. There has been comparatively little focus on the willingness of SEP holders to engage in good faith negotiations—that is, whether the SEP holder is a willing licensor. Would you agree that there is a burden on the SEP holder to demonstrate the value of its SEP portfolio, a burden that is generally not discharged by merely quoting a rate, particularly when the rate clearly exceeds traditional industry benchmarks?

In my view, the potential licensor of a FRAND-encumbered SEP does not discharge its duty to negotiate in good faith by merely quoting a rate.

15. The Commission statement accompanying its decision relating to Google's abuse of certain standard essential patents indicated that "Google's settlement with the Commission requires Google to withdraw its claims for injunctive relief on FRAND encumbered patents around the world."

a. How many of those claims for injunctive relief have been withdrawn and how many are still open?

b. What is the Commission doing to ensure compliance with its Order?

Under the terms of the order, Google cannot seek any new injunctions on FRAND-encumbered standard essential patents unless and until it follows the processes set out in the order. In addition, the order prohibits Google from obtaining or enforcing any injunctions in current actions without first following the processes set out in the order. Since the proposed order was accepted for public comment, Google has not obtained or enforced any injunctions on standard essential patents and many of those actions have been resolved. To our knowledge, Google is currently complying with the terms of the order, even though at this point the order is not final. When the order becomes final, the Commission will monitor and enforce the order as it does any other order.

16. In testimony before our Committee last July, you expressed concerns about anticompetitive abuse of standard essential patents and stated that the Commission "believes that the ITC has the authority under its public interest obligations . . . to deny an exclusion order if the holder of the FRAND-encumbered SEP has not complied with its FRAND obligation." You also suggested that if the ITC did not act appropriately, Congress should consider giving the ITC more flexibility to deny exclusion orders in such cases.

a. In your view, has the ITC responded to the concerns you raised?

Yes. The ITC issued Notices of Review in several investigations involving FRAND-encumbered SEPs in which it sought briefing from the public and the parties on a wide range of FRAND topics. For example, in an investigation involving Apple products, it asked the parties whether: (1) "the mere existence of a [F]RAND obligation preclude[s] issuance of an exclusion order[;]" (2) a patent owner that has refused to offer or negotiate a license on [F]RAND terms should be able to obtain an exclusion order; and (3) a patent owner should be able to obtain an exclusion order if it has offered a [F]RAND license, and that license has been rejected by the alleged infringer.[7] The ITC's actions demonstrate that it is taking seriously competitive concerns about exclusion orders for FRAND-encumbered SEPs.

b. Do you worry about ITC decisions in cases involving FRAND-encumbered SEPs, given that the only available ITC remedy is an exclusion order?

Yes. I am concerned that a patentee might voluntarily commit to license its intellectual property on FRAND terms as part of the standard-setting process, and then escape that licensing obligation by seeking an exclusion order for

[7] *In re Certain Wireless Communication Devices*, Inv. No. 337-TA-745, Notice of Commission Decision to Review in Part a Final Initial Determination Finding a Violation of Section 337 at 4-5 (June 2012).

infringement of the FRAND-encumbered SEP. The threat of the exclusion order undercuts the pro-competitive goals of the FRAND commitment. A potential licensee is likely to accept an unreasonable royalty demand if the alternative is an order that blocks its products from the market. Even a relatively small risk of that disruptive outcome can force an implementer to accept licensing terms that far exceed what it would have paid to license the patent before the standard was adopted. More broadly, unexpectedly high costs undermine the competitive value of the standard-setting process. And the uncertainty associated with the threat of an injunction can discourage firms from investing to implement the standard.

c. Do you believe that enforcement action based on anticompetitive abuse of FRAND-encumbered SEPs could and should be pursued under Section 2 of the Sherman Act?

The FTC does not have direct authority to enforce the provisions of Section 2 of the Sherman Act. Section 5 of the FTC Act, however, is understood to incorporate conduct that violates Section 2, and it can reach more broadly. Enforcement actions based on anticompetitive abuses of FRAND-encumbered SEPs are highly fact-specific and the FTC will use all of its enforcement tools to address these abuses, where appropriate.

