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Hearing: "Pay for Delay Deals: Limiting Competition and Costing Consumers"

Before the Senate Judiciary Subcommittee on Antitrust, Competition Policy, and Consumer Rights

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Chairman Klobuchar, Ranking Member Lee, and Members of the Subcommittee:

Good morning. My name is Diane Bieri, and I am a partner in the law firm of Arnold & Porter LLP, appearing today on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA is a non-profit association whose members are the leading research-based pharmaceutical and biotechnology companies. PhRMA's mission is to advocate in support of public policies that encourage the discovery and development of life-saving and life-enhancing medicines. In 2012 alone, PhRMA's members invested an estimated $48.5 billion in discovering and developing new medicines, and they have invested more than $500 billion since 2000.[1] PhRMA member companies also provide significant support to the economy. The U.S. biopharmaceutical sector employs more than 810,000 workers, supports a total of 3.4 million jobs across the country, and contributes more than $789 billion in economic output, when direct, indirect and induced effects are considered.[2] PhRMA appreciates the invitation to participate in today's hearing on pharmaceutical companies' settlements of patent disputes.

This testimony first describes the larger context that gives rise to decisions by innovator and generic companies to settle some patent disputes by reaching agreements that provide for generic product entry prior to patent expiration and consideration flowing from the innovator to the generic company. We explain the importance of patent protection to pharmaceutical innovation, the incentives established by Congress for generics to challenge innovators' patents, and the reality that innovators must retain the ability to settle patent litigation in order to realize the full value of their patents. We then discuss the recent Supreme Court decision in *Federal Trade Commission v. Actavis*[3], which resolved the important threshold question of the appropriate legal lens through which to evaluate these patent settlement agreements. Finally, we address the legislation that would impose a presumption of illegality on all such agreements. We respectfully submit that there is no reason to depart from basic antitrust principles in order to apply such a presumption to these settlements, particularly where the Supreme Court so recently rejected the idea and confirmed that the traditional antitrust rule of reason analysis should apply.

I. Patent Settlements Between Innovator and Generic Pharmaceutical Companies in the Hatch-Waxman Context Can Promote Innovation and Generate Significant Savings for Consumers

[1] PhRMA, *Pharmaceutical Industry 2013 Profile* 30, 31 fig. 10 (2013), *available at* http://phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf (hereinafter *2013 Profile*).

[2] Battelle Technology Partnership Practice, *The Economic Impact of the Biopharmaceutical Industry* (July 2013).

[3] *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

A. Patent Protection Is An Essential Building Block for Pharmaceutical Innovation

In terms of their impact on personal and public health, pharmaceutical innovations surely stand among the most important advances in recent history. According to two University of Chicago economists, "[o]ver the last half century, improvements in health have been as valuable as all other sources of economic growth combined."[4] New medications have played a significant role in those societal gains. However, the innovative treatments that PhRMA member companies bring to health care providers and patients do not come easily or cheaply.

A research-based company seeking to bring a new drug product to market goes through a time-consuming and expensive process to secure FDA approval of a New Drug Application, or "NDA." It requires, on average, more than $1 billion and 10 to 15 years to bring a single new medicine from laboratory through FDA approval to the marketplace.[5] For every 5,000 to 10,000 compounds that enter the pipeline, only one receives approval, and even medicines that reach clinical trials have only a 16% chance of being approved.[6]

Innovator companies are able to undertake this costly, time-consuming research despite the relatively low chance of success only because patent protection offers at least the possibility of recovering their investment during the period of patent exclusivity. One economist has noted that "[w]ithout a well-structured system of patent protection, neither the research pharmaceutical industry nor the generic industry would be able to grow and prosper, as the rate of new product introductions and patent expirations would decline significantly."[7] Indeed, without patent protection, an estimated 65 percent of pharmaceutical products would never have been brought to market.[8]

B. The Hatch-Waxman Act Creates Incentives That Fuel Patent Challenges On Most Innovator Drugs, With Very Little Regard for the Generic's Chances of Success in Patent Litigation

Patents provide incentives for investment because, traditionally, they have been given due respect in the law. By Congressional enactment, an issued patent is afforded the presumption of validity.[9] In the antitrust context, courts have held that antitrust laws

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[4] Kevin Murphy & Robert Topel, *Measuring the Gains from Medical Research: An Economic Approach*, 4 (2003).

