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 OF *AMICUS CURIAE* REPRESENTATIVE HENRY A. WAXMAN IN SUPPORT OF PETITIONER

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In re Cardizem CD Antitrust Litig.,
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In re Ciprofloxacin Hydrochloride Antitrust Litig.,
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In re K-Dur Antitrust Litig.,
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Mova Pharm. Corp. v. Shalala,
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In re Tamoxifen Citrate Antitrust Litig.,
466 F.3d 187 (2d Cir. 2006), *cert. denied*,
551 U.S. 1144 (2007) 20, 21

TorPharm, Inc. v. Thompson,
260 F. Supp. 2d 69 (D.D.C. 2003), *aff'd sub nom. Purepac Pharm. Co. v. Thompson*,
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Warner-Lambert Co. v. Apotex Corp.,
316 F.3d 1348 (Fed. Cir. 2003) 24

Woods Exploration & Producing Co. v. Aluminum Co. of Am., 438 F.2d 1286
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H.R. Rep. No. 98-857, Pt. 2 (Aug. 1, 1984) 13, 14
S. Rep. No. 107-167 (June 20, 2002) 16, 17, 24
130 Cong. Rec. 24425 (Sept. 6, 1984) 12
130 Cong. Rec. 24427 (Sept. 6, 1984) 14
149 Cong. Rec. S8190 (June 19, 2003) 15
149 Cong. Rec. S8193 (June 19, 2003) 15, 18
149 Cong. Rec. S8194 (June 19, 2003) 18

Other:

CBO, *Cost Estimate: S. 27, Preserve Access to Affordable Generics Act* (2011), http://aging.senate.gov/publications/s27.pdf 10

CMS, *National Health Expenditure Projections 2011-2021*, www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2011PDF.pdf 4, 5

CMS, *National Health Expenditures 2011 Highlights*, www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf 4, 6

CMS, *National Health Expenditures Tables*, www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/tables.pdf 5

Express Scripts, *Drug Trend Quarterly* (Nov. 2012), http://digital.turn-page.com/i/95262 8

FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (2013), www.ftc.gov/os/2013/01/130117mmareport.pdf 10

FTC, *FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market* (Jan. 17. 2013), www.ftc.gov/opa/2013/01/mmarpt.shtm ... 11

GAO, *Drug Pricing: Research on Savings from Generic Drug Use* (2012), www.gao.gov/assets/590/588064.pdf 4, 7, 9

GAO, *PRESCRIPTION DRUGS: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004* (Aug. 2005), www.gao.gov/new.items/d05779.pdf.. 5

GAO, *Prescription Drugs: Trends in Usual and Customary Prices for Commonly Used Drugs*, (2011), gao.gov/assets/100/97284.pdf. 6, 7

IMS Inst. for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2011* (2012), www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf..... 4, 7, 8, 9

Aaron S. Kesselheim, Michael A. Fischer & Jerry Avorn, *Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects on Medicaid Spending, 25* Health Affairs (2006), http://content.healthaffairs.org/content/25/6/1637.full.html 10

Stephen W. Schondelmeyer & Leigh Purvis, *Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Medicare Beneficiaries 2005 to 2009* (2012), www.aarp.org/content/dam/aarp/research/public_policy_institute/health/rx-pricewatch-march-2012-AARP-ppi-health.pdf..... 6, 7

INTEREST OF *AMICUS CURIAE*[1]

Representative Henry A. Waxman is a member of the United States House of Representatives representing California's 33rd Congressional District. Representative Waxman has served in the House since 1974. He is currently Ranking Minority Member of the House Energy and Commerce Committee, the jurisdiction of which includes health care policy, regulation of prescription drugs and the pharmaceutical industry, and consumer protection, all of which are implicated by this case.

Representative Waxman has long been a leader on health issues, including health insurance reform, Medicare and Medicaid coverage, tobacco, AIDS, nursing home quality standards, women's health research and reproductive rights, and the availability and cost of prescription drugs. Most significantly for purposes of this case, Representative Waxman was one of the two principal sponsors of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly referred to as the Hatch-Waxman Amendments. That legislation, and the policies it reflects, is directly at issue in this case. Representative Waxman was also a leading advocate of the reforms to the Hatch-Waxman Amendments included in the Medicare Prescription Drug, Im-

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[1] This brief was not authored in whole or in part by counsel for a party. No one other than *amicus curiae* or his counsel made a monetary contribution to preparation or submission of this brief. A letter from counsel for the petitioner consenting to all amicus briefs is on file with the Clerk, as are letters from counsel for each of the respondents consenting to the filing of this brief.

provement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

Representative Waxman files this brief because he believes that judicial decisions shielding reverse-payment agreements between brand-name and generic drug manufacturers from stringent antitrust scrutiny stand as a significant obstacle to the fulfillment of the important public policies embodied in the Hatch-Waxman Amendments and their 2003 revisions. Those pieces of legislation sought to speed the introduction of generic competitors to brand-name drugs, not to facilitate anticompetitive agreements among pharmaceutical companies to keep generics off the market. Representative Waxman wishes to provide the Court with additional information about the policies underlying these important pieces of legislation to assist it in resolving this case.

