No. 12-416

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

ACTAVIS, INC., ET AL.,

Respondents.

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

BRIEF FOR HEALTH ECONOMICS AND LAW PROFESSORS AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICI CURIAE

Amici curiae are professors of health economics and law.[1] A list of signatories may be found in Appendix A. The interest of amici in this case is to encourage the development of patent and antitrust law in a direction that protects the health and welfare of current and future consumers of health care.

Amici have filed this brief because Petitioner takes a strong position against reverse payment settlements of Paragraph IV challenges without adequate appreciation of the economics of the pharmaceutical industry or of drug patents. Recent health economics literature suggests that the assumptions underlying Petitioner's arguments are incorrect. If this Court accepts Petitioner's position and holds reverse payment settlements presumptively illegal, we fear that consumers may, on balance, be harmed.

Amici ask that the Court decline to hold reverse payment settlements presumptively illegal at least until courts have adequate experience with the economic impact of these settlements to expedite their treatment in antitrust cases. Amici do not object to the Eleventh Circuit's scope-of-the-patent rule.

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[1] The parties have consented to the filing of this brief. Written evidence of Respondents' consents accompanies this filing. Petitioner lodged a blanket consent with the Clerk of the Court. No counsel for a party authored this brief in whole or in part, and no person (other than amici curiae or their counsel) made a monetary contribution intended to fund the preparation or submission of this brief.

SUMMARY OF ARGUMENT

Petitioner urges the Court to hold reverse payment settlements of Paragraph IV patent challenges presumptively illegal. Petitioner requests a rule that is stronger than the usual "quick look" rule of reason. It asks the Court to permit a pioneer drug company that is party to a reverse payment settlement—the "antitrust defendant"—a limited number of defenses, *i.e.*, only two possible defenses: that the antitrust defendant's reverse payment covers only its avoided litigation costs or that the payment is consideration for unrelated property or services. FTC Br. at 17.

Amici agree with Respondent Solvay Pharmaceuticals that, because these defenses are largely impracticable, Resp. Solvay Pharm. Br. at 22, Petitioner is actually requesting that the Court hold *per se* illegal reverse payment settlements that cannot make either of these narrow defenses. To succeed, Petitioner must demonstrate that reverse payment settlements that cannot make those two narrow defenses are so likely to harm consumers that it is not worth a court's time to inquire into the value of those settlements to consumers. Petitioner is not able to make such a demonstration.

Petitioner does not explicitly offer an economic theory explaining how extending the antitrust defendant's patent harms consumers. Implicitly, however, it relies on two factual claims: (1) that the patent, by keeping drug prices high, harms consumers, and (2) that patents associated with reverse payment settlements do not encourage socially valuable innovations. Petitioner does not provide any evidence to demonstrate either claim.

Taking heed of this Court's warning that the appropriate antitrust rule for an industry must "recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies," *Verizon Commc'ns v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 411 (2004), amici provide evidence from the health economics literature that drug patents, even those associated with reverse payment settlements, both (1) do not harm consumers and (2) generate socially valuable research.

First, amici highlight a series of studies that show that drug patents do not appear to reduce consumers' access to drugs, the primary economic harm from higher drug prices. An important reason is that the vast majority of consumers have health insurance and many of those who do not currently have insurance will under the Patient Protection and Affordable Care Act. Health insurance charges consumers a copay to purchase drugs. These copays lower the price of drugs faced by patients to roughly the same level generics would charge. As a result, drugs sales are not affected by patent expiration. This is true whether the defendant's patent is associated with a reverse payment settlement or not.

Second, the high prices that a patent enables a pioneer drug company to charge do not have anticompetitive effects. Any profits that the antitrust defendant appears to make by sustaining a drug patent through a reverse payment settlement overstates the actual profits it makes because the settlement amount largely neglects expenditures incurred during the race to invent the drug. That race for research and development (R&D) is the

appropriate market for this Court to consider when assessing the antitrust defendant's market power. The R&D market, however, is competitive and dissipates patent holders' expected profits. The available evidence suggests that antitrust defendants' revenues barely cover their actual cost of capital, *i.e.*, these defendants do not make the supra-competitive profits indicative of market power. This is true even if one includes any profits defendants make through reverse payment settlements.