[5] *2013 Profile*, *supra* note 1, at 32, 38 fig. 10.

[6] *Id.* at 32.

[7] Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT'L ECON. L. 849, 853 (2002).

[8] Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI., 173, 175 (1986).

[9] 35 U.S.C. § 282.

should be interpreted not to supplant legitimate patent rights.[10] Consistent with the antitrust laws, a patent holder may exclude others from producing a patented article, or may grant limited licenses, within the defined scope and term of the patent.[11]

Even as we recognize the critical role that patents and other intellectual property protections play in incentivizing pharmaceutical innovation, we should also acknowledge that generic medicines play an important part in our healthcare system. The Drug Price Competition and Patent Term Restoration Act of 1984 (better known as "the Hatch-Waxman Act") was designed to balance the interests of innovative and generic companies; it granted certain IP protections to innovators to preserve incentives for innovation, and at the same time, created a pathway for and incentives to bring generic drugs to market. The Act allows generic drug makers to obtain regulatory approval to market generic drugs using a radically less expensive and faster process, the Abbreviated New Drug Application, or "ANDA," essentially piggy-backing on the innovator's NDA. In contrast to the huge sums spent on bringing an innovator drug to market, the cost of preparing and filing an ANDA is about $1 million.[12] Firms pursuing this approach must show only that their generic product has the same active ingredients and is bioequivalent to a reference drug that previously has been approved. Further, a company can seek approval from the FDA to market the generic drug before the expiration of a patent relating to the innovator drug by certifying that the patent in question is invalid or not infringed by the generic product (a "Paragraph IV certification").[13]

From the standpoint of the generic company, one of the most attractive features of the Hatch-Waxman Act is the ability to initiate a challenge to the patent without incurring any liability in doing so. The Act includes a provision that allows companies to develop information to submit to FDA without these activities constituting patent infringement.[14] Filing a Paragraph IV certification, in and of itself, constitutes an act of patent infringement that enables the innovator to bring a patent infringement suit.[15] The generic challenger is not required to bring products to market as a prerequisite to the challenge, and therefore, the patent holder does not sustain any damages.[16] Normally,

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[10] *See Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) ("[T]he patent laws . . . are *in pari materia* with the antitrust laws and modify them *pro tanto*.").

[11] *See, e.g.*, *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456 (1940).

[12] Emily Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 262 (2012).

[13] 21 U.S.C. § 355(j)(2)(vii).

[14] 35 U.S.C. § 271(e)(1).

[15] *Id.* § 271(e)(2)(A).

[16] *See* Gerald Sobel, *Consideration of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Act Settlements*, 20 FED. CIR. B.J. 47, 51 (2010) ("Unlike the usual patent case, there are ordinarily no damages claims against the generic because Hatch-Waxman forces the litigation to occur in the period prior to marketing by the generic. As a result, no sales or profits

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the generic drug company's chief risk in challenging a patent is that it will spend money on legal fees and FDA filings that it may not recover (or may recover only after patent expiration) if it loses the litigation. Further, the Hatch-Waxman Act grants 180 days of marketing exclusivity to the first generic company (or companies) to challenge an innovator's patents and gain FDA approval for its product.[17]

Ultimately, this combination of factors in the Hatch-Waxman Act creates significant incentives for generic drug companies to challenge patents even where the patent holder is highly likely to prevail in court. The result of these skewed incentives under the Hatch-Waxman framework is stunning. In its study of authorized generic drugs, the Federal Trade Commission stated that "for a drug with [annual] brand sales of $130 million, a generic that does not anticipate [authorized generic] competition will expect a patent challenge to be profitable if it has at least a 4 percent chance of winning . . . ."[18] But even this statistic vastly understates the magnitude of generic drug companies' skewed incentives. Most innovator drugs have annual sales well over $130 million. According to a recent analysis, for almost 90% of innovator drug sales (measured in dollars), a first-filing generic challenger balancing upside gain under Hatch-Waxman against downside risk limited to litigation costs can justify filing a Paragraph IV certification if it believes it has a *1.3% chance of success* in a patent case.[19]

When a drug with significant sales is involved, it is economically rational for a generic company to challenge the patent even if there is virtually no reason to think that the patent is infirm.[20] Statistics regarding the number of Paragraph IV certifications prove this point. According to research by Duke University economist Henry Grabowski, 75% of innovative medicines faced a Paragraph IV patent challenge in 2008, up from just 17% in 1995.[21] Moreover, given the incentives to challenge patents, it is not unusual for drugs to attract multiple generic challengers.[22]

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are lost by the patentee to the generic. While patent infringement suits are often settled by compromise of a damages claim, that vehicle is typically not available in Hatch-Waxman cases.").