SUMMARY OF ARGUMENT

At issue in this case is the authority of the Federal Trade Commission (FTC) to enforce the antitrust laws against anticompetitive agreements between brand-name and generic drug manufacturers that result in the withholding of generic drugs from the market. Facilitating the entry of generic drugs into the marketplace is critical to containing the cost of health care, as prices of brand-name prescription drugs continue to rise at much faster rates than other health expenses. Agreements that delay entry of generic drugs are antithetical to the policies behind both the Hatch-Waxman Amendments and their 2003 revisions, which were "designed to speed the introduction of low-cost generic drugs to market" by "facilitate[ing] the approval of generic drugs as soon as pa-

tents allow." *Caraco Pharm. Labs. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).

In concluding that settlement agreements under which generic manufacturers are paid to keep their drugs off the market are virtually immune from antitrust scrutiny, the Eleventh Circuit and other courts that have agreed with it have turned the policy of the underlying federal legislation on its head. The Hatch-Waxman Amendments' intention was to promote competition by generic drug manufacturers. The possibility of agreements such as those involved in this case is an unintended consequence of the legislation. Hatch-Waxman was never intended to foster such agreements, still less to render the antitrust laws' prohibition of anticompetitive agreements among competitors inapplicable to agreements allowing generic manufacturers to exact a portion of a brand-name manufacturer's monopoly profits in return for withholding entry into the market.

ARGUMENT

I. Rising Prices and Expenditures for Brand-Name Drugs Burden Both Consumers and the Federal Budget.

The escalating cost of health care in the United States—and, in particular, of prescription drugs—is an enormous, nationwide problem. According to the federal Centers for Medicare and Medicaid Services (CMS), total annual health spending in this country reached $2.7 trillion in 2011, with about 10%, or $263 billion, representing retail prescription drug spend-

ing.[2] Total spending on prescription drugs, including drugs administered in hospital settings, is considerably higher but difficult to quantify because costs are not broken out. The IMS Institute for Healthcare Informatics estimated in April 2012, however, that total prescription drug spending in 2011 reached $320 billion.[3] Over the next decade, expenditures are expected to rise still further, with total health spending reaching nearly $4.8 trillion and retail prescription drug sales exceeding $483 billion.[4]

This ever-increasing spending on prescription medications burdens not only consumers but also, increasingly, the federal government. With the implementation in 2006 of the Medicare Part D prescription drug benefit, federal expenditures on prescription drugs jumped substantially. By 2010, federal spending on prescription drugs reached approximately $84 billion, with Medicare accounting for nearly $60 billion of the total, and the rest primarily attributable to Medicaid and military spending.[5] By 2021, CMS esti-

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[2] CMS, *National Health Expenditures 2011 Highlights* 1-2, www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf.

[3] IMS Inst. for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2011* 19 (2012), www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf.

[4] CMS, *National Health Expenditure Projections 2011-2021*, Table 2, www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2011PDF.pdf.

[5] GAO, *Drug Pricing: Research on Savings from Generic Drug Use* 6 (2012), www.gao.gov/assets/590/588064.pdf.

mates that Medicare prescription drug spending will have more than doubled, to almost $136 billion; Medicaid prescription drug spending will exceed $52 billion; and other federal prescription drug spending will reach $18 billion, for a total of more than $200 billion.[6]

Over the past several decades, increases in health costs have substantially outstripped general inflation rates, with the result that health expenditures have markedly increased as a share of gross domestic product (GDP). Health expenditures rose from 5.2% of GDP in 1960, to 7.2% in 1970, 9.2% in 1980, 12.5% in 1990, and 13.8% in 2000, then jumped to 17.9% by 2010.[7]

Meanwhile, prescription drug spending increased significantly as a percentage of overall health spending. According to the Government Accountability Office (GAO), "Prescription drug spending as a share of national health expenditures increased from 5.8 percent in 1993 to 10.7 percent in 2003 and was the fastest growing segment of health care expenditures."[8] Since then, prescription drug spending has increased roughly in line with overall health spending, so that prescription drug expenditures continue to represent

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[6] CMS, *National Health Expenditure Projections*, *supra*, Table 11.

[7] CMS, *National Health Expenditures Tables*, Table 1, www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/tables.pdf.