Third, patents in the pharmaceutical industry do not involve a tradeoff between consumers and producers. Instead, drug patents involve a tradeoff between present consumers and future consumers. The reason lies in how pharmaceutical R&D is financed. Drug companies rely on retained earnings to finance R&D because the high risk associated with drug development limits access to external financing. Thus, an existing patented drug generates revenue from current consumers that funds R&D for future drugs that benefit future consumers. Indeed, the health economics literature has found a remarkable correspondence between current revenues and current R&D expenditures, consistent with this present versus future consumer tradeoff. While antitrust law may have a preference for consumer welfare over producer welfare, careful thought is required before committing it to prefer one set of consumers over another set.

Fourth, Petitioner ignores certain benefits that patents generate in the pharmaceutical industry but not in other industries. Unlike patents in other industries, patents in the pharmaceutical industry are essential for the conduct of certain research *after*

the grant of a patent—clinical trials—that provides valuable information to consumers. Drugs are typically patented before they are tested in clinical trials. Yet without a patent no pioneer drug company would conduct a clinical trial on a drug: generic drug companies could use the results of the trial to enter the market for that drug and the pioneer drug company would not recoup the costs of the trial. Moreover, clinical trials on a drug—even if that drug is covered by a reverse payment settlement—are socially valuable because they inform patients how safe and effective that drug is. This research is post-patent, and it is valuable whether the patents are associated with reverse payment settlements or not.

Moreover, profits from a commercially successful drug—even if the patent is associated with a reverse payment settlement—offset the costs of research on commercially less successful drugs, including drugs with uncontested patents. Because Paragraph IV challenges target commercially profitable drugs, they undermine this cross-subsidy. In this manner, a challenge to one patented drug may also undermine another drug with an uncontested patent. From this perspective, the social value of a particular patent, even one subject to a Paragraph IV challenge, should be judged by the social value of the portfolio of patents held by the same pioneer drug company.

To be clear, amici do not take the position that reverse payment settlements always benefit consumers. But the evidence does suggest that it is premature—if not incorrect—to conclude that reverse payment settlements are so likely to harm

consumers that they should be presumptively illegal. That is so even if—as Petitioner contends—reverse payment settlements extend the duration of the defendant's patent or protect a patent that might lose in litigation.

Furthermore, it is unclear that Petitioner's proposed rule would benefit consumers even under its own logic. Assume, for the sake of argument, that Petitioner is correct that reverse payment settlements extend the expected duration of a pioneer drug company's challenged patent, harming consumers. By Petitioner's logic, it is still also the case that generic drug companies expect they would financially benefit from reverse payment settlements more than from litigating Paragraph IV challenges to judgment. Otherwise these generics—like the pioneer drug companies—would not have settled.

This implies that declaring reverse payment settlements presumptively illegal would reduce the financial return to generic drug companies from bringing Paragraph IV challenges. In other words, Petitioner's reasoning implies that, while a rule discouraging reverse payment settlements might benefit consumers after a Paragraph IV challenge is brought, it might also harm consumers by reducing the number of such challenges brought. Whether consumers would on balance be better or worse off is uncertain.

ARGUMENT

I. Petitioner Must Demonstrate that Reverse Payment Settlements Are So Unlikely to Benefit Consumers that this Court Should Judge Them Presumptively Illegal

Petitioner urges that reverse payment settlements be categorized as a presumptively illegal contract. Under this view, courts would treat a reverse payment settlement as illegal under antitrust law unless the defendant showed that the defendant's payments to a generic drug company under the settlement reflect either its litigation costs or consideration for unrelated property or services. FTC Br. at 17. Under Petitioner's view the antitrust defendant would not be allowed to defend a reverse payment settlement on the ground that its patent does not harm consumers. *Ibid.* In other words, Petitioner urges the Court to declare reverse payment settlements *per se* illegal except in narrow circumstances.

In order to prevail on such a bold claim, Petitioner must demonstrate to the Court that a particular set of reverse payment settlements—those that include payments from a defendant that exceed its litigation costs or that do not reflect consideration for unrelated property or services—are so likely to harm consumers that it is not worth the court's time and effort to determine whether a specific settlement in that set may still benefit consumers. *See, e.g., Broadcast Music, Inc. v. Columbia Broadcasting System*, 441 U.S. 1, 9 (1979). *See also California Dental Ass'n*, 526 U.S. at 770 (stating that a presumption of illegality under "quick look" rule of reason "carries the day when the great

likelihood of anticompetitive effects [on consumers] can be easily ascertained").