17. At our Subcommittee's hearing last week, there was much discussion of legislation that would impose a presumption that all patent settlements between innovator pharmaceutical companies and generic companies are anticompetitive. By statute, the Commission is already entitled to receive notice of such settlements, so it has ample opportunity to review such settlements for any anticompetitive problems. Both federal statute and Supreme Court case law state that patents are presumed to be valid. 35 U.S.C. § 282; *Microsoft Corp. v. i4i Limited Partnership,* 131 S.Ct. 2238 (2011). Indeed, patent invalidity must be proved by the elevated standard of clear and convincing evidence. *Microsoft,* 131 S.Ct. at 2252. In addition, it is well-settled law that settlements of litigation are highly favored. Yet, your position on patent settlements legislation seems to contradict quite squarely these two well-settled, time-tested principles.

a. How can you reconcile your position with these principles, particularly when the settlement occurs within the term of the patent?

b. Do you really believe that all such settlements are necessarily anticompetitive?

c. Under what conditions might such a settlement be procompetitive in its effect?

I do not understand the bill introduced by Senators Klobuchar and Grassley to impose the broad presumption you describe. Instead, the proposed legislation

addresses what are known as "pay-for-delay" agreements, in which the brand-name-drug firm pays its would-be generic rival and the generic drug firm agrees to abandon its Hatch-Waxman patent challenge and forgo entry for a period of time, often several years. The vast majority of brand-generic settlements do not involve compensation to the generic patent challenger.[8] Thus, most Hatch-Waxman patent settlements would not be affected by the bill.

I do not believe that all patent settlements between brand-name drug manufacturers and generic drug companies should be treated as presumptively anticompetitive or that all such settlements are necessarily anticompetitive. I do believe, however, that treating pay-for-delay agreements as presumptively anticompetitive is sound antitrust policy. As the Commission's brief to the Supreme Court in *FTC v. Actavis* explains, a settlement in which the brand-name drug firm pays the generic patent challenger and the generic agrees to refrain from competing inherently aligns the generic firm's interest with the brand's interest in extending its monopoly. This aligning of the parties' incentives means the generic will accept a later entry date than it otherwise would accept based on its expectations about the likely outcome of the patent suit. As a result, the parties share a pool of profits that is made larger by their agreement not to compete. Such treaties between competitors, actual or potential, are at the core of what the antitrust laws proscribe. In contrast, the other ways that drug companies settle patent suits, such as with royalty payments by the allegedly infringing generic or waivers of accrued damage claims, do not have this inherent tendency to harm competition and consumers.

A legal rule that recognizes the inherent risk of harm from pay-for-delay agreements does not conflict with the statutory presumption of validity. The Supreme Court has never suggested that the presumption of validity gives the patent holder the right to share monopoly profits to induce potential competitors to abandon their efforts to compete. Moreover, the rationale for treating pay-for-delay settlements as presumptively anticompetitive does not rest on any assumption that the patent at issue is necessarily invalid or not infringed. Rather, such agreements are problematic because it is the payment, not the strength of the patent, which thwarts the competitive process that would otherwise operate to protect consumers.

The public policy favoring settlements is important, but it does not trump the important public values embodied in the antitrust laws. Were the law otherwise, private parties could use settlements to shield a wide range of anticompetitive activity. No one, however, suggests that parties who chose to settle their litigation by means of a price fixing agreement could avoid liability on the ground that public policy favors settlement. Moreover, arguments that limiting the use of payments will make it impossible to settle Hatch-Waxman patent cases are not

[8] *2012 Annual Report* at 2 (noting that more than 70% of brand-generic settlements are resolved without compensation to the generic).

borne out by the evidence noted above, which shows the vast majority of such settlements do not involve payment to the generic.