[8] GAO, *PRESCRIPTION DRUGS: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004* 1 (2005), www.gao.gov/new.items/d05779.pdf.

about 10% of the nation's still growing expenditures on health care.[9]

Not only has overall spending on prescription drugs continued to increase even in the face of economic conditions that have suppressed demand, but prescription drug *prices* have continued to rise faster than the prices of medical services generally, and much faster than overall consumer prices. A 2011 GAO study found that from 2006 through the first quarter of 2010, prices for 100 commonly prescribed drugs rose by a total of nearly 30%, with annual increases ranging from a low of 5.4% to a high of 8.1%.[10] Meanwhile, the medical consumer price index, which measures the inflation rate for all medical services and goods, rose between 2.8% and 4.7% annually over the same period, while the overall inflation rate reflected in the urban consumer price index averaged only 2.2%.[11] An AARP study of a broader range of over 500 prescription drugs found that while drug price increases lagged a bit behind the general inflation rate in 2005, 2006, and 2007, drug prices continued to rise after the economy went into recession, so that the rate of increase in drug prices exceeded that of the overall urban consumer price index in 2008.[12]

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[9] CMS, *National Health Expenditures 2011 Highlights*, *supra*, at 2.

[10] GAO, *Prescription Drugs: Trends in Usual and Customary Prices for Commonly Used Drugs*, at 16-17 (2011), gao.gov/assets/100/97284.pdf.

[11] *Id.* at 16.

[12] Stephen W. Schondelmeyer & Leigh Purvis, *Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Medicare Beneficiaries 2005 to 2009*, at 2 (2012),

(*Footnote continued*)

By 2009, the rate of inflation of drug prices hit 4.8%, even as the urban consumer price index *deflated* by .3%.[13]

These prescription drug price increases, and the resulting increases in overall prescription drug expenditures, are entirely attributable to the prices of brand-name drugs. Generic prices, on average, are about 75% lower than prices for brand-name drugs.[14] Thus, although about 80% of prescriptions written annually in the United States are filled by generic drugs, generics account for only about 27% of national prescription drug spending.[15]

Moreover, brand-name and generic drug prices have headed in opposite directions over the last several years: Brand-name prices have risen sharply, while generic drug prices have *fallen*. The GAO, for example, found that the brand-name drugs in its 2011 study rose in price by a total of 37.7% from 2006 to the first quarter of 2010, with annual increases ranging from 7.1% to 9.6%.[16] Meanwhile, the generic drugs studied fell in price in every year studied, with a total drop in price over the study period of 9.9%.[17] Similarly, AARP's analysis showed that generic drugs fell in

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www.aarp.org/content/dam/aarp/research/public_policy_institute/health/rx-pricewatch-march-2012-AARP-ppi-health.pdf.

[13] *Id.*

[14] GAO, *Drug Pricing: Research on Savings from Generic Drug Use*, *supra*, at 1.

[15] IMS, *The Use of Medicines in the United States*, *supra*, at 26.

[16] GAO, *Prescription Drugs: Trends in Usual and Customary Prices*, *supra*, at 18-19.

[17] *Id.*

price every year from 2005 through 2009, dropping by 7.8% in 2009 while brand-name prices rose by 8.3%.[18]

A more recent survey by the pharmacy benefits management company Express Scripts indicates that these trends are intensifying: Over the nearly five-year period from 2008 through the third quarter of 2012, Express Scripts found that prices for a commonly prescribed market basket of brand-name drugs had increased by a whopping 63%, compared with an increase of only 9% in the overall consumer price index for the same period.[19] Prices for a market basket of commonly used generics, by contrast, had fallen 39% over the same period, with a nearly 22% drop in 2011 alone.[20]

Indeed, pricing of brand-name drugs has in recent years been so high as to produce increases in overall drug prices and spending even in the face of falling overall demand for prescription drugs attributable to economic difficulties, falling generic drug prices, and shifts in prescriptions from brand-name to generic drugs.[21] As AARP concluded, "the continued growth in drug prices for the brand and specialty market baskets has more than offset the still substantial decreases in retail prices for generics."[22]

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[18] Schondelmeyer & Purvis, *Rx Price Watch Report*, *supra*, at 3, 5.

[19] Express Scripts, *Drug Trend Quarterly* 15 (Nov. 2012), http://digital.turn-page.com/i/95262.

[20] *Id.*

[21] *See* IMS, *The Use of Medicines in the United States*, *supra*, at 19-26.

[22] Schondelmeyer & Purvis, *Rx Price Watch Report*, *supra*, at 5.

