"ANTITRUST AND INNOVATION: REBALANCING THE SCALE"
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Thank you, Jan, for the kind introduction, and thanks to the IBA for inviting me to share with you my views on the role that antitrust agencies can play in protecting and promoting innovation.

Before I dive into substance, let me briefly introduce the U.S Federal Trade Commission since although I know that you are sophisticated practitioners in your own jurisdictions, I don't expect you to be completely cognizant of our day-to-day mission.

At the FTC, we like to say that we are a "small but mighty agency." We are small in headcount compared with many US agencies, but our portfolio and people cover a lot of ground across broad sectors of the economy. We are the only federal agency with both consumer protection and competition jurisdictions. Our dual mission is to prevent business practices that are anticompetitive, and to stop deceptive or unfair practices that harm consumers. We seek to accomplish our twin goals without unduly burdening legitimate business activity, and we do so through a variety tools given to us by the U.S. Congress, including effective law enforcement; and policy and research development through hearings, workshops, conferences, and reports. This latter role – which I like to call policy thought leadership – has proven particularly important with respect to innovation and its siblings, competition and patents.

Innovation considerations are relevant to our mission in several contexts, and span both our policy and enforcement work. We have a longstanding interest in the intersection of intellectual property and antitrust, both of which can promote innovation. We have worked hard to ensure that our policy pronouncements and enforcement priorities in this important area are grounded in sound legal theory and business reality. Our interest is also bipartisan, held by Commissioners of all political stripes and spanning across various administrations.

In our role as a policy thought leader, we have held numerous workshops and hearings alongside the U.S. DOJ to examine competition, innovation, and patents. Through these efforts, we have obtained input from a wide spectrum of stakeholders -- business representatives from large and small firms, the independent inventor community, leading patent and antitrust organizations and practitioners, consumer groups, and scholars. This extensive effort has led to some important policy pronouncements: the FTC-DOJ joint Intellectual Property Guidelines, as well as the FTC's three seminal intellectual property reports.[1]

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[1] FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf; U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION (2007), *available at* http://www.ftc.gov/reports/innovation/P040101PromotingInnovationandCompetitionrpt0704.pdf; FED. TRADE COMM'N, THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION (2011), *available at* http://www.ftc.gov/os/2011/03/ 110307patentreport.pdf. Our second report, in 2007, was co-written with DOJ.

We have more recently begun to pay close attention to so-called patent assertion entities – known in the vernacular as patent trolls – and the role they might play in enhancing or distorting incentives to innovate in the patent marketplace. We anticipate that, as in the past, our expertise will be put to good use in taking a close look at the activities of patent assertion entities in the near future.[2]

As with our policy work, many of our law enforcement efforts lie at the crossroad between patents, antitrust, and innovation. We have long focused enforcement resources on abuse of patent rights by high-tech firms in the standard-setting process. And like our other work in this space, our efforts here have been bipartisan, beginning 16 years ago in the *Dell Computer*[3] matter, brought during the Clinton administration, and continuing through the *Rambus*[4] and *N-Data* cases, both brought during the Bush administration. More recently, in the *Google/MMI* matter, the current FTC under Democratic chairmanship followed in the footsteps of these earlier cases.[5] I believe the FTC's order in Google/MMI sets a template for the resolution of FRAND-encumbered SEP licensing disputes across many industries, thus reducing the costly (and inefficient) need for companies to amass patents for purely defensive purposes in industries where standard-compliant products are the norm. A clear win for both competition and consumers.

Today, I want to focus on another set of enforcement efforts that illustrates particularly well the role our agency plays at the interface between innovation, patent, and antitrust policy. That is the agency's hard fought campaign against pharmaceutical reverse payments – a practice we at the FTC refer to as "pay-for-delay." As timing would have it, the U.S. Supreme Court recently resolved the issue on terms favorable to our agency – and, more importantly, consumers - in *FTC v. Actavis, Inc.*[6] I can therefore think of no better way to map out my views on the intersection of antitrust and innovation than through the prism of the Court's landmark *Actavis* opinion.

First, let me briefly describe the U.S. public policy context for pay-for-delay to those of you who have not tracked the issue closely. This context is central to understanding the role played by the FTC for more than a decade now in defending competition in the face of pharmaceutical reverse payments.

It's hard to talk about pay-for-delay agreements without first introducing the statutory scheme to which they relate. The scheme, known as the Hatch-Waxman Act, came into force in 1984.[7] As envisaged at that time, the legislation struck a carefully calibrated balance between encouraging

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[2] *See, e.g.,* "FTC's Brill Voices Support for Broad "Patent Troll" Probe", LAW 360, July 31, 2013. http://www.law360.com/articles/461432/ftc-s-brill-voices-support-for-broad-patent-troll-probe; Chairwoman Ramirez, Opening Remarks at the CCIA and AAI Program: Competition Law & Patent Assertion Entities: What Antitrust Enforcers Can Do (June 20, 2013). http://ftc.gov/speeches/ramirez/130620paespeech.pdf.