Petitioner's argument rests on certain economic theories about why drug patents judged valid by a court are economically desirable and why patents not affirmatively judged valid by a court harm consumers. Amici begin by describing these theories, without conceding they are correct. We will then highlight recent research from the field of health economics—specifically, research that focuses on the pharmaceutical drug market—that undermines these theories. This research has been neglected by Petitioner and by prior legal scholarship on reverse payment settlements. Amici will demonstrate that even the set of reverse payment settlements that involve reverse payments that exceed litigation costs or the value of unrelated property or services may not harm—and may even improve—consumer welfare. Therefore, these settlements should not be presumed illegal.

II. Petitioner's Argument Relies on a Contested Economic Theory About Patents and Patent Law

Petitioner's argument relies on the textbook economic model of patents to explain why patents judged valid may improve welfare, but patents whose validity has not yet been adjudicated do not. According to that model, patent law's 20-year limit on the duration of patents balances the costs and benefits of patents. Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 Harv. L. Rev. 1813, 1823, 1825-26 (1984). That 20-year limit gives the pioneer drug company holding a patent a 20-year period during which only the pioneer may

legally sell the patented drug in the U.S., *i.e.*, a monopoly that does not run afoul of antitrust laws. During this monopoly period, consumers pay a high monopoly price for the drug.

According to economic theory, a monopoly has anticompetitive effects on social welfare because this monopoly price stops certain consumers from purchasing the drug, consumers who would be willing to pay the marginal cost of the drug but not the higher monopoly price. This exclusion of consumers reduces the quantity of drug sales and thereby generates a loss to consumer welfare or surplus. FTC Br. at 22-23. Economists call this cost from patents, "static inefficiency." This cost is tolerated because the profits obtained by the pioneer drug companies rewards—and thereby incentivizes—a pioneer to incur the research and development costs to invent the patented drug. Kaplow, *Patent-Antitrust Intersection* at 1823. Economists call this benefit of patents, "dynamic efficiency."

While no one contends that the 20-year limit perfectly balances the static inefficiency and dynamic efficiency, it does achieve a certain balance that ought to be respected. Efforts to extend patent life beyond the limits set by patent law raise antitrust concerns because they limit competition in a manner that harms consumers. FTC Br. at 25-26.

According to Petitioner's view, patent law's balance between static inefficiency and dynamic efficiency applies only to patents that, if challenged, would be upheld in litigation. Such patents would meet patent law's standards of novelty, non-obviousness, and usefulness. The purpose of these

standards is to identify patents that have social value. The negative implication is that patents that are challenged and declared invalid by a court would not meet this standard and thus would not be socially valuable.

But Petitioner takes this implication further and suggests that patents that are challenged and settled—even though they are not declared invalid by a court—also lack social value. (Inexplicably, Petitioner does not extend the logic to patents that are not challenged, but if they were, would be declared invalid.) Thus Petitioner suggests that patents involved in reverse payment settlements generate static inefficiency, but no dynamic efficiency. FTC Br. at 18; Br. for the States of New York et al. as Amici Curiae in Support of Petitioner at 7-8; Br. Amici Curiae of 118 Law, Economics, and Business Professors and the American Institute in Support of Petitioners at 8, 20. Under Petitioner's legal theory, there is no value to incentivizing the creation of drugs covered by patents involved in reverse payment settlements.

The reason why Petitioner condemns reverse settlements is that the first generic to file a Paragraph IV challenge and a pioneer drug company holding the challenged patent can collude to hurt the consumer. According to basic market economics, the pioneer's monopoly profits (if its patent were left in place) are greater than the duopoly profits that the pioneer and first generic each get during the period of exclusivity (if the patent were invalidated). The pioneer can offer the first generic a part of this wedge to settle its challenge in the pioneer's favor. This side payment—called a "reverse payment"—

could increase the period of time during which the pioneer retains its profits. FTC Br. at 16 and 21. (Petitioner does not claim that reverse payment settlements extend a patent past the 20 years allowed by patent law. There is no theory or evidence to suggest reverse payment settlements accomplish that. Moreover, the Eleventh Circuit's scope-of-the-patents test would not allow such an extension. Pet. App. 28a.)

