No. 12-416

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION,
PETITIONER,
v.
WATSON PHARMACEUTICALS, INC. ET AL,
RESPONDENTS.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR AARP, AMERICAN MEDICAL ASSOCIATION, NATIONAL LEGISLATIVE ASSOCIATION FOR PRESCRIPTION DRUG PRICES AND U.S. PUBLIC INTEREST RESEARCH GROUPS AS AMICI CURIAE IN SUPPORT OF PETITIONER

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STATEMENTS OF INTEREST OF AMICI CURIAE[1]

Amicus Curiae AARP is a nonpartisan, nonprofit organization dedicated to addressing the needs and interests of people aged fifty and older. AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Affordable prescription medication is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has experienced an increasing rate of prescription drug use. From 2005 to 2008, sixty-five percent of persons age sixty-five and older used three or more prescriptions within the past month, versus just thirty-five percent who did so from 1988 to 1994. Centers for Disease Control and Prevention, *Health, United States, 2011*, Table 99 (May 2012), *available at* http://www.cdc.gov/nchs/data/hus/hus11.pdf#list tables.

Significantly, in a 2005 AARP survey, one in four Americans, ages 50 and older, who took a

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[1] In accordance with Supreme Court Rule 37.6, Amici Curiae state that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than amici, their members and counsel have made a monetary contribution to the preparation or submission of this brief. Parties were timely informed with 10-days notice of the intent to file this amicus brief, and the written consents of the parties to the filing of this brief have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.2.

prescription drug in the past five years said they did not fill a prescription written by their doctor in the past two years. Cost was reported as the main deterrent. Linda L. Barrett, AARP, *Prescription Drug Use Among Midlife and Older Americans* 2 (2005), a*vailable at* http://assets.aarp.org/rgcenter/health /rx_midlife_plus.pdf. Since prescription drug spending has skyrocketed over the last decade and a half, and national health expenditures on prescription drugs have quadrupled, AARP supports the Medicare Part D prescription drug benefit, and continues to advocate for lower prescription drug costs for all consumers. *See, e.g.,* AARP, *Rx PriceWatch Report*: *Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Medicare Beneficiaries 2005 to 2009* (March 2012), *available at* http://www.aarp.org/content/dam/aarp /research/public_policy_institute/health/rx-pricewatc h -march-2012-AARP-ppi-health.pdf.

Amicus Curiae American Medical Association ("AMA") is the largest professional association of physicians, residents and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all United States physicians, residents and medical students are represented in the AMA's policy making process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health. The AMA joins this brief because of its concern that pay-for-delay agreements extend patent monopolies excessively. These agreements artificially inflate health care costs and obstruct physicians'

ability to treat their patients with necessary medications. The AMA believes that pay-for-delay agreements undermine the Hatch-Waxman Act's compromise between the interest in spurring innovation through the patent system and the interest in fostering competition through the development of generic drugs.

Amicus Curiae National Legislative Association for Prescription Drug Prices ("NLARx") is a national nonprofit, nonpartisan organization of state legislators who support policies to reduce prescription drug prices and expand access to affordable medicines; and has promoted policies since 2000 to expand access to generics drugs and increase competition in the market place.

Amicus Curiae U.S. PIRG, the federation of state Public Interest Research Groups ("PIRGs"), works on behalf of American consumers, through public outreach to advocate for affordable health care and prescription drugs. U.S. PIRG's mission is to deliver result-oriented public interest activism that protects consumers, encourages a fair, sustainable economy, and fosters responsive, democratic government. U.S. PIRG regularly advocates before state and federal regulators and legislators on both consumer protection and competition policy issues in the payment system marketplace.

SUMMARY OF ARGUMENT

The ruling below that exclusion payment agreements are with few exceptions *per se* lawful under Section 1 of the Sherman Act will have a devastating impact on American consumers if left to stand. Prescription drug spending in the United States has skyrocketed over the last two decades. Competition from generic drugs is the most effective means of slowing the spiraling cost of pharmaceuticals.