[17] 21 U.S.C. § 355(j)(5)(B)(iv).

[18] Fed. Trade Comm'n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* at iii n.7 (2011), *available at* http://1.usa.gov/0GSilg.

[19] Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, CPI ANTITRUST CHRONICLE 2 (2012), *available at* http://bit.ly/VMMTTS.

[20] *See* Morris, *supra* note 12, at 262 ("In effect, the Hatch-Waxman Act actually makes pharmaceutical patents weaker than any other type of patent by making challenges to pharmaceutical patents easier and more attractive than for any other type of patent.").

[21] H.G. Grabowski et al., *Evolving Brand-name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 HEALTH AFFAIRS 2157, 2157-66 (2011).

[22] *See* Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 520-21, n.177 (2007)("Highly profitable

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C. The Ability To Settle Patent Litigation On Terms Acceptable To Both Parties Is A Crucial Component of Patent Enforcement

Pharmaceutical companies, like all patent owners, are entitled to assert their patents in court. Nevertheless, Hatch-Waxman litigation imposes significant burdens on innovator companies. First and foremost, it puts at risk the billion-dollar-plus investment that an innovator company has made in bringing a new medicine to market, as well as the company's ability to fund new technological breakthroughs. In addition, the innovator must incur the many direct and indirect costs of litigation. Such costs include the non-negligible amount of time spent by firm employees preparing the case, producing documents, working with lawyers on litigation strategy, being deposed, traveling for lawsuit-related events, testifying at trial, and observing legal proceedings.[23] Discovery also imposes risks, including loss of control of sensitive competitive information and harm to business relationships.[24] An ongoing litigation may tax an innovator's resources in more subtle ways as well. For example, "[t]he length of patent litigation may mak[e] marketing, research and development, and other business planning difficult while the outcome of the case remains uncertain."[25]

Because of the considerable costs and risks of litigation, the law strongly favors resolution of litigation through compromise.[26] In addition to the costs to the parties, litigation entails social costs in the expenditure of judicial resources overseeing litigation that can take up to a decade, through trial and eventual appeal.[27] Settlements resolve disputes with far less risk, time and expense than litigation. They ease the burden on the already taxed court system. And they provide certainty for all parties, allowing companies to focus on running their business rather than litigating disputes.

The benefits offered by settlements certainly extend to patent litigation, which is a notoriously costly and unpredictable process. Regardless of an innovator's own confidence in the strength of a patent, "[n]o one can be certain that he will prevail in a

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drugs with tremendous therapeutic utility should and do generally attract multiple generic challengers."); Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 377, n.59 (2010); *see also* Smith & Gleklen, *supra* note 19 (showing FTC data on incentives for generic firms that do not enjoy the benefit of 180-day exclusivity).

[23] Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698, 703-704 (2004).

[24] *Id*. at 704.

[25] *Id.* at 704.; *see also Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075-1076 (11th Cir. 2005) (recognizing that "[p]atent litigation breeds a litany of direct and indirect costs").

[26] See, e.g., *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994).

[27] *See id*.; *see also D. H. Overmyer Co. v. Loflin*, 440 F.2d 1213, 1215 (5th Cir. 1971).

patent suit."[28] The risk that a judge or jury will not understand the technical complexities of modern patents is inherent in any patent litigation.