In order for Petitioner to show that it is correct that reverse payment settlements should be presumptively illegal under antitrust law, it must demonstrate its theory of patents applies to drug patents. If drug patents—whether involved in a reverse payment settlement or not—impose little or no static inefficiency, or if longer patent terms—even if secured by reverse settlements—do not on balance harm consumers at the expense of consumers, then reverse payment settlements may fall in the category of contracts that restrain trade but ought not and are not condemned by the Sherman Act and the FTC Act. If even patents covered by reverse payment settlements are valuable for dynamic efficiency, as Petitioner admits is the case for patents that are not challenged or that are litigated and upheld, then antitrust law should not label reverse payment settlements presumptively illegal.

A. Petitioner Overestimates the Cost of Drug Patents to Consumers

Courts must be "attuned to the particular structure and circumstances of the industry at issue" when applying antitrust law. *Trinko*, 540 U.S. at 411 (2004); FTC Br. at 30. The appropriate antitrust rule for an industry must "recognize and reflect the

distinctive economic and legal setting of the regulated industry to which it applies." *Trinko,* 540 U.S. at 411. The strict treatment of reverse payment settlements urged by Petitioner does not satisfy this requirement. It employs a conventional theory of patents that does not make any allowance for how pharmaceutical innovation takes place, the role of patents in the innovative process, and the structure of market competition for drug innovation and drug sales. As a consequence, it overestimates the cost of drug patents to consumers.

1. Empirical evidence suggests drug patents do not harm consumers by denying them access to drugs

A critical assumption of Petitioner's economic theory of patents is that it harms consumers by denying them access to patented products. Recent research in health economics suggests, however, that the monopoly conferred by a drug patent, whether that patent is associated with a reverse payment settlement or not, may not price any consumer out of the market.

The conventional economic model of patents to which Petitioner subscribes asserts that the patent holder, by virtue of its monopoly, is able to charge a high monopoly price for its drug that exceeds the price that would be charged if the drug were produced by a number of competing, generic drug companies. According to economic theory, the primary harm from patents is that this monopoly price would exclude a certain class of consumers from the market, specifically, consumers who value the patented drug more than the competitive price of the drug but not as much as the monopoly price of

the drug. Economists call this exclusion "deadweight loss" or static inefficiency. Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in National Bureau of Economic Research, The rate and direction of inventive activity: Economic and social factors, 609, 617 (1962).

The details of this conventional patent model, specifically its understanding of the harm from a monopoly, are illustrated in Figure 1 on the following page. The diagonal curve depicts consumer "demand" for the patent holder's product. The lower is the price charged for the product, the more consumers will demand of that product.

The monopoly conferred by a patent allows the patent holder to choose whichever price it wants to charge consumers for its product. If the patent holder chooses a price equal to the incremental cost of manufacturing an additional unit of the patented product, *i.e.*, equal to its "marginal cost", it would earn no profits. The revenue for each unit sold would just cover the cost of manufacturing each unit sold. There is, however, a higher price, described in the figure as the "monopoly price" that would earn the patent holder greater profits. At this higher price, the demand curve reveals that consumers would not purchase very much of the product, only the "monopoly quantity". Because the price is higher than the patent holder's marginal cost, however, the patent holder will earn a profit on each unit it sells. The aggregate profit the patent holder earns is equal to the quantity it sells multiplied by the profit it makes on each unit, *i.e.*, the shaded area labeled "monopoly profit."

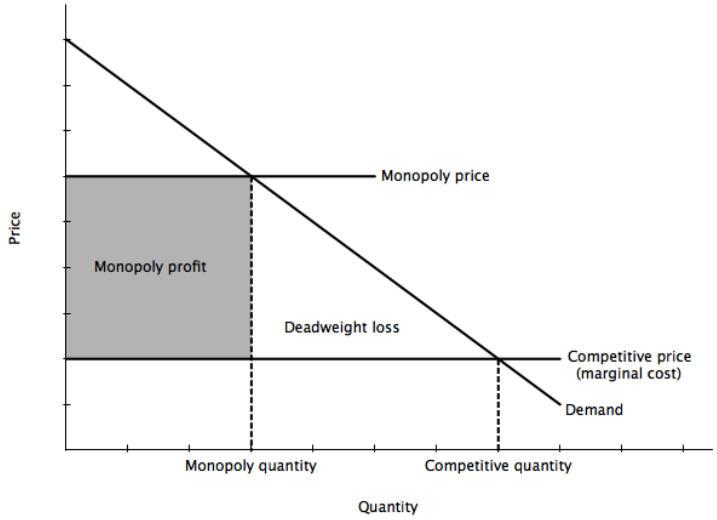


Figure 1. Illustration of the harm to consumers from monopoly pricing under the conventional model of patents.