Generics typically sell for a fraction of the cost of their branded counterparts. When generics enter the market they quickly capture the majority of unit sales. Overall generics have saved consumers $1.07 trillion between 2002 and 2011. Press Release, Generic Pharmaceutical Association, New Study Finds Use of Generic Prescription Drugs Saved Consumers and the U.S. Health Care System $1 Trillion over Past Decade (Aug. 2, 2012), *available* at http://www.gphaonline.com/media/press-releases/2012/new-study-finds-use-generic-prescription-drugs-sav ed-consumers-and-us-heal.

Recognizing the clear consumer benefit that accompanies generic drug competition, Congress sought to speed up generic entry by enacting the Hatch-Waxman Act (Public Law 98-417).

Brand-name firms have used exclusion agreements to delay entry of generics by an average of seventeen months and to terminate patent challenges that would otherwise generate *billions* of

dollars in consumer savings. Delaying the entry of affordable generic drugs not only prevents competition, but the lack of low cost treatment options reverberates throughout the entire health care system. Even for those patients who are insured but who are on fixed or limited incomes, having a generic option is often the difference between having access to a health care treatment and not having any treatment option at all. Economists at the FTC estimate that, if nothing changes, exclusion payment settlements will cost consumers $35 billion over the next ten years. Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 2 (Jan. 2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. If *Watson* remains controlling law, the patent-challenge provisions of the Hatch-Waxman Act would be eviscerated, and American consumers would be left to pay the price.

REASONS FOR REVERSING THE ELEVENTH CIRCUIT

INTRODUCTION

The ruling below that exclusion payment agreements are with few exceptions *per se* lawful under Section 1 of the Sherman Act will have a devastating impact on American consumers if left to stand. According to the Eleventh Circuit, the presumption of validity enjoyed by patents, 35 U.S.C. § 282, entitles patentees to pay alleged infringers not to contest validity and to stay out of the market so long as the settlement falls within the exclusionary

scope of the patent. *FTC v. Watson Pharm.*, 677 F.3d 1298, 1309, 1312 (2012).

Competition from generic drugs is one of the most effective means of slowing the spiraling cost of pharmaceuticals. Generics typically sell for one-third to one-fourth the cost of their branded counterparts and quickly capture the majority of unit sales, saving consumers literally hundreds of millions of dollars on a blockbuster drug such as Solvay's AndroGel™. If generic entry had occurred it would have significantly reduced the cost of the product and generics would have captured a significant share of the market. See AndroGel™ Sales Data (Nov. 2012), http://www.drugs.com/stats/AndroGel.

I. THE ELEVENTH CIRCUIT'S DECISION THAT EXCLUSION PAYMENTS ARE *PER SE* LAWFUL DEFEATS THE PROTECTIONS OF THE HATCH-WAXMAN ACT AND UNDERMINES ENFORCEMENT OF THE SHERMAN ACT

Prescription drug spending in the United States has skyrocketed over the last two decades from $40 billion in 1990 to over $320 billion in 2011. Kaiser Family Foundation, *Prescription Drug Trends* 1 (Sept. 2008), *available at* http://www.kff.org/rxdrugs/upload/3057_07.pdf; Press Release, IMS Health, Breakthrough Treatments, Fewer Doctor Office Visits, Reduced Use of Medicines Impact U.S. Healthcare in 2011, According to IMS Study (Apr. 4, 2012), *available at* http://www.imshealth.com/portal/site/ims/menuitem.d248e29c86589c9c30e81c0

33208c22a/?vgnextoid=81c63fc68b876310VgnVCM10000076192ca2RCRD.