Just as the right to litigate is vital to realizing fully a patent's protective purpose, so too is the right to resolve that litigation through a negotiated settlement. Faced with the substantial uncertainty inherent in all patent litigation, many pharmaceutical innovators quite reasonably choose to settle challenges to their patents, just as patent holders do in the vast majority of cases. Indeed, across all patent cases, 95% are resolved by settlement.[29] For innovators, the prospect of being forced to subject their most successful patents to the vagaries of litigation with limited options available for settlement could chill the massive investments they make in developing and marketing life-saving medications. The impact of restrictions on patent settlements could be particularly significant for smaller pharmaceutical companies whose entire market value often rests on protecting the patent rights that support a handful of products. For these companies, "the uncertainty of litigation can be untenable -- even when the company has no doubt about the validity, scope, and term of its patents."[30] The ability to settle Hatch-Waxman litigation is thus essential to preserving the incentives to innovate.

D. Settlements are a Procompetitive Byproduct of the Hatch-Waxman Regulatory Framework

Consideration flowing from the innovator company to the alleged infringer is not a sign of an anticompetitive scheme. To the extent settlements following a Paragraph IV challenge differ from settlements in ordinary infringement litigation, those differences reflect the special features of the Hatch-Waxman Act. Because Hatch-Waxman litigation, by Congress's design, is triggered when the Paragraph IV certification is filed (and deemed an act of infringement) but before any damages would be incurred, the usual form of consideration from the patent holder to the infringer—declining to collect a portion of the damages—does not yet exist.

Antipathy toward Hatch-Waxman settlements appears to be driven by a belief that patent owners are willing to settle litigation primarily because the patents in question are weak. There is virtually no support for that contention. In reality, statistics show that for the 171 Paragraph IV cases litigated to court decisions between 2000 and 2009,

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[28] *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J.); *see also Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003) ("Given the assymetries of risk and large profits at stake, even a patentee confident in the validity of its patent may pay a potential infringer a substantial sum in settlement.").

[29] Marc G. Schildkraut, *Patent-Splitting Settlements & the Re-verse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1048 (2004).

[30] CHARLES-ANDRÉ BROUWERS ET AL., BOSTON CONSULTING GROUP, EMERGING BIOPHARMACEUTICAL COMPANIES: ENSURING A FAVORABLE ENVIRONMENT FOR CONTINUED INNOVATION, (2011).

innovator companies prevailed in 52% of them.[31] More recent data on cases decided between 2009 and 2012 support these findings[32], and in 2012 alone, innovator companies won 72% of Hatch-Waxman cases.[33] Faced with the uncertainties inherent in litigation and a roughly 50% probability of winning, it is no surprise that both parties often prefer to settle rather than litigate to final judgment.

The adverse consequences of deterring innovation by declaring all settlements where consideration flows from the innovator to the generic to be presumptively unlawful would be severe. Benefits from innovation are far more valuable to consumers than static price competition.[34] To take just one very specific example, since 1980, life expectancy for cancer patients has increased by about three years, with 83% of the gains attributable to new treatments, including medicines.[35]

In addition to preserving incentives to innovate, Hatch-Waxman settlements, including those with consideration flowing to the alleged infringer, also benefit patients and payers by facilitating entry of generic competitors prior to the expiration of innovators' patents. Of the 22 generic drugs that entered the marketplace in 2011, 17 of the entries resulted from the settlement of patent infringement litigation.[36] One generic manufacturer estimated that the early generic entry permitted by its settlements alone "removed 138 years of monopoly protection" and saved consumers $128 billion.[37] Indeed, despite claims that patent settlements with consideration would cripple the ability of generic drugs to enter the market, the generic industry estimates that the amount of consumer savings due to generic drugs has hit new record highs in each of the past ten years, in substantial part due to the ability of parties to arrive at litigation settlements.[38] Limiting

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[31] Royal Bank of Canada (RBC) Capital Markets Corp. Report, *Industry Comment: Pharmaceuticals: Analyzing Litigation Success Rates* (2010).

[32] Gregory Glass, *Legal Defenses and Outcomes in Paragraph IV Litig.*, 10 J. GENERIC MEDS. 4 (2013) (finding that innovator companies won 54% of Paragraph IV cases litigated to court decisions between 2009 and 2012).

[33] PwC, *2013 Patent Litig. Study: Big Cases Make Headlines While Patent Cases Proliferate* (2013).

[34] See Mark A. Lemley, *A New Balance Between IP & Antitrust*, 13 SW. J. LAW & TRADE AM. 237, 248 (2007).