If the patent holder's monopoly were removed, competitors could enter the market. Competition would drive the price of the product down to marginal cost. If one competitor tried to charge its customers more than marginal cost, another competitor could steal the first competitor's customers by offering a lower price, specifically its marginal cost, and still break even. This potential discourages competitors from charging anything other than marginal cost. Therefore, the figure labels marginal cost the "competitive price." At this price, consumers demand a high quantity of products, specifically "competitive quantity."

According to the conventional model of patents, the primary harm to consumers from a patent is that consumers are able to purchase more of the product in the absence of a patent than in the presence of a

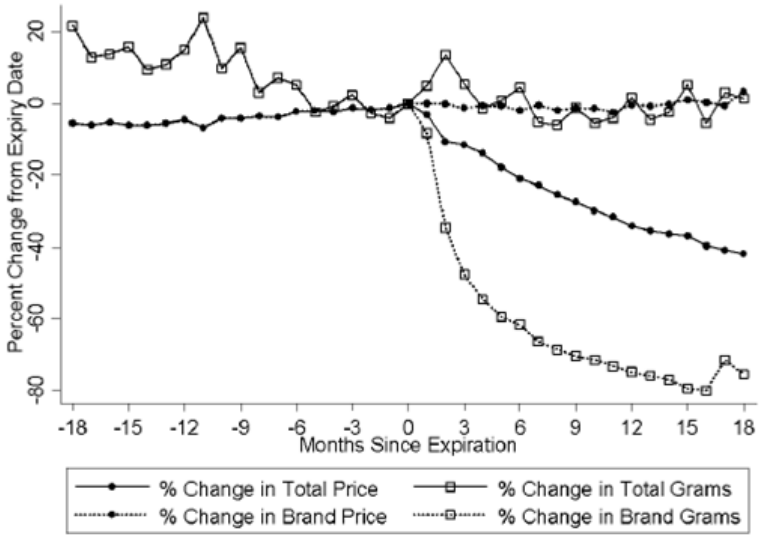
patent. The additional amount they are able to purchase is the difference between the competitive quantity and the monopoly quantity. The value to consumers of being able to purchase this additional amount is how much each unit is valued by consumers, *i.e.*, consumers' demand for each unit at that quantity, minus the cost of manufacturing each unit, *i.e.*, the marginal cost at that quantity. Since the demand curve is diagonal, the total loss suffered by consumers is the triangle labeled "deadweight loss."

An important feature of this consumer loss is that it is proportional to the difference between the amount of the product sold when it is under patent—the monopoly quantity—and the amount of the product sold when it is not under patent, the competitive quantity. That difference is the base of the deadweight loss triangle. If the difference is large there is a lot of harm to consumers. If the difference is zero, then there may be no harm to consumers.

The key prediction of the conventional model of patents is that, when a drug goes off patent, generic companies should enter, prices should fall, and—importantly—the quantity of drugs sold should rise. This prediction is what generates a difference between the monopoly quantity (under patent) and the competitive quantity (off patent), the difference that in turn determines deadweight loss.

This prediction is contradicted, however, by recent empirical data from pharmaceutical markets. While average drug prices certainly fall after patent expiration, overall drug sales do not rise. Darius Lakdawalla and Tomas Philipson, *Intellectual*

Property and Marketing, J. Law & Econ. (forthcoming 2013) (available at http://www.nber.org/papers/w12577); Frank R. Lichtenberg and Gautier Duflos, *The Effect of Patent Expiration on U.S. Drug Prices, Marketing, and Utilization by the Public*, 11 Med. Progress Rep. at 7 (2009) (Figure 6) (available at http://www.manhattan-institute.org/pdf/mpr_11.pdf); Ernst R. Berndt, Margaret K. Kyle, and Davina C. Ling, *The Long Shadow of Patent Expiration: Generic Entry and Rx-to-OTC Switches*, in Robert C. Feenstra and Matthew D. Shapiro, eds., Scanner Data and Price Indexes 229, 249-52 (2003) (available at http://www.nber.org/chapters/c9737.pdf).