The rate of increase in many brand-name prescription drug prices continues to accelerate and outpace inflation. For example, in the twelve-month period ending in March 2010, the price of brand name prescriptions most widely used by Medicare beneficiaries increased by 9.7 percent, the highest rate of increase observed since AARP began tracking these prices in 2002. AARP, *Rx Watchdog Report: Brand Name Drug Prices Continue to Climb Despite Low General Inflation Rate* 1 (May 2010), *available at* http://assets.aarp.org/www.aarp.org_/articles/health/207961rxwatchdog0510.pdf.

When clinically appropriate for a patient, using a generic drug over a branded project can be the most effective way to slow the spiraling cost of pharmaceuticals. Generics typically sell for a fraction of the cost of their branded counterparts and quickly capture the majority of unit sales, thus having saved consumers over $1.07 trillion between 2002 and 2011. Press Release, Generic Pharmaceutical Association, New Study Finds Use of Generic Prescription Drugs Saved Consumers and the U.S. Health Care System $1 Trillion over Past Decade (Aug. 2, 2012), *available* at http://www.gphaonline.com/media/press-releases/2012/new-study-finds-use-generic-prescription-drugs-saved-consumers-and-us-heal. A recent survey found that the prices of the most commonly used brand-name medications increased by 13.3%, while prices for generic medications fell 21.9% for the 12 months ending

September 2012. Press Release, Express Scripts, Express Scripts Publishes Inaugural Drug Trend Quarterly (November 28, 2012), *available at* http://phx.corporate-ir.net/phoenix.zhtml?c=69641&p=irol-newsArticle&ID=1762296&highlight. The gap in growth rates in the cost between branded drugs and generics is the largest recorded since Express Scripts began collecting this data in 2008.

When patients and their prescribers who may have a lower-cost generic option available select instead higher-cost branded drugs, this "generates unnecessary medical expenditures, the costs of which are borne by the public in the form of higher copayments, increased health insurance costs, and higher Medicare and Medicaid expenses," according to research published in January 2013. Eric G. Campbell et al., *Physician Acquiescence to Patient Demands for Brand-Name Drugs: Results of a National Survey of Physicians*, JAMA Internal Medicine, January 7, 2013, *available at* http://archinte.jamanetwork.com/article.aspx?articleid=1555818.

Recognizing the clear consumer benefit that accompanies generic drug competition, Congress sought to speed up generic entry by enacting the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355, commonly referred to as the Hatch-Waxman Act, which "institutionalize[d] and provide[d] incentive for a system of attacks on presumptively valid patents" by generic manufacturers. *Innovation and Patent Law Reform: Hearings on H.R. 3285, H.R. 3286, and H.R.*

3605 Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the H. Comm. on the Judiciary, 38th Cong. 2d Sess., Part 1, at p. 444 (1984).

In creating the incentive to challenge patents, Congress was not seeking to enrich the generic drug manufacturers. Hatch-Waxman challenges were supposed to be vehicles for earlier entry of generic drugs into the marketplace, thus giving consumers earlier access to lower-priced prescription drug alternatives. H. R. Rep. No. 98-857, pt. 1 at 1 (1984), *reprinted* in 1984 U.S.C.C.A.N. 2647 (explaining that the purpose of the Hatch-Waxman Act "is to make available more low cost generic drugs by establishing a generic drug approval procedure"). Indeed, generics make up nearly seventy percent of drugs prescribed today, whereas generics constituted only twelve percent of prescription drugs dispensed prior to the passage of the Hatch-Waxman Act. *See* AARP, *Rx Watchdog Report*, Vol.6, Issue 4 at 4 (May 2009), *available at* http://www.aarp.org/content/dam/aarp/aarp_foundation/litigation/amicus_brief_pdfs/Louisiana_Wholesale_Drug_Co_v_Bayer.pdf. *See also*, Food and Drug Administration, *Protecting America's Health Through Human Drugs: Greater Access to Generic Drugs* (Jan. 2006), *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm.