The disparities between generic and brand-name drug prices underscore the critical importance of promoting the introduction of generic drugs at the earliest date consistent with the legitimate rights of brand-name drug manufacturers under our patent laws and the Food, Drug, and Cosmetic Act. Estimates of the savings realized by the substitution of generic for brand-name drugs exceed $1 trillion for the twelve-year period from 1999 to 2010, with savings of $157 billion in 2010.[23] For Medicare Part D alone, estimated savings from the substitution of generic for brand-name drugs were $33 billion in 2007.[24]

A large portion of the amount saved through the use of generics is directly attributable to the expiration of patent protection for brand-name drugs. In 2011, one estimate of the "dividend" to the nation of savings resulting from the expiration of prescription drug patents was $14.9 billion, and the total over the five years from 2007 to 2011 was approximately $65 billion.[25]

These savings, however, are not realized when brand-name drug manufacturers extend their monopolies beyond the period in which they may legitimately claim patent protection (often by making dubious claims of patent protection for features of their products other than their basic design and use). One study concluded, for example, that delays ranging from 21 to 33 months in the availability of generic substitutes

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[23] GAO, *Drug Pricing: Research on Savings from Generic Drug Use*, *supra*, at 10.

[24] *Id.*

[25] IMS, *The Use of Medicines in the United States*, *supra*, at 19.

for three drugs—delays partly attributable to invalid claims of patent protection after earlier patents had expired—cost the Medicaid program alone more than $1.5 billion between 2000 and 2004.[26]

Pay-for-delay settlements that allow brand-name drug manufacturers to preserve their monopolies regardless of the actual validity of their patent claims thus have the potential to impose substantial costs on consumers and the federal government and to aggravate the serious national problem of excessive prescription drug prices and spending. The Congressional Budget Office (CBO) has conservatively estimated that eliminating pay-for-delay settlements postdating November 2009 (while leaving in place earlier settlements) could save $11 billion over the ten-year period from 2012-2021.[27] The CBO's estimate, however, preceded the availability of data indicating that the number of potential pay-for-delay settlements has increased markedly: The FTC has reported a record 40 such settlements in fiscal year 2012 alone.[28] The FTC

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[26] Aaron S. Kesselheim, Michael A. Fischer & Jerry Avorn, *Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects on Medicaid Spending, 25* Health Affairs 1637, 1643 (2006), http://content.healthaffairs.org/content/25/6/1637.full.html.

[27] CBO, *Cost Estimate: S. 27, Preserve Access to Affordable Generics Act* 5-6 (2011), http://aging.senate.gov/publications/s27.pdf.

[28] FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, at 1 (2013), www.ftc.gov/os/2013/01/130117mmareport.pdf.

currently estimates that the annual cost to consumers of pay-for-delay settlements is $3.5 billion.[29]

II. The Hatch-Waxman Amendments Were Intended to Protect Consumers Against Excessive Drug Costs by Enhancing Competition Between Brand-Name and Generic Drug Manufacturers.

The Hatch-Waxman Amendments, enacted in 1984, attempted to address the problem of high prescription drug prices by encouraging competition against brand-name drugs from generic drugs. The legislation established a procedure whereby a manufacturer could obtain accelerated FDA approval of a generic drug by filing an "abbreviated new drug application," or ANDA, and demonstrating the drug's equivalence to an already-approved brand-name drug. 21 U.S.C. § 355(j). Moreover, the generic manufacturer could obtain permission to begin marketing a drug within the term of an existing patent by certifying either that the patent was invalid or that it would not be infringed by manufacture of the generic. *Id.* § 355(j)(2)(A)(vii)(IV). The legislation further encouraged introduction of generic versions of patented drugs by granting the first generic manufacturer to file a challenge to a patent on a brand-name drug a 180-day period of marketing exclusivity for the generic drug, beginning on the earlier of the first day of commercial marketing, or the date of a judicial deci-

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[29] FTC, *FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market* (Jan. 17. 2013), www.ftc.gov/opa/2013/01/mmarpt.shtm.

sion holding the patent on the drug to be invalid or not infringed. *Id.* § 355(j)(5)(B)(iv).

Of course, the Hatch-Waxman Amendments did not abrogate the patent rights of manufacturers of brand-name drugs. Rather, they sought to speed resolution of disputes over the validity and scope of drug patents by requiring a company filing an ANDA to give notice to the patent-holder, and by providing a 45-day period within which the patent-holder could obtain a 30-month stay of the FDA's approval of the ANDA if it filed a patent infringement action against the generic manufacturer. *Id.* §§ 355(j)(2)(B) & (j)(5)(B)(iii). The Amendments further required that any such infringement action be expedited. *Id.* § 355(j)(5)(B)(iii). Absent an infringement action, the Amendments directed the FDA to approve a proper ANDA within 180 days of filing, with the approval effective immediately. *Id.* § 355(j)(5)(A).