[35] E. Sun, et al., *The Determinants of Recent Gains in Cancer Survival: An Analysis of the Surveillance, Epidemiology and End Results (SEER) Database*, 26 J. OF CLINICAL ONCOLOGY suppl. 15 (2008).

[36] GPhA, *Savings: 1.1 Trillion over Ten Years: Generic Drug Savings in the U.S.* at 7 (2012), *available at* http://www.gphaonline.org/media//cms/IMSStudyAug2012WEB.pdf.

[37] *See* Teva Pharms. USA, Press Release, *Teva Pharmaceuticals Issues Statement in Response to Federal Trade Commission Claims on Patent Settlements* (June 24, 2009), *available at* http://tinyurl.com/TevaStatement.

[38] Paul Bender, et al., *S. 214's Inappropriate Interference With the Fundamental Right to Settle Litigation*, 9-10 (March 2013), *available at*

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settlement options could result not only in fewer settlements, but ultimately in fewer patent challenges because generics will face greater risks in challenging patents.

II. The Supreme Court's Decision in *FTC v. Actavis* Establishes a Definitive Legal Standard for Evaluating the Potential Antitrust Implications of Certain Types of Patent Settlements

In June, the U.S. Supreme Court issued a decision in *FTC v. Actavis, Inc.*, bringing clarity to the antitrust treatment of Hatch-Waxman settlements involving consideration flowing from innovator companies to generic competitors.[39] Prior to the Court's decision, several circuit courts of appeal had split on the issue of the appropriate lens through which to evaluate these agreements.[40]

Prior to the *Actavis* decision, three courts of appeals--the Eleventh Circuit[41], the Second Circuit[42], and the Federal Circuit[43]--had adopted a "scope of the patent" approach. Under the scope of the patent analysis, a settlement that fell within the exclusionary potential of the patent would essentially be immune from antitrust attack unless the patent was obtained by fraud or the underlying litigation was a sham.[44] This approach focused on the need to give full effect to the exclusionary power of a presumptively valid patent.

In contrast, the Third Circuit had held that settlements containing a transfer of value from the innovator company to the generic were presumptively illegal and that courts reviewing such agreements should proceed under a "quick look approach."[45] The "quick look" approach, which was advocated by the FTC as an amicus in the Third Circuit, effectively mimics a statutory presumption of illegality. It rests on the premise that, barring convincing evidence from defendants of the procompetitive effects of the settlement agreement, all so-called reverse payment settlements should be found to violate the antitrust law.[46]

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http://www.gphaonline.org/media/cms/S._214_Is_Harmful_and_Inappropriate_Legislation_3-22_.pdf

[39] *Actavis,* 133 S. Ct. at 2231, 2237-38.

[40] *Id.* at 2230.

[41] *See FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012).

[42] *See Joblove v. Barr Labs (In re Tamoxifen Citrate Antitrust Litg.)*, 466 F.3d 187, 202 (2d Cir. 2006).

[43] *See Ark. Carpenters Health & Welfare Fund v. Bayer AG (In re Ciprofloxacin Hydrochloride Antitrust Litg.)*, 544 F.3d 1323, 1336 (Fed. Cir. 2008).

[44] *See Actavis*, 133 S. Ct. at 2230 (citing *Watson*, 677 F.3d at 1312 and describing Second Circuit and Federal Circuit approaches as "similar").

[45] *See In re K-Dur Antitrust Litig.*, 688 F.3d 197, 214-218 (3d Cir. 2012).

[46] *See Actavis*, 133 S. Ct. at 2237.

In *Actavis,* the Court rejected both the scope of the patent and the "quick look" approaches and opted instead for the more conventional rule of reason analysis.[47] The rule of reason analysis, the Court explained, strikes the proper balance between the goals of the patent system and those of the antitrust laws.[48] Under the rule of reason approach, courts weigh a multitude of factors including "likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations in the circumstances"[49] as well as specific industry context[50]. The Court stated that under the rule of reason analysis the FTC may be able to prove its prima facie case without litigating the validity of the patent, given that "the size of the unexplained reverse payment can provide a workable surrogate for the patent's weakness."[51] The Court also noted, however, that when evaluating reasonableness, "'the quality of proof required should vary with the circumstances.'"[52] There is nothing in the majority opinion that suggests that the strength of the patent is irrelevant or that prohibits an antitrust defendant from arguing that the payment had not harmed competition because the patent holder would have won the underlying patent litigation, thus preventing generic entry until patent expiration. The rule of reason analysis, the Court concluded, thus allows trial courts to "structure antitrust litigation so as to avoid, on one hand, the use of antitrust theories too abbreviated to permit proper analysis, and on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed . . . ."[53]