The rise of exclusion payment agreements, however, has had a drastic effect on generic drug entry prior to patent expiration. Brand-name firms have used exclusion agreements to delay entry of

generics by an average of seventeen months and to terminate patent challenges that would otherwise generate *billions* of dollars in consumer savings. Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 2 (Jan. 2010), available at http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. See also data from the AARP Public Policy Institute examining brand-name drug price increases for drugs closest to patent expiration. AARP, *Rx Price Watch Report: Retail Prices for Widely Used Brand Name Drug Increase Considerably Prior to Generic Competition* 4-6 (March 2011), *available at* http://www.aarp.org/health/drugs-supplements/info-08-2010/rx_price_watch.html.

Under the exclusion payment agreement here, for example, Solvay paid the generic competitors Watson, Par and Paddock between $31-42 million annually in exchange for the generics' agreement to stay out of the market for 9 of the remaining 15 year life of the AndroGel™ patent. In other words, Defendants' agreement ensured that consumers would have to wait another 9 years to buy lower-priced generic AndroGel™. This delayed generic entry is the antithesis of what Congress intended when it enacted the Hatch-Waxman Act. See *In re Barr Labs., Inc.,* 930 F.2d 72, 76 (D.C. Cir. 1991) ("Congress sought to get generic drugs into the hands of patients at reasonable prices-fast.").

II. INCREASED USE OF EXCLUSION PAYMENTS PREVENTS COMPETITION AND HARMS CONSUMERS

At the end of 2008, brand name drug manufacturers were attempting to block generic entry on products with roughly $90 billion in pharmaceutical sales. Fed. Trade Comm'n, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 2 (Jan. 2010), available at http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf [hereinafter FTC, Pay-for-Delay]. Delaying the entry of affordable generic drugs not only prevents competition, but the lack of low cost treatment options reverberates throughout the entire health care system. The price of a brand drug can be prohibitive for uninsured patients who do not have help covering the cost of their prescription drugs. Even for those patients who are insured but who are on fixed or limited incomes (but who may not qualify for Medicare Part D's low-income subsidy), having a generic option is often the difference between having access to a health care treatment and not having any treatment option at all.

The enormous consumer gains resulting from generic entry are well documented. The Federal Trade Commission (FTC) has cited that successful patent challenges to just four major brand-name drugs (Prozac, Zantac, Taxol and Platinol) have saved consumers more than $9 billion. Prepared Statement of the Federal Trade Commission before the Committee on the Judiciary of the United States Senate, *Anticompetitive Patent Settlements in the*

Pharmaceutical Industry: The Benefits of a Legislative Solution at 4 (Jan. 17, 2007), *available at* http://www.ftc.gov/speeches/leibowitz/070117Anticompetitivepatentsettlements_senate.pdf. Had exclusion payments been permissible, none of these consumer savings likely would have occurred.

In the midst of Barr Laboratories' challenge to the patents protecting Eli Lilly's drug Prozac, for example, Barr stated that it would settle only if the settlement included an exclusion payment of at least $200 million. *See* Bethany Mclean, *A Bitter Pill*, Fortune, Aug. 13, 2001, at 5. Lilly refused the demand because, as acknowledged by Lilly's CEO, "such a settlement violated antitrust laws, and it isn't morally right." *Id.* So Barr continued litigating the case and ultimately obtained a judgment invalidating the Prozac patents. The resulting early entry of generic Prozac saved consumers an estimated $2.5 billion. *See* Comment of the Generic Pharm. Ass'n in Support of Citizen Pet. Docket No. 2004P-0075/CP1 3 (May 21, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00003-vol1.pdf.

Allowing exclusion payments that "grant monopoly privileges to the holders of invalid patents," *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-01 (1993), results in lost consumer health and welfare greatly disproportionate to the relatively modest costs of patent litigation. *See* Herbert Hovenkamp et al., *Balancing Ease & Accuracy In Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 717 (Feb. 2004).