The Amendments contained other provisions aimed at encouraging innovation in the development of prescription drugs by granting 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, *see* 35 U.S.C. § 156, and by granting innovative new drugs periods of market exclusivity during which no generic drugs could be approved, *see* 21 U.S.C. §§ 355(c)(3)(D) & (j)(4)(D). The Amendments thus sought to achieve a careful balance between their objectives of protecting legitimate patent rights and encouraging generic competition. *See* 130 Cong. Rec. 24425 (Sept. 6, 1984) (statement of Rep. Waxman) (describing "fundamental balance of the bill").

Notwithstanding the Amendments' concern for legitimate patent rights, the purpose of their provisions concerning generic drugs was clear: "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." H.R. Rep. No. 98-857, Pt. 1, at 14 (June 21, 1984). The Amendments reflected the concern that then-existing FDA procedures, which required generic drug manufacturers to complete the lengthy process for new drug approval after patents protecting the brand-name drug expired, "had serious anti-competitive effects," the result of which was "the practical extension of the monopoly position of the patent holder beyond the expiration of the patent." H.R. Rep. No. 98-857, Pt. 2, at 4 (Aug. 1, 1984). Through the ANDA procedure, which speeded approval for generics that were equivalent to approved drugs, the Amendments sought to combat these anticompetitive effects and to "implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent" on the original drug. *Id.* at 9.

But the Amendments' framers did not limit their efforts to permitting licensing of generic drugs only after expiration of patents on brand-name drugs; rather, they made clear that "a generic manufacturer may request FDA approval to begin marketing before the patent on the drug has expired," so long as it alleges "that the existing patent is invalid or will not be infringed." *Id.* at 5. By placing the burden on the patent-holder to initiate litigation and by providing only for a limited stay of FDA approval of the generic even if such litigation were sought, the drafters provided that "the FDA will approve the generic application, even if the drug is still on patent." *Id.* Moreover, the

legislation's backers rejected amendments that would limit FDA authority to license generic versions of patented drugs because such amendments would "substantially delay generics from getting onto the market when they seek to challenge the validity of a patent." *Id.* at 10.

The ultimate goal of the Amendments was to "provide[] low-cost, generic drugs for millions of Americans," resulting in "a significant savings to people who purchase drugs." 130 Cong. Rec. 24427 (Sept. 6, 1984) (statement of Rep. Waxman). The Amendments aimed to "do more to contain the cost of elderly care than perhaps anything else this Congress has passed, because [they] will bring about lower priced generic alternatives to brand-name drugs once the patent has expired or if there is no valid patent and the courts decide that there is no valid patent in order to give that monopoly protection." *Id.* (statement of Rep. Waxman).

III. Congress Reaffirmed Its Commitment to Competition Between Generic and Brand-Name Drugs When It Passed the Medicare Drug Benefit Legislation of 2003, Which Contained New Provisions to Combat Abuses That Had Arisen After Hatch-Waxman.

Although the Hatch-Waxman Amendments achieved the purpose of streamlining the approval of generic versions of brand-name drugs, two decades of experience under the Amendments showed that pharmaceutical companies were sometimes able to use anticompetitive devices to thwart the objective of promoting competition from generic drug manufacturers. Concerns that drug manufacturers were able

to "'game' the system" ultimately led Congress to include in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, new provisions that underscored the pro-competitive purposes of the Hatch-Waxman Amendments. 149 Cong. Rec. S8190 (June 19, 2003) (statement of Sen. McCain) (quoting testimony of former FTC Chairman Timothy Muris); *see also id.* at S8193 (statement of Sen. Gregg) ("What we saw, regrettably, under Hatch-Waxman, was there were games being played.").

The concerns that led to the 2003 amendments largely involved two devices employed by brand-name manufacturers to slow generic competition against drugs claiming patent protection. The first was abuse of the 30-month stay of FDA approval once patent infringement litigation was filed: Pharmaceutical companies, Congress learned, had been able to obtain multiple, successive 30-month stays by invoking multiple patents allegedly protecting the same drug, resulting in "basically interminable stays." 149 Cong. Rec. S8193 (June 19, 2003) (statement of Sen. Gregg).