[3] In the Matter of Dell Computer Corp., FTC Docket No. C-3568, June 17, 1996, *available at* http://www.ftc.gov/opa/1996/06/dell2.shtm.

[4] In the Matter of Rambus Inc., FTC Docket No. 9302, May 14, 2009, *available at* http://www.ftc.gov/opa/2009/05/rambus.shtm.

[5] In the Matter of Motorola Mobility LLC and Google Inc., FTC File No. 121-0120, (July 24, 2013), *available at* *http://www.ftc.gov/os/caselist/1210120/130724googlemotorolado.pdf*.

[6] U.S., 133 S. Ct. 2223 (2013).

[7] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

generic drug entry, and thus generic drug competition, while at the same time increasing brand name incentives to innovative.[8] In the words of the legislation's co-sponsor Representative Henry Waxman, this was the "fundamental balance of the bill."[9] Yet Representative Waxman noted for the Congressional record that the overarching goal of the legislation was to "provide [] low-cost, generic drugs for millions of Americans," resulting in a "significant savings to people who purchase drugs", including the taxpayer.[10]

So what exactly were the contours of this "fundamental balance"? Well, with respect to generic competition, Hatch-Waxman reconfigured the existing generic drug approval process in order to speed up generic drug introduction to the market, while at the same time ensuring that generics were as safe and effective as their branded equivalents. Specifically, the legislation created a new type of drug approval application that allowed generics to rely on the branded drug's studies.[11] The legislation also encouraged generics to challenge invalid or uninfringed patents in court by creating a 180-day marketing exclusivity period for the first generic firm to do so. [12]

But Hatch-Waxman did not only foster generic competition. Congress also recognized the important role played by branded drug innovation in the pharmaceutical marketplace, and the legislation contained provisions aimed at maintaining incentives for this innovation. First, Congress granted an extended term to drug patents to take into account delays in FDA approval that otherwise could cut into the value of a patent on a drug.[13] Second, Congress gave innovative new drugs periods of market exclusivity during which no generic drugs could be approved – regardless of whether they were patented - something that had not existed prior to Hatch-Waxman.[14]

The Hatch-Waxman Act has met with significant success since 1984. On the branded side of the scale, nearly half of the top 20 "blockbuster" drugs in 1997 received patent extensions of at least 2 years.[15] The average period of exclusive brand marketing rose from approximately 9 years before Hatch-Waxman to about 11.5 years in the early 1990s.[16] Thus, the provisions of the Act intended to foster brand drug innovation have worked.

On the generic side of the scale, about 80% of prescriptions written annually in the United States are now filled by generic drugs.[17] Generic prices, on average, are 75% lower than prices for brand-name drugs. Thus, although about 80% of prescriptions are filled by generic drugs generics account for only about 27% of national drug spending.[18] The success of the generic

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[8] Brief of Amicus Curiae Representative Henry Waxman, at 12 (internal citations omitted).
[9] 130 CONG. REC. 24425 (Sept. 6, 1984) (statement of Rep. Waxman).
[10] FTC v. Actavis, Inc.., Brief of Amicus Curiae Representative Henry Waxman, at 14 (citing Cong. Rec. 24425 (Sept. 6, 1984) (statement of Rep. Waxman)).
[11] 21 U.S.C. § 355(j).
[12] 21 U.S.C. § 355(j)(5)(B)(iv).
[13] 35 U.S.C. § 156(c), g(6).
[14] 21 U.S.C. § 355(j)(5)(F)(ii).
[15] Alfred B. Engleberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?* 39 IDEA 489, 426 (1999).
[16] Cong. Budget Office, *HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY,* 39 (1998).
[17] INST. FOR HEALTHCARE INFORMATICS, *The Use of Medicines in the United States: Review of 2011,* 26.
[18] *Id.*

drug industry in the United States stems in significant part from the Hatch-Waxman Act. And generic drug competition has become the primary means through which the U.S. health care system achieves savings in prescription drug spending – which totaled over $260 billion in 2011.[19]

The careful balance struck by the Hatch-Waxman Act has, however, been under significant threat in recent years from reverse payments, or pay-for-delay. Pay-for-delay refers to a practice whereby branded and generic drug companies agree to settle Hatch-Waxman litigation – through which the Act intended to create a pathway for generic drug competition - with a payment from the brand to its generic rival to ensure delayed generic entry. These payments can even exceed the amount the generic could have earned had it entered the market and competed. The threat is therefore that rather than competing with branded drug firms and thus lowering prescription drug prices for consumers, generic firms will instead join forces with brands by sharing in monopoly rents.