Those increased costs may ultimately harm the well-being of patients and the delivery of healthcare. Patients may skip doses of prescribed medicines due to their high cost. Barrett, *supra*. For the same reason, they may also simply decline to have a prescription filled. This phenomenon, sometimes known as "abandonment," has been on the rise since 2010. Patients with private health insurance abandoned nearly one in ten new prescriptions for brand-name drugs in the second quarter of 2010. This increase comes as patients see a rise in the cost of prescription medications. Kaiser Family Foundation, *Prescription Drug Costs: Background Brief* (Dec. 2012), *available at* http://www.kaiseredu.org/Issue-Modules/Prescription-Drug-Costs/Background-Brief.aspx. As an example, a mother in Montana who arrived at a pharmacy to discover that medication for her depression and her son's asthma would cost her $335 despite her private insurance. The mother abandoned both prescriptions before purchasing a cheaper, alternative medication for her son. Jonathan D. Rockoff, *More Balk at Cost of Prescriptions*, Wall St. J., Oct. 12, 2010 (citing data from a Wolters Kluwer Pharma Solutions study), *available at* http://online.wsj.com/article/SB10001424052748703927504575540510224649150.html.

A Consumer Reports survey found that 18% of people with prescription drug coverage declined to fill prescriptions in 2012 because of cost, up from 16% in 2011, and 45% of people without prescription drug coverage skipped a refill due to costs, up from 27% in

2011. Consumer Reports, *Sluggish Economy Forces Americans to Cut Corners to Pay for Medications: Those without Prescription Drug Coverage Nearing Crisis Point* (Sept. 2012), *available at* http://www.consumerreports.org/cro/2012/09/sluggish-economy-forces-americans-to-cut-corners-to-pay-for-medications/index.htm.

When patients do not obtain necessary treatment because no financially feasible options are available, conditions left untreated can worsen and may result in a higher cost of care over time. Statement for the Record, American Medical Association before the Subcomm. on Commerce, Trade, and Consumer Protection for the House Committee on Energy and Commerce, *Impact of "Pay-for-Delay" Settlements On Patient Access to Affordable Generics and Overall Health Care System Costs* (April 13, 2009). Economists at the FTC estimate that, if nothing changes, exclusion payment settlements will cost consumers $35 billion over the next ten years. FTC, Pay-for-Delay, *supra*, at 2; *see also* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 650 (2009) (estimating that exclusion payments have already cost consumers over $12 billion).

For this reason, one of the FTC's top priorities has been stopping "pay-for-delay" agreements between brand-name pharmaceutical companies and generic competitors that delay the entry of lower-priced generic drugs into the market. FTC Chairman Leibowitz noted that, "[a]greements to eliminate

potential competition and share the resulting profits are at the core of what the antitrust laws proscribe, and for that reason the Commission believes strongly that these pay-for-delay settlements are prohibited under the antitrust laws." Prepared Statement of The Fed. Trade Comm'n before the U.S. Senate Comm. On the Judiciary, Subcommittee on Antitrust, Competition Policy and Consumer Rights, *How the Federal Trade Commission Works to Promote Competition and Benefit Consumers in a Dynamic Economy*, (June 9, 2010) *available at* http://www.ftc.gov/os/testimony/100609dynamiceconomy.pdf.

Unfortunately, these pay for delay agreements are increasing. An FTC report to Congress released this month found that the number of pay for delay agreements increased by over 40% in the year ending September 2012 excluding generic competition for drugs accounting for over $8.3 billion in sales annually. Bureau of Comp., Fed. Trade Comm'n, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*: *Overview of Agreements Filed in Fiscal Year 2012* 1 (Jan. 2013), *available at* http://www.ftc.gov/os/2013/01/130117mmareport.pdf.

If Watson remains controlling law and allows exclusion payments between brand-name and generic firms through patent litigation settlements, these settlements will increase and consumers will continue to pay more for vital drugs and the patent-

challenge provisions of the Hatch-Waxman Act will be eviscerated.