Under a legal rule that treats pay-for-delay settlements as presumptively anticompetitive, defendants may seek to rebut the presumption. The Commission's brief to the Supreme Court describes some general ways that parties might do so: showing that the compensation to the generic firm was for something other than delay; showing that the payment merely reflected litigation costs avoided by the settlement; or identifying some unusual business circumstance such that the payment creates an offsetting competitive benefit. As the brief notes, however, lower courts have had little opportunity to date to consider possible countervailing procompetitive justifications and evidence supporting any such rebuttals is likely to be in the possession of the defendants. Consequently, the specific conditions under which a presumptively anticompetitive settlement might be deemed on balance procompetitive would be a subject for further development in the courts.

18. The Commission's estimated cost savings associated with legislation providing the FTC with additional authorities to prevent parties from settling Hatch-Waxman patent litigation appears to differ from both Office of Management and Budget (OMB) numbers in the President's FY 2014 proposal and previous Congressional Budget Office (CBO) cost savings figures. In fact, there appear to be three entirely different estimates of what, if any, savings there may be.

a. In light of these discrepancies, what effort has the Commission taken to coordinate information sharing of studies, proposals, or assumptions with OMB and CBO to determine the accuracy and validity of estimated cost savings?

FTC staff have had numerous discussions with OMB and CBO about various estimates of the financial impact of pay-for-delay settlements (as noted in response to Question 17, the proposed legislation would not prevent parties from settling Hatch-Waxman patent litigation without compensation). While we cannot be certain of the exact methodology underlying the CBO and OMB estimates, it appears that the discrepancies are largely due to differing objectives. The FTC staff focused on predicting the harm to consumers from existing and anticipated future anticompetitive settlements that delay the entry of lower cost generic drugs.

CBO has produced estimates of the likely budgetary impact of several pieces of legislation related to these settlements. These estimates were prospective, generally predicting the amount of future harm that a law prohibiting pay-for-delay settlements could prevent. The FTC's studies have been retrospective, assessing the current and ongoing costs of settlements that already have been reached. A second difference is that CBO's primary goal was to estimate the

impact of proposed legislation on government expenditures, whereas the FTC's estimate was of the cost to all drug purchasers, private and public.

Like CBO, OMB also estimated the impact on government spending from future pay-for-delay settlements that would be prevented by legislation. But unlike CBO, this estimate included spending both on small molecule (or chemical) and large molecule (or biologic) drugs. Due to data limitations, the FTC's analysis was limited to small molecule drugs.

Consistent with the FTC's analysis, however, both CBO and OMB concluded that these agreements delay competition and significantly harm consumers.

b. What information related to patent settlements has the Commission received from either CBO or OMB?

We have had informal discussions with both CBO and OMB about techniques to estimate the impact of these settlements, but have not received any specific information from them related to patent settlements.

c. Has the Commission received any data or information from other public or private organization on patent settlements upon which it has relied in making assumptions about savings from patent settlements? If so, which entities?

The FTC staff's analysis relied on information from a variety of sources. The most important data came from our review of the settlements themselves, which companies are required to file with the FTC and the Antitrust Division under a provision of the MMA. The settlement data was supplemented with information from the FDA about Paragraph IV challenges by potential generic competitors, and information on the patents covered by the settlements, which is publicly available. The FTC also licensed commercially available sales data from IMS Health on the timing and market consequences of generic entry, as well as the level of expenditures impacted by the settlements.[9]

19. Many in the IP community are concerned by the growing number of instances in which established operating companies transfer their patents to patent assertion entities (PAEs), so that these entities can target the established company's competitors. Some reports suggest that the operating companies often retain a revenue interest in the assertion of the transferred patents, which have included patents that are subject to commitments to license on FRAND terms. Last week, the Commission's directors of both economics and competition said that they support the issuance of a Section 6(b) order to investigate the PAE industry.

[9] *See, e.g.*, C. Scott Hemphill & Bhaven Sampat, *Drug Patents in the Supreme Court*, 339 SCIENCE 1386 (2013) (reporting results of study of the adverse consequences of pay-for-delay settlements).

a. Would you support such an order? If not, why not?

The Commission's Section 6(b) authority is an investigative tool that allows the FTC to conduct studies to support our enforcement and policy missions. The increased litigation activity of PAEs raises a number of difficult questions and a well-designed 6(b) study may be a useful mechanism to explore the harms and efficiencies of PAE activity.