Of course, the branded drug firms do not lose out either. In fact, one CEO notoriously announced to analysts that a settlement – which subsequently became the subject of an FTC challenge – had bought the company "[s]ix more years of patent protection. That's $4 billion in sales that no one expected."[20] And that was just *one* drug. Overall, FTC economists have estimated that pay-for-delay costs consumers on average $3.5 billion each year.[21]

When viewed through an antitrust lens, pay-for-delay agreements are straightforward agreements not to compete. Not surprisingly then, in the early days of the practice, plaintiffs met with some success in challenging the agreements under the antitrust laws. In the first litigated case involving pay-for-delay allegations, the practice was found to be *per se* illegal.[22] But over time, courts began to show increasing judicial deference to defendants in pay-for-delay cases, such that by 2005 the practice had become practically *per se* legal. As courts increasingly placed their thumbs on the Hatch-Waxman scales, it was in large part because they gave greater weight to patents than they did to competition. In its 2005 opinion in *Schering Plough*[23] - a case brought by the FTC - the Eleventh Circuit court of appeals found that cases involving patents "[b]y their nature . . . cripple competition . . [and] create an environment of exclusion."[24] The court went on to establish the "scope of the patent" test which, in essence, looked no further than the extent to which the settlement agreements exceeded the scope of the patent's term.[25] Anything within the scope of the patent was deemed beyond antitrust's reach.

Unsurprisingly, decisions like *Schering Plough*, which upset the careful Hatch-Waxman balance, led to an uptick in pay-for-delay settlements, such that the FTC reported a record 40 suspect

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[19] CTRS. FOR MEDICARE & MEDICAID SERVS., *National Health Expenditures 2011 Highlights*, 1-2.
[20] FTC v. Cephalon, Inc., No. 08-cv-2141 (E.D. Pa. complaint filed Feb. 13, 2008), http://www2.ftc.gov/os/caselist/0610182/080213complaint.pdf.
[21] FTC, PAY FOR DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (Jan. 2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.
[22] *In re* Cardizem Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003).
[23] FTC v. Schering-Plough Corp., 402 F.3d 1056 (11th Cir. 2005).
[24] FTC v. Schering-Plough Corp., 402 F.3d 1056, 1065-66 (11th Cir. 2005),
[25] *Id*.

settlements in 2012 alone.[26] The years between 2005 and 2012 were lonely ones for the FTC, as we continued to fight pay-for-delay deals, and were viewed by increasingly hostile opponents as the "pay-for-delay Don Quixote tilting at windmills.[27] Thankfully, however, we did not give up the good fight on behalf of consumers, competition, and ultimately innovation.

Our dogged effort to balance the scales of innovation and competition continued with the *Actavis* case, which we filed in January 2009.[28] The case involved a pay-for-delay settlement over the product Androgel, a topical gel used to treat male testosterone deficiency. In finding against the FTC, the Eleventh Circuit noted in passing that from a brand drug firm's perspective "no rational actor [] would take [the] risk" of investing millions of dollars in drug research and development "without the prospect of a big reward" in the form of a legal right to recoup monopoly profits.[29] In other words, the court erased competition from the congressional Hatch-Waxman equation balancing innovation and competition.

Fortunately, not all courts agreed with the Eleventh Circuit. Shortly after the Eleventh Circuit's *Actavis* decision, the Third Circuit found, in a case involving K-Dur, a drug used to treat low potassium levels, that antitrust did in fact apply to pay-for-delay agreements. In so doing, the Third Circuit attached considerable weight to the "fundamental balance" of the Hatch-Waxman Act. In words that were music to this FTC Commissioner's ears, the *K-Dur* court said that "[j]udicial policy preferences such as those expressed by the Eleventh Circuit should not displace countervailing public policy objectives or, in this case, Congress's determination – which is evident from the structure of the Hatch-Waxman Act and the statements in the legislative record."[30]

The Third Circuit's decision created a clear split among the U.S. circuit courts with respect to pay-for-delay, thus clearing the path to the U.S. Supreme Court. The FTC was cautiously optimistic that the Supreme Court would find in our favor. After all, earlier in the year the Supreme Court had ruled in favor of the agency in the *Phoebe Putney* case (involving a hospital merger) in order to uphold "the fundamental national values of free enterprise and economic competition that are embodied in the federal antitrust laws."[31]

I believe that these "national values" went to the heart of the Supreme Court's *Actavis*[32] decision in which the Court held that antitrust laws apply to pay-for-delay agreements. The Court rejected the scope of the patent test, finding that it conferred "near automatic antitrust immunity"[33] on pay-for-delay settlements. Instead, the Court found that the legality of agreements not to compete between a patent holder and a would-be rival are to be assessed using