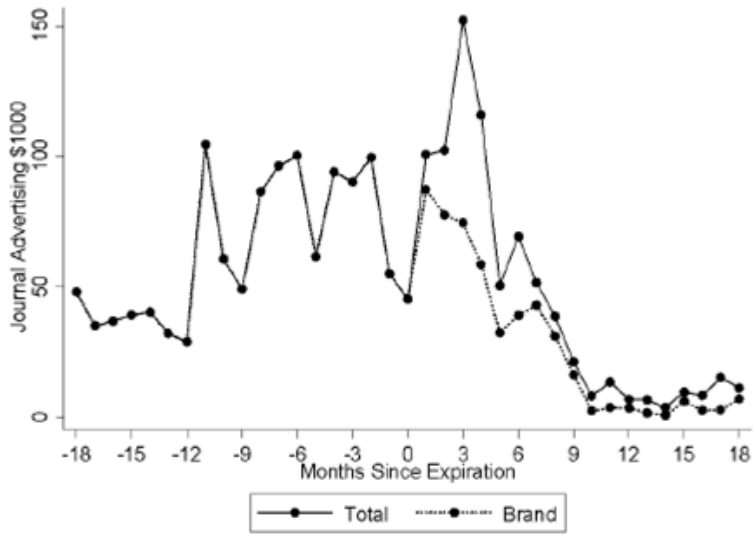
Source: IMS Generic Spectra database. Graph shows the percent change between the month of patent expiration and the month shown on the x-axis. In all cases, price is per gram.

Figure 2. Drug quantity does not rise after patent expiration. Source: Lakdawalla and Philipson, *Intellectual Property and Marketing* (Figure 5).

This remarkable finding is depicted in Figure 2. After patent expiration (the 0 point on the x-axis), the pioneer drug company's price ("% Change in Brand Price") does not change but due to the entry of low price generics, the average price falls ("% Change in Total Price"). As a result, the pioneer drug company's sales ("% Change in Brand Grams") fall. What is surprising is that total sales including sales by the generics ("% Change in Total Grams") do not rise relative to pre-expiration levels.

The finding that drug sales do not increase after a drug goes generic suggests that patents do not deny consumers access to drugs. The finding does not distinguish between patents associated and not associated with settlements. From this one may conclude that there may be no deadweight loss or static inefficiency from patents in drug markets—even patents subject to reverse payment settlements—and the conventional model of patents may not apply to drug markets. Lichtenberg and Duflos, *Effect of Patent Expiration* at 12 ("[O]ur findings imply that, in practice, weaker (or shorter) patent protection would not increase Americans' access to prescription drugs").

A natural question is why drug quantity does not rise after patent expiration. One need not answer this question to conclude that there may be no static inefficiency from drug patents, but the answer does illuminate the gap between legal thinking about reverse payment settlements and health economic thinking about such settlements. The literature offers two possible explanations for why drug sales do not rise after patent expiration.



Source: IMS Generic Spectra database. Graph shows journal advertisement spending for the average molecule and the average branded molecule.

Figure 3. Advertising falls after patent expiration. Source: Lakdawalla and Philipson, *Intellectual Property and Marketing* (Figure 8).

The simplest explanation is that pioneer drug companies advertise their drugs and this advertisement raises sales. *See* Lichtenberg and Duflos, *Effect of Patent Expiration* at 6, 9, 12. As a result, even at monopoly prices, patients consume the same amount of drugs as they would at competitive prices. When patents expire, pioneer drug companies stop advertising because they do not fully appropriate the benefits of the ads, which increase both pioneer and generic sales. The decline in pioneer or "Brand" drug advertising is depicted in Figure 3. This decline in advertising offsets the increased consumption due to the price decline after patent expiration.

A second explanation for why drug patents may not prevent consumers from purchasing a drug is that consumers do not face the monopoly price of patented drugs. Most consumers do not pay for drugs out of pocket. Instead they have health insurance that covers the cost of drugs. Health insurance does not directly charge consumers the full price of drugs; rather it charges a copay, *e.g.*, $10 per prescription filled. This copay is not far from the competitive price of drugs. As a result, health insurance permits consumers to purchase the same amount of a patented drug as they would if it were not patented but sold at a competitive price by generic drug companies. Darius Lakdawalla and Neeraj Sood, *Innovation and the welfare effects of public drug insurance*, 93 J. Pub. Econ. 541, 541, 546 (2009); Darius Lakdawalla and Neeraj Sood, *Health insurance as a two-part pricing contract*, National Bureau of Economic Research Working Paper 12681 at 1-2 (2006) (available at http://www.nber.org/papers/w12681); Darius Lakdawalla and Neeraj Sood, *Health insurance as a two-part pricing contract*, Unpublished manuscript (2012).