Significantly, the Court unanimously rejected the presumption of illegality standard proposed in *Actavis* by the FTC. Writing for the majority, Justice Breyer concluded that so-called reverse payment patent settlements are too complex to meet the criterion for applying a presumptive rule.[54] Thus, the Court held that a presumption of illegality is not appropriate and the FTC must prove its case as in traditional rule of reason cases.[55] The dissenting Justices would have adopted the scope of the patent approach but joined the majority in inexorably, if implicitly, rejecting the FTC's proposed presumption of illegality standard.[56]

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[47] *Id.* at 2231, 2237-38.

[48] *Id.* at 2231 (citing *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948)).

[49] *Id.* at 2231.

[50] *Id.* at 2237.

[51] *Id.* at 2236-37.

[52] *Id.* at 2237-38 (citing *Cal. Dental Ass'n. v. FTC*, 526 U.S. 756, 780 (1999).

[53] *Id.* at 2237-38.

[54] *Id.*

[55] *Id.*

[56] *Id.* at 2243 (Roberts, C.J., dissenting) ("Our cases establish that antitrust law has no business prying into a patent settlement so long as that settlement confers to the patent holder no

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III. Legislation To Establish a Presumption Of Illegality for So-Called Reverse Payment Settlements Is Unnecessary and Inconsistent With Longstanding Principles of Antitrust and Patent Law

A. The Supreme Court Has Confirmed That Patent Settlements Should Be Evaluated On a Case-By-Case Basis

The question of the appropriate legal standard to apply when evaluating settlements where the generic enters before patent expiration and the innovator provides something of value to the generic company has been exhaustively debated in the courts, in both chambers of Congress and among a host of antitrust practitioners and economists for more than a decade. By the time the *Actavis* case reached the Supreme Court, the debate had largely crystallized into a binary dispute, with the FTC and its amici advocating that virtually all such settlements should be presumed unlawful, and the innovator and generic companies and their amici arguing that these settlements should only be considered anticompetitive if their terms exceeded the scope of the innovator's presumptively valid patent. This debate was squarely before the Court -- it was, unquestionably, at the heart of the *Actavis* case.

The Supreme Court accepted briefs, heard oral arguments, considered both sides' views and wrote a comprehensive opinion. It addressed the question of the appropriate legal standard head-on and concluded that neither the presumption of illegality nor the scope of the patent test should apply. Instead, as described above, the Court chose the traditional rule of reason standard. The Court provided some guidance on what the rule of reason analysis ought to involve. But ultimately, by refusing to draw any bright lines in favor of or against these types of settlements, the Court determined that, as with most antitrust cases, lower courts should have the flexibility to review the details and likely consequences of the agreements on a case by case basis.

In light of the Supreme Court's unambiguous holding, we now have, for the first time, a national legal standard that will apply to all so-called reverse payment settlements. While it is not the standard either side advocated in the *Actavis* case, the rule of reason is familiar territory for courts, agencies and litigants alike. Moreover, innovator and generic companies will take this standard into account as they attempt to resolve their patent disputes going forward. Under these circumstances, there is no need for legislation to ensure that courts will apply the same legal standard and analyze the competitive effects of these types of settlement agreements in a comprehensive fashion.

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monopoly power beyond what the patent conferred--unless, of course, the patent was invalid, but that . . . is a question of patent law, not antitrust law.").

Moreover, legislation to reverse the Supreme Court's rejection of a presumption of illegality is not warranted. The Court's decision in this regard is fully consistent with well-established precedent. The rule of reason, after all, is "the prevailing standard of analysis" when evaluating agreements for potential anticompetitive impact.[57] In contrast, as described further below, treating these settlements as presumptively illegal would represent a marked and unjustified departure from both antitrust and patent law principles.