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[26] FTC, *AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003,* at 1 (2013).
[27] Ed Silverman, *Tilting at PTD Windmills*, Contract Pharma, (Nov. 10, 2010), available at http://www.contractpharma.com/issues/2010-11/view_pharma-beat/tilting-at-ptd-windmills/.
[28] FTC v. Watson Pharm., Inc., 677 F. 3d 1298 (2012).
[29] *Id.* at 1300.
[30] *In re* K-Dur Antitrust Litig., 686 F. 3d 197, 217 (3d. Cir. 2012).
[31] FTC v. Phoebe Putney Health Sys., Inc., No. 11-1160, 570 U.S. _ (2013), slip op, 7.
[32] FTC v. Actavis, Inc. 133 S. Ct. 2223 (2013).
[33] *Id.* at 2237.

"traditional antitrust factors."[34] These factors include "likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents."[35] In striking this balance, I believe that the Court sought to restore the "fundamental balance" established by Congress in the 1984 Hatch-Waxman Act.

Just days after the *Actavis* opinion issued, DG Comp announced fines totaling 145 million euros in a pay-for-delay case involving the Danish firm Lundbeck. In announcing the decision, Vice-President Almunia observed in his remarks that it is "crucial that European citizens are not deprived of cheaper health bills by anticompetitive practices."[36] He added that "competition by generics is [] a dynamic force which stimulates pharmaceutical companies to continue to invest in research and to develop innovative treatments, as they cannot rely forever on their blockbuster products."[37]

I couldn't have put it better myself.

The FTC's long-standing bi-partisan concerns about pay-for-delay, Vice-President Almunia's focus on the issue, and the U.S. Supreme Court's recent pronouncements all point to some universal principles for law enforcers, industry, private practitioners, and policy makers to keep in mind. Further, these principles are arguably of general application to the interplay between antitrust, patents, and innovation, not just in the pay-for-delay context.

From my standpoint, these principles are as follows.

First, public policy favoring competition matters greatly when weighing these issues. In 2005, the Eleventh Circuit concluded its opinion in *Schering-Plough* by stating that the result it reached "reflects policy."[38] But even a casual reading of the Hatch-Waxman Congressional record shows that the Eleventh Circuit had the public policy exactly backwards. It is clear from the record that Congress certainly intended to reward investment in pharmaceutical innovation through improved and extended patent protection, but there was a quid pro quo. That quid pro quo was a clearer pathway to generic competition, not the ability to buy it off.

Second, once the public policy context is clear - and in the case of pay-for-delay, I would submit that it couldn't have been clearer – the antitrust agencies must be prepared to advocate for the public interest, and do so in the long-term. The antitrust agencies are repeat players in this game, and should act - and react - accordingly. The stakes are simply too high for us not to. All an antitrust agency needs to know is that, in the United States, retail prescription drug expenditures are expected to total $483 *billion* by 2021.[39] Thanks to the FTC's persistence and advocacy to promote pharmaceutical competition, this number will be lower.

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[34] *Id.* at 2231.
[35] *Id.*.
[36] Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines: statement by Vice-President Almunia. SPEECH/13/553, 06.19.2013.
[37] *Id.*
[38] 402 F.3d at 1076.
[39] CTRS. FOR MEDICARE & MEDICAID SERVS., *National Health Expenditure Projections,* 2011-2021, tbl. 2.

Third, it's important for industry and the private bar to understand that if the antitrust agencies won't speak for competition, then who will? You see - with all due respect to my European counterparts - competition is as American as apple pie. Innovation is as American as apple pie too: where would the world be without Thomas Edison and Gordon Moore, Chairman emeritus of Intel and author of Moore's Law? Of course, patents play an important role in fueling the innovation engine. But they are not iron clad property rights beyond the reach of antitrust. The public has a keen interest in competition, and it's our job – the job of antitrust agencies – to ensure that they get it. In other words, we must step up and seek to rebalance the scale.

And the FTC plans to do just that with its continuing efforts against pay-for-delay deals.[40] Our activities will include pursuing matters currently in litigation to which the FTC is a party; monitoring private litigations involving pay-for-delay and where appropriate filing *amicus* briefs; and continuing to investigate pay-for-delay deals that raise anticompetitive concerns. In other words, our work to rebalance the scale between innovation, patent policy, and competition will continue.

Thank you all for listening to my views on the role that antitrust agencies can play in protecting and promoting innovation. I look forward to hearing the panel discussions on this important issue as the day progresses.

[40] *Pay-for-Delay Deals: Limiting Competition and Costing Consumers*: Hearing Before the Subcomm. on Antitrust, Competition Policy and Consumer Rights of the Sen. Comm. on the Judiciary, July 23, 2013. Prepared Statement of the Federal Trade Commission.