This is an important issue and one that I will be considering and discussing with my fellow Commissioners.

20. Both China and India have draft guidelines or policies that would make it an abuse of intellectual property rights for a dominant company unconditionally and unilaterally to refuse to license its critical intellectual property rights to a competitor who needs access to those rights to compete and innovate. These initiatives are clearly inconsistent with the DOJ's and FTC's Antitrust Guidelines for the Licensing of Intellectual Property, as well as U.S. case law, and could significantly harm innovative American companies operating overseas by undermining their intellectual property.

a. What is the Commission doing about these broad intellectual property abuse policies that are emerging in key foreign jurisdictions?

b. Because unconditional refusals to license strike at the heart of intellectual property rights, are you also working with USTR and the PTO to develop a holistic approach for influencing activities overseas?

c. Are you concerned that open-ended tests for abuse may allow foreign governments to use antitrust policy as a backdoor means for usurping the intellectual property rights of U.S. companies?

The Commission regularly engages with our counterpart agencies in both India (the Competition Commission of India) and China (MOFCOM, NDRC, and SAIC) on antitrust policy and implementation matters, including with regard to intellectual property-related antitrust issues. In our dialogues with the Chinese and Indian agencies, we have regularly emphasized the importance of intellectual property rights to innovation, competition, and consumer welfare, and encouraged them to avoid applying antitrust law as a tool to constrain the legitimate exercise of intellectual property rights.

Intellectual property laws and antitrust laws can work together to promote innovation. We have been advancing this message through a number of mechanisms. The FTC, along with the Department of Justice Antitrust Division, entered into a Memorandum of Understanding with the three Chinese antitrust agencies in 2011 and with India's agency (as well as its parent Ministry) in 2012.

These MOUs confirm our joint commitment to an ongoing dialogue on antitrust matters as well as other cooperative activities related to antitrust enforcement and competition policy, such as the provision of technical assistance. We expect that the MOUs will provide for increased opportunities for engagement on issues involving intellectual property and antitrust.

We, along with the Antitrust Division, have conducted numerous technical assistance workshops in both China and India on antitrust matters, including workshops for China's agencies in 2010 and 2012 on how the United States antitrust agencies apply U.S. antitrust law to conduct involving intellectual property. In addition, we have commented on draft competition laws and regulations in both countries, including those relating to the application of antitrust law to intellectual property.

The FTC also participates regularly in U.S. government inter-agency dialogues involving the USTR and the PTO, as well as the Department of Commerce, the State Department, and others, providing our input and experience regarding competition and intellectual property issues and helping to build a coordinated U.S. government position on intellectual property and antitrust issues in other countries.

21. Some have expressed concern about consumer harm in the prescription eyeglass and contact lens industry. Requiring consumers to obtain a prescription prior to purchasing a product impedes free market forces. Circumstances in which the prescriber is also the retailer of the prescribed product presents a conflict of interest that may lead to anticompetitive behavior. This is especially true when the product is prescribed by brand, locking a consumer into purchasing the brand selected by the prescriber. The Commission has historically taken steps to promote consumer choice in such markets, such as by promulgating the Eye Glass Rule in the late 1970s and the Contact Lens Rule, which implemented the Fairness to Contact Lens Consumers Act, nearly a decade ago. Both of these rules guarantee that upon completion of an eye exam, a consumer has the automatic right to receive copies of his prescriptions without having to make a request, pay a fee, or sign a waiver. These rules provide consumers with the opportunity to exercise that choice when buying contact lenses or eyeglasses.

a. Despite the requirement that patients receive eyeglass prescriptions including all "written specifications. . . necessary to obtain lenses for eyeglasses,"[10] pupillary distance (P/D) measurement is instead typically taken at the store where the eyeglasses are purchased. Now that eyeglasses are available online, it is important that P/D is included in prescriptions given consumers—as required by law—allowing them freedom to purchase eyeglasses where they want, whether at a brick-and-mortar store or online. To help ensure that consumers have this choice, will the Commission issue

[10] 16 CFR 456.1(g).

guidance reminding prescribers of their legal obligation to include on prescriptions all parameters necessary to produce lenses, including the P/D?