B. There Is No Justification for Applying A Presumption of Illegality To Certain Patent Settlements

The Supreme Court has stated unequivocally that so-called reverse payment settlements should not be presumed to be unlawful.[58] Specifically, the Court followed its previously established principle that conduct may be condemned using a "quick look" presumption of illegality only when "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999). In *California Dental*, the Court held that "quick look" treatment was inappropriate because the challenged restrictions "might plausibly be thought to have a net procompetitive effect, or possibly no effect at all on competition." *Id*. at 771.

Likewise, there is no basis to believe that settlements that include consideration flowing from the innovator to the generic company inevitably have an anticompetitive effect. Patent holders often prevail in infringement litigation, and any settlement that allows early entry by an infringer that would otherwise be off the market for the life of the patent has a net *procompetitive* effect regardless of the presence of a transfer of value from the patent holder to the infringer.

This is not a hypothetical argument. The cases reveal concrete examples of pharmaceutical patent owners that settled with some generics with arrangements that have been characterized as reverse payments and early entry and then litigated with other generics and prevailed, keeping these later infringers off the market. For example, after the settlement at issue in the Second Circuit's *Cipro* case, the patent was repeatedly upheld as valid in other Hatch-Waxman litigation, meaning that absent the settlement there likely would have been no early entry by any generic at all. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 519-520 (E.D.N.Y. 2005) (summarizing results of litigation where Bayer defeated two generic companies' validity challenges on summary judgment and overcame another generic's validity challenge after a nine-day bench trial). The same outcome occurred after the

[57] *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 49 (1977) (citing *Standard Oil Co. v. U.S.*, 221 U.S. 1 (1911)).

[58] *Actavis*, 133 S. Ct. at 2237 (noting that the complexities involved in analyzing the competitive effects of these settlements "lead us to conclude that the FTC must prove its case as in other rule-of-reason cases").

settlements at issue in *In re Tamoxifen Citrate Antitrust Litigation* were reached, 466 F.3d 187 (2d Cir. 2006), where the patent was repeatedly upheld as valid. *See Zeneca Ltd. v. Novapharm Ltd.*, No. 9601364, 1997 WL 168318(Fed. Cir. Apr. 10, 1997); *Zeneca Ltd. v. Pharmachemie B.V.*, No. CIV.A.96-12413-RCL, 2000 WL 34335805 (D. Mass. Sept. 11, 2000). Similarly, after the FTC blocked a so-called "reverse payment" settlement between Bristol-Myers Squibb (BMS) and Apotex involving the drug, Plavix, BMS took the patent case to trial and won. *Sanofi-Synthelabo v. Apotex, Inc.*, 492 F. Supp. 2d 353, 397 (S.D.N.Y. 2007). These examples demonstrate that settlements with consideration flowing from an innovator company to a generic firm can have procompetitive effects by permitting generic entry that would not have occurred in the absence of the settlement.

C. Applying a Presumption of Illegality Would Turn the Well-Established Presumption of Patent Validity On Its Head

Finally, the concept of a presumption of illegality for certain types of patent settlements ignores the statutory directive that all patents "shall be presumed valid."[59] An issued patent is presumed valid until it is adjudicated otherwise. As the Supreme Court recently recognized, in the face of similar arguments in a different context, neither allegations of "bad" or "weak" patents nor purported flaws in the patent system justify adoption of a legal standard that ignores the Congressional intent of the presumption of patent validity.[60]

Quite simply, the Hatch Waxman Act was intended to give generic drug companies the incentive to challenge patents, which it clearly does. The Supreme Court's decision in *Actavis* permits an antitrust review of each and every settlement using the traditional antitrust analysis of the rule of reason announced almost a century ago in *Chicago Board of Trade*.[61] There is no need to replace this approach with an industry-specific presumption of illegality that would further undermine the value of patents.

Thank you again for the chance to speak with you today. We welcome your interest in this issue, and look forward to working with members of the Subcommittee and others in Congress as you address these and other important policy issues relating to innovation and access to medicines.

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[59] 35 U.S.C. § 282.

[60] *See Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2251-52 (2011) (policy arguments concerning "bad" patents cannot override Congress' intent that the presumption of a patent's validity can be overcome only by clear and convincing evidence).

[61] *Chicago Board of Trade v. United States*, 246 U.S. 231 (1918).