III. THE ELEVENTH CIRCUIT'S DECISION THAT EXCLUSION PAYMENTS ARE *PER SE* LAWFUL WILL NOT PROTECT INCENTIVES TO INNOVATE

Congress passed the Hatch-Waxman Act with the explicit purpose "to speed the introduction of low-cost generic drugs to market," *Caraco Pharm. Labs. Ltd.* v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012). The Hatch-Waxman Act employs two mechanisms to facilitate generics' entry to market. First, it provides an avenue for an accelerated regulatory review by providing for a generic to demonstrate its bioequivalency to another drug that has successful navigated the onerous New Drug Application ("NDA") process. 21 U.S.C. § 355(j)(2)(A)(ii) and (iv) (2006). Second, the Hatch-Waxman Act provides the generic with a mechanism for quickly resolving a patent infringement lawsuit by a brand manufacturer. 21 U.S.C. § 355(j)(2)(A)(vii)-(viii) (2006). These mechanisms invite generic competition and innovation with the stated goal of leading to low-cost generic products becoming available for consumers.

Some may argue that the Eleventh Circuit's rule of *per se* legality is necessary to provide the incentive for generic firms to innovate and attempt to enter the market. But this argument presupposes that generic firms will not challenge a patent unless it is able to settle the litigation *with an exclusion*

payment. Such an argument is inconsistent with the facts, public policy, and law.

First, earlier in the last decade, when the law condemned exclusion payments, branded and generic firms entered into numerous settlements without exclusion payments. Exclusion payments are a relatively recent development, and there was significant generic entry and innovation before these payments occurred. Moreover, parties frequently settle patent infringement litigation without extending the terms of the settlement to include exclusionary terms. *See, e.g.*, Herbert Hovenkamp et al., *Balancing Ease & Accuracy In Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 712-14 (Feb. 2004). In fact, in 2012 more than 70% of ANDA settlements did not include an agreement by the generic firm to delay entry into the market in exchange for compensation from the brand firm. Bureau of Comp., Fed. Trade Comm'n, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in Fiscal Year 2012* 2 (Jan. 2013), available at http://www.ftc.gov/os/2013/01/130117 mmareport.pdf. This suggests that concerns that reverse payments are needed for product innovation are overblown, and instead that reasonable, pro-consumer settlements that do not include exclusion agreements are still attainable.

Second, the drafters of the Hatch-Waxman Act intended that generics would foster competition through patent challenges, and specifically provided

other mechanisms to promote innovation. *See* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 43-45 (Oct. 2009) (discussing patent term extensions, non-patent-based exclusivity, and the automatic 30-month stay of FDA approval).

Third, a rule of *per se* legality distorts the incentive system. Rather than a system that provides incentives and rewards for inventing non-infringing products or successfully invalidating patents, a rule of *per se* legality encourages a generic firm to sue to settle and secure the exclusion payment. The Third Circuit recognized this paradigm and reasoned that it is "logical to conclude that the *quid pro quo* for [a reverse] payment was an agreement by the generic firm to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (2012) (cert pending). If these payments are effectively scrutinized under the antitrust laws, the incentives would be restored to what Congress intended – a spur to generic entry.

It is important not to confuse the idea of incentivizing generic innovation with incentivizing generic challenges to brand patents. The two are not the same. Generic investment in challenging the validity or infringement of brand patents will benefit consumers only if it leads to additional entry. If, however, a generic's Abbreviated New Drug Application ("ANDA") application is little more than a litigation tactic to secure a settlement, then the practice in question does not promote innovation and

is not beneficial for society. Instead, it is a mere transfer of supracompetitive profits from the brand to the generic at the expense of the consumer welfare contemplated by the Hatch-Waxman Act.

CONCLUSION

The judgment of the Court of Appeals should be reversed.

January 29, 2013

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