The second device that provoked Congress's disapproval (and that has led to this case) was the use of settlement agreements in patent litigation, where a manufacturer of a brand-name drug paid a generic manufacturer that had filed an ANDA to withhold the generic drug from the market even after the expiration of the 30-month stay on FDA approval. A 2002 Senate Report explained the problem as follows:

> The pharmaceutical industry has been able to reap significant profits by selling vitally important drugs to all consumers, especially senior citizens. However, the industry has recently wit-

> nessed the creation of pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market. Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law that was intended to promote generic alternatives. ….
>
> Under Hatch-Waxman, manufacturers of generic drugs are encouraged to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices. The law as it stands gives temporary protection from competition to the first manufacturer that gets permission to sell a generic drug before the patent on the brand name drug expires, giving the generic firm a 180-day head start on other companies making generic versions of the drug. The Federal Trade Commission reports that some firms are exploiting that provision of law by entering into secret deals to allow a maker of the generic drug to claim the 180-day grace period in order to block other generic drugs from entering the market, while at the same time getting paid by the brand name manufacturer for withholding sales of the generic version.

S. Rep. No. 107-167, at 4 (June 20, 2002).[30]

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[30] Senate Report No. 107-167 concerned legislation passed by the Senate but not the House during the 107th Congress, which contained provisions that were ultimately included in the Hatch-Waxman Amendment revisions passed by the 108th Congress as part of the 2003 Medicare drug benefit legislation. There is no separate report concerning the amendments as enacted in the 108th Congress, other than a very brief discussion in the Confer-

(*Footnote continued*)

The Senate Report went on to explain how the economics of the prescription drug market created incentives for such anticompetitive agreements:

> Both the initial introduction of the generic version of the drug and the subsequent marketing of competing generic versions of the drug could be delayed if the [patent-holder] and the generic drug firm reach an agreement under which the generic firm delays or abstains from marketing its version of the drug. Such agreements may be attractive to both firms, because the price charged for the generic version of a drug generally is significantly lower than the price charged for the brand name version, and the price of the generic version drops further when competing versions enter the market. Therefore, the profit lost by the [patent-holder] following the entry of the generic version generally substantially exceeds the profit gained by the generic firm; both firms could be made better off by sharing some of that difference in profits instead of competing.
>
> Delaying or preventing the initial introduction of the generic version of a drug by the firm that filed the [first ANDA] and delaying the entry of generic versions marketed by other firms would both result in higher costs for prescription drugs to consumers and to the government.

Id. at 10.

The same concerns about anticompetitive agreements between brand-name and generic manufactur-

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ence Report focusing on other issues. H. Conf. Rep. 108-391, at 835-36 (Nov. 21, 2003).

ers that were set forth in the 2002 Senate Report were repeated in the 2003 floor debates surrounding the Medicare drug legislation. Senator Gregg, one of the principal sponsors of the amendments to the Hatch-Waxman Amendments, explained that the "games" that gave rise to the amendments included "games on the generic side where they might team up with a brand name and take advantage of the 180-day exclusivity clause and never bring the drug to market even though they had filed." 149 Cong. Rec. S8193 (June 19, 2003). Senator Collins elaborated on the problem of anticompetitive settlement agreements between brand-name and generic manufacturers:

> One case involved the producer of a heart medication which brought a lawsuit for patent and trademark infringement against the generic manufacturer in early 1996. Instead of asking the generic company to pay damages, however, the brand name manufacturer offered a settlement to pay the generic company more than $80 million in return for keeping the generic drug off the market. In the meantime, the consumers of this heart medication, which treats high blood pressure, chest pains, and heart disease, were paying about $73 a month, while the generic would have cost them only $32 a month.

Id. at S8194.

The 2003 reforms sought to further the Hatch-Waxman Amendments' original goals of speeding the introduction of generic drugs to the market in a number of ways. First, they altered the 30-month stay provisions to address the problem of generics being blocked by multiple, successive stays. *See* Pub. L. No. 108-173 § 1101, 117 Stat. 2448 (amending 21 U.S.C.

§ 355(j)). Second, they added provisions to enhance the ability of a generic manufacturer that had filed an ANDA to bring a declaratory judgment action with respect to the validity or infringement of a patent covering the brand-name drug even if the brand-name manufacturer did not itself bring an infringement action, thus expediting the elimination of uncertainty that might otherwise inhibit marketing of the generic version. *See id.* § 1101(a)(2)(C), 117 Stat. 2450 (adding 21 U.S.C. § 355(j)(5)(C)). Third, and most importantly here, the amendments required that all agreements between brand-name and generic manufacturers concerning the marketing of drugs subject to an ANDA be submitted to the FTC and the Justice Department for review, and provided that the generic manufacturer would forfeit its 180-day exclusivity rights if, as a result of enforcement action by either the FTC or the Justice Department, such an agreement were found to violate the antitrust laws or the FTC Act. *Id.* § 1102, 117 Stat. 2458-59, *codified at* 21 U.S.C. § 355(j)(5)(D); *id.* §§ 1111-18, 117 Stat. 2461-64, 21 U.S.C. § 355 note.