Table 1 on the following page illustrates this point. It shows that for drugs whose sales are largely to consumers who have health insurance (third row, "75th percentile" insurance penetration), patent expiration is associated with no increase in drug quantity. For drugs whose sales are largely to consumers not well covered by insurance (first row, "25th percentile" insurance penetration), there is an increase in drug quantity after patent expiration.

Table 1. Patent expiration raises quantity only for drugs that are not well-insured. (Bold numbers indicate significantly different from zero.) Source: Lakdawalla and Sood, *Health insurance as a two-part pricing contract* (2012) at 4, 23.

Insurance Penetration Percentile	Insurer Share of Spending	Effect of Patent Expiration On:	
		Quantity	Branded Revenue
25th percentile	41%	**+11%**	**-22%**
Median	57%	**+5.3%**	**-30%**
75th percentile	78%	-1.9%	**-40%**

Admittedly not all consumers currently have health insurance and so may not be protected against high drug prices by that insurance. Going forward, however, nearly all American will have health insurance. The 2010 Patient Protection and Affordable Care Act imposes an individual mandate that requires nearly everyone to buy health insurance. 26 U.S.C. § 5000A. Moreover, it provides most American households making less than $90,000 additional tax breaks to purchase insurance, 42 U.S.C. § 18081, or provides them government insurance by 2014, 42 U.S.C. §1396a(a)(10)(A)(i)(VIII). As a result, very shortly nearly all drug sales will be to consumers with insurance coverage.

Remarkably, health insurance not only lowers the price that consumers pay for patented drugs, it does so without necessarily lowering the price that pioneer drug companies receive for patented drugs. The insurance company can pay the pioneer a monopoly price and at the same time charge the consumer a near-competitive price for the drug. The reason is that health insurance is a two-part pricing scheme much like that used at amusement parks, where one pays a large up-front fee to enter the park but then gets tickets for rides in the park at a relatively low cost.

With health insurance, the consumer is charged a large entry price (the premium) for the right to buy individual units of drugs at a low marginal price (the copay). Lakdawalla and Sood, *Health insurance as a two-part pricing contract* (2012) at 1-2. This decoupling of the price of drugs that consumers face from the price of drugs that pioneer drug companies receive eliminates the tradeoff between dynamic efficiency and static inefficiency that is at the heart of the conventional model of patents and that plagues patents in non-pharmaceutical markets. *Id.* at 2 ("[M]onopolies in health care—whether due to patents, limited market size, or historical factors—may have smaller or even no deadweight costs in the goods market.").

A natural concern with how health insurance addresses the deadweight loss from patents in pharmaceutical markets is that such insurance merely transplants that loss to other markets, specifically, the health insurance market. If consumers consume a competitive quantity of patented drugs, but the insurer pays monopoly

prices for those drugs, surely that will increase health insurance premiums. Will the resulting increase in premium not reduce insurance consumption?

There is certainly some increase in the price of health insurance premiums due to drug patents. But this increase is likely to be nominal. Nearly 70% of all drug sales are sales of generic drugs. C. Scott Hemphill and Bhavan N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Emp. Legal Stud. 613, 614 (2011). The prices of generic drugs are not affected by reverse settlements. Overall drug expenditures, including both branded and generic drugs, are roughly 10% of overall health expenditures. Therefore, drugs costs are a small driver of health insurance premiums. U.S. Census Bureau, Statistical Abstract of the United States: 2012 at 102 (Table 136). Most important, only a small fraction of branded drugs are involved in reverse payment settlements. Thus, reverse settlements have a minor impact even on the price of branded drugs.

Moreover, there are two reasons to think that any increase in premiums due to reverse payment settlements will not stop consumers from purchasing health insurance, the critical test of static inefficiency in that market.

First, the U.S. tax code subsidizes the purchase of employer-sponsored health insurance. This subsidy reduces the price that consumers face for insurance and thus the extent to which drug patents reduce consumption of insurance. Jonathan Gruber and Michael Lettau, *How elastic is the firm's demand for health insurance?* 88 J. Pub. Econ. 1273, 1274

(2004). Not surprisingly, a survey of the health economics literature reveals that "demand for health insurance is, in general, price inelastic." Su Liu and Deborah Chollet, *Price and Income Elasticity of the Demand for Health Insurance and Health Care Services: A Critical Review of the Literature*, Mathematic Policy Research Ref. No. 6203-042 at ix (2006) (available at http://www.mathematica-mpr.com/publications/pdfs/ priceincome.pdf).