I agree that prescription portability gives consumers the ability to comparison shop for optical goods, thereby promoting competition and helping to make markets more responsive to consumer needs and preferences. We remain committed to protecting optical goods consumers by enforcing the Eyeglass Rule, the Fairness to Contact Lens Consumers Act (FCLCA), the Contact Lens Rule, and the FTC Act.

We continue to monitor compliance with these laws and regulations, and to educate businesses and consumers about prescriber obligations and consumer rights, including the requirement that prescriptions include all of the information and parameters necessary to obtain the right lenses. While a substantial amount of guidance already exists regarding the optical goods rules, we will consider the need for additional guidance, especially as the optical goods marketplace evolves and online sales continue to grow.

22. Under your predecessor, the Commission showed leadership in supporting the development of transparency and procedural fairness norms internationally. That work has been done in the OECD and is now being conducted in the ICN. It has also been incorporated into the Trans-Pacific Partnership and there will be an opportunity to do so in the US-EU Transatlantic Trade and Investment Partnership.

a. What do you think about the need for increased transparency and due process in antitrust proceedings globally?

b. Do you plan to continue to work in a similar vein as your predecessors in bringing these issues to forefront of the international antitrust policy debate?

Transparency and due process are essential elements of antitrust agencies' investigative processes. There is increasing recognition at the international level that fair, predictable, and transparent processes facilitate effective agency enforcement. Recognizing the concerns regarding the levels of transparency and due process internationally, promoting the discussion of these issues among antitrust agencies is a priority for the FTC. We will continue to play a key role in supporting and advancing opportunities for such dialogue in our bilateral and multilateral work.

In 2010 and 2011, the OECD's Competition Committee held three roundtable discussions on transparency and procedural fairness. The FTC, together with the Antitrust Division, made written submissions and contributed to the discussions. The OECD summary of the key points from the discussions highlighted examples

of steps that many countries have taken to improve transparency and procedural fairness.

In 2012, the International Competition Network initiated a multi-year project on competition agencies' investigative processes. The FTC, along with the Directorate General for Competition of the European Commission, co-chairs the project, which involves agencies from over 40 jurisdictions along with leading representatives of the business community. The investigative process project addresses: the investigative tools that agencies use to obtain evidence; transparency and predictability; the ability of parties to present evidence and views during an investigation; agencies' internal checks and balances; the role of third parties; and confidentiality and legal privileges. Through this project, ICN member agencies and non-governmental advisors share experiences regarding agency powers and investigational procedures, with an eye towards developing guidance or recommendations. In 2013, the project delivered reports on investigative tools and transparency practices, highlighting common principles and effective practices across many jurisdictions. The FTC led a panel discussion of agency transparency practices at the recent ICN annual conference.

The FTC believes that transparent, predictable, and fair processes are not only beneficial to parties but also lead to better enforcement, informed by substantive input from parties. We will continue to promote the values of fairness, open dialogue with parties, and sound decision-making with our international counterparts and to keep these issues at the forefront of the international antitrust policy agenda.

23. Competition policy advocacy has traditionally been an important part of the Commission's role. As part of this function, the Commission recently sent comments to the Colorado PUC to discourage potential taxi regulations that would have had a negative impact on apps like Uber. You recently said that you hope to make the Commission's "research function" a priority during your term as Chair.

a. Will you commit to devote the Commission's research and advocacy functions to support the development of new entrants to markets that bring competition to consumers and generally lower prices?

Pursuant to our authority under Sections 6(a) and (f) of the FTC Act, the Commission regularly gathers and compiles information concerning certain business activity in order to better promote competition. One of the Commission's primary activities in this area is competition advocacy. This advocacy takes the form of submitting filings in support of competition principles to state legislatures, regulatory boards, and officials; state and federal courts; other federal agencies; and professional organizations. The Commission also organizes public workshops and issues reports on current competition topics.

This kind of research and advocacy is a critical component of the Commission's competition mission, and one that I support.