By subjecting agreements of the type at issue in this case to stringent governmental scrutiny and providing an additional penalty if they were found to violate the antitrust laws, the 2003 reforms underscored that the Hatch-Waxman Amendments were never intended to foster such anticompetitive arrangements. Indeed, the 2003 revisions were specifically designed to counter anticompetitive practices that had arisen in the years following the Amendments' passage and to re-emphasize the Hatch-Waxman Amendments' original goal of enhancing competition between generic and brand-name drug manufacturers.

IV. Shielding Pay-for-Delay Settlements from Antitrust Liability Undermines the Hatch-Waxman Amendments' Pro-Competitive Policy.

This Court has recently had occasion to emphasize that the Hatch-Waxman Amendments should be construed to give effect to their overarching goal of increasing competition in the pharmaceutical marketplace by accelerating the introduction of generic drugs. *See Caraco*, 132 S. Ct. at 1676, 1681-88. But in the decision below and in its previous decision in *Schering-Plough Co. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), the Eleventh Circuit turned the pro-competitive policy embodied in the Hatch-Waxman Amendments and their 2003 revision on its head by asserting that the provisions of the Amendments somehow provided a *justification* for agreements under which generic manufacturers withhold their products from the market in return for payments from brand-name drug makers.

In *Schering-Plough*, quoting *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003), the Eleventh Circuit criticized the FTC for "neglect[ing] to understand" that "reverse payments are a natural by-product of the Hatch Waxman Act process." 402 F.3d at 1074. Similarly, a divided panel of the Second Circuit asserted that "reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206 (2d Cir. 2006). These courts appear to have concluded that because the Amendments created a situation where generic drug manufacturers *could*

extract settlement payments in return for keeping their products off the market, such agreements were competitively justified and, indeed, endorsed by the Hatch-Waxman Amendments.

To be sure, the Amendments enhanced the bargaining position of generic manufacturers in settlement negotiations by removing regulatory barriers to their entry into the market. But the reason the Amendments enhanced the position of the generics was to encourage them to enter the market, *not* to authorize them to use their increased leverage to exact a share of a brand-name drug owners' monopoly profits in return for *staying out of the market*. Courts that have rejected antitrust scrutiny of reverse payment settlements have confused an unintended consequence of the original legislation—its creation of incentives for anticompetitive as well as competitive behavior—with a natural and intended effect.

Other courts and judges, by contrast, have correctly recognized that the opportunities for anticompetitive agreements were by no means *natural* outgrowths of the Hatch-Waxman Amendments' purposes, but distortions of its intended effect. As the Third Circuit has put it, "The goal of the Hatch-Waxman Act is to increase the availability of low cost generic drugs. … That goal is undermined by [allowing] the patent holder to pay its potential generic competitors not to compete." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 217 (2012). Likewise, in *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010), a panel of the Second Circuit, although holding itself bound by the earlier *Tamoxifen* decision to uphold the legality of a reverse-payment settlement, called on the Second Circuit to reconsider its

approval of such settlements in light of their inconsistency with the policies of the Hatch-Waxman Amendments. *Id.* at 108-10. Judge Pooler, dissenting from the court's eventual denial of rehearing, accurately observed that "exclusion payment settlements seem plainly inconsistent with the stated purpose of the Hatch Waxman Act, which is to encourage patent challenges as a way of increasing consumer access to low-cost drugs." 625 F.3d 779, 781 (2d Cir. 2010).

Even the *Ciprofloxacin* decision relied on by the Eleventh Circuit in *Schering-Plough* recognized that use of the Hatch-Waxman process to delay a would-be generic competitor's entry into the market through reverse payments is an "*unintended* consequence of altering the litigation risks of patent lawsuits." *Ciprofloxacin*, 261 F. Supp. 2d at 252 (emphasis added). Similarly, the D.C. Circuit has recognized that the statutory scheme creates an "unfortunate" opportunity for the "first applicant [to] collude[] with the pioneer drug company to eliminate generic competition." *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1067, 1072 (D.C. Cir. 1998). That result, however, is "at odds with Congress's apparent purposes, in enacting [the Hatch-Waxman Amendments], of rewarding innovation and bringing generic drugs to market quickly. Indeed, the first applicant could even collude with the original patent-holder to prolong their litigation, and thereby keep the second applicant's drug off the market indefinitely." *Id.* at 1072; *see also Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 768 (D.N.J. 1999) (stating that "taking advantage of the exclusivity period in an anticompetitive manner" would "fal[l] squarely within what the court in *Mova* speculated would be an abuse of the statute"); *In re Cardizem CD Antitrust Litig.,* 218 F.R.D.

508, 534 (E.D. Mich. 2003) (recognizing that Congress has "worked to amend Hatch-Waxman's exclusivity provisions to curb the very abuses alleged in this action"), *aff'd in part and app. dism'd in part*, 391 F.3d 812 (6th Cir. 2004).

In some sense, it may be "natural" for industry participants to respond to a statute designed to foster competition by agreeing *not* to compete in order to share higher monopoly profits—"natural" in that industry often tends toward anticompetitive behavior. But that tendency, whether "natural" or not, does not provide a competitive justification for such agreements when they are challenged under the antitrust laws—which, after all, are designed principally to curb such tendencies—nor does it demonstrate that the anticompetitive behavior is consistent with the aims of the underlying statute. Rather, "actions taken to 'subvert' [a regulatory] scheme 'for anticompetitive purposes' are subject to the antitrust laws." *Woods Exploration & Producing Co. v. Aluminum Co. of Am.*, 438 F.2d 1286, 1303 (5th Cir. 1971).

Thus, a correct approach to antitrust analysis of reverse-payment settlements should recognize that use of the Hatch-Waxman process to prevent generic competition is impermissible because it would "turn the intent of the Hatch-Waxman Act on its head" and "allow, in effect, a monopoly … when such rights could not be obtained through the normal patent process." *Alcon Labs., Inc. v. Allergan, Inc.*, 256 F. Supp. 2d 1080, 1089 (C.D. Cal. 2003) (criticizing brand-name manufacturer's attempt to "effectively circumvent the rationale and intent of the Hatch-Waxman Act" by bringing an action for inducing infringement against a competing generic manufacturer prior to

FDA approval); *see also TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 83 n.15 (D.D.C. 2003) (noting need to ensure that "the incentive structure created by the Hatch-Waxman Amendments" not "be turned on its head"), *aff'd sub nom. Purepac Pharm. Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004). Drug manufacturers should not be permitted to invoke the Amendments as a "sword" to promote anticompetitive conduct because "[t]hat would certainly not advance the purpose of making available 'more low cost generic drugs,' and was not what Congress intended." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1359 (Fed. Cir. 2003).

Moreover, allowing reverse-payment settlements to escape stringent antitrust scrutiny significantly undermines the effectiveness of the 2003 revisions of the Hatch-Waxman Amendments. Those revisions were designed to enhance the federal government's authority to police anticompetitive agreements between generic and brand-name drug manufacturers and to create a significant disincentive to such agreements: forfeiture of the 180-day exclusivity period granted to the first generic manufacturer to challenge a patent if the generic is found to have entered an agreement with a brand-name manufacturer that violates the antitrust laws. In enacting the provisions for FTC and DOJ review of agreements between generic and brand-name manufacturers, as well as the new forfeiture provision, Congress relied on the adequacy of *existing* principles of antitrust law to condemn agreements whereby generics withheld drugs from the market in exchange for a share of the brand-name manufacturer's monopoly profits. *See* S. Rep. No. 107-167, at 1.

The Eleventh Circuit's permissive approach to the agreement in this case, and its erroneous notion that settlement agreements involving payments to generics to keep their products off the market are a natural consequence of Hatch-Waxman, threatens to render the mechanism Congress created to police anticompetitive agreements toothless. Because it rests in part on the notion that Hatch-Waxman somehow dictates application of weaker-than-normal antitrust constraints to anticompetitive agreements such as those at issue here, the decision below stands as a significant obstacle to the accomplishment of Congress's intent, in the 2003 legislation, to correct the abuses that had arisen under the Hatch-Waxman Amendments and to shore up the Amendments' principal purpose of increasing competition in the prescription drug market for the benefit of consumers.

The Eleventh Circuit concluded its opinion in *Schering-Plough* by stating that the result it reached "reflects policy." 402 F.3d at 1076. But the policy the Eleventh Circuit followed in *Schering-Plough* and adhered to in this case was one of its own invention, not the one chosen by Congress when it enacted the Hatch-Waxman Amendments and their 2003 revisions. *Congress's* clearly stated goal was to lower drug prices by enhancing generic drug competition. The policy chosen by the Eleventh Circuit, however much it may benefit brand-name manufacturers who wish to preserve their monopoly profits and generic manufacturers who seek a slice of those profits, "is bad policy from the perspective of the consumer, precisely the constituency *Congress* was seeking to protect." *K-Dur*, 686 F.3d at 217 (emphasis added). Judicial policy preferences "should not displace countervailing public policy objectives or, in this case, Congress's determi-

nation—which is evident from the structure of the Hatch–Waxman Act and the statements in the legislative record—that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers." *Id.* The predictable result of the policy that the Eleventh Circuit has substituted for that of Congress will be less competition and higher drug prices for all Americans.

CONCLUSION

For the foregoing reasons, the judgment of the Eleventh Circuit should be reversed.

Respectfully submitted,

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