Second, the Affordable Care Act includes a mandate requiring nearly all individuals to buy insurance. 26 U.S.C. § 5000A. To try to ease the burden of that mandate, the Act provides premium tax credits to individuals below 400% of the federal poverty level. The Act also expands Medicaid coverage for individuals too poor to afford health insurance. In this manner, the Affordable Care Act mandate, combined with its tax and Medicaid benefits, reduces—and perhaps eliminates—the possibility of an increase in the pool of uninsured due to reverse payment settlements. Therefore, whatever its other flaws or merits, one positive side effect of the Affordable Care Act is that it may mitigate the static inefficiency from drug patents by way of health insurance.

Admittedly, the tax subsidy for the purchase of health insurance and the Affordable Care Act's new premium tax credits and Medicaid expansion may increase government expenditures on health care. But for the same reasons that reverse settlements are likely to have only nominal effects on insurance premiums, they are likely to have only nominal effects on government expenditures. Moreover, the effects on government expenditures are smaller since

the government shares only a portion of the cost of health insurance premiums. In any case, even if there were some consumers harmed by the nominal increase in insurance premiums or government expenditures due to reverse settlements, their losses would likely be offset by the benefits consumers obtain from the new drugs developed by virtue of reverse payment settlements.

To summarize, recent health economics research suggests that drug patents do not reduce consumers' access to drugs or insurance, the key measure of deadweight loss or harm to consumers according to the conventional model of patents. This conclusion does not hinge on whether the drug is associated with a reverse payment settlement. Thus, even drug patents subject to reverse payment settlements may not harm consumers, a critical link in Petitioner's argument that such settlements should be help presumptively illegal.

2. Reverse payment settlements may not help producers at the expense of consumers

Implicit in Petitioner's economic model of patents is the idea that, if the patent holder's monopoly were ended, the patent holder's monopoly profits would accrue to consumers. Using this logic, Petitioner suggests that reverse payment settlements, by extending the expected duration of a pioneer drug company's patent, increases the resulting pioneer drug company's profits at the expense of consumers. FTC Br. at 16 and 21. While amici do not agree with Petitioner that reverse payment settlements necessarily extend the expected duration of a drug

patent, we do not think reverse payment settlements would harm consumers even if they did.

First, the pioneer drug company's profits during the patent period overstate producer welfare from the patent. Second, and more importantly, because pioneer drug companies finance innovation with retained earnings, profits from a patented drug sold to existing consumers are used to fund research and development into drugs that will benefit future consumers. Therefore, the duration of drug patents trades off the welfare of today's consumers with the welfare of future consumers. It does not, as the conventional theory of monopoly suggest, tradeoff the welfare of existing consumers and the welfare of producers. Petitioner fails to explain why antitrust law should take a strong stand in a battle between current and future consumers, as Petitioner's position on reverse payment settlements requires.

The profits that the pioneer drug company makes while its drug is under patent—including the additional period of exclusivity afforded by a reverse payment settlement—overstate the producer welfare obtained from a patent. These profits ignore the patent race that preceded the award of that patent. As Judge Posner observed long ago, when the government offers a monopoly such as a patent, firms will expend resources equal to expected monopoly rents to obtain that monopoly. Richard A. Posner, *The Social Costs of Monopoly and Regulation*. 83 J. Pol. Econ. 807, 807 (1975).

In the context of patents, the resources expended are R&D spending. Economists call the competition to obtain a patent a patent race. If the race to invent a given drug is competitive, *i.e.*, involves more than

one competitor, the total R&D expenditures across all the firms that compete in a race will dissipate the expected profits entering the race. Glenn Loury, *Market Structure and Innovation*, 93 Q. J. Econ. 395, 406-407 (1979).

The implication is that, notwithstanding the fact that some company will win and be observed earning positive profits during the patent period, in expectation the firms in the race may collectively make zero (or perhaps negative) expected profits. Moreover, even if the patent period were extended by a reverse payment settlement, firms that race for a patent will simply dissipate any additional prospective profits by increasing their R&D expenditures to obtain that patent. Thus, reverse payment settlements may not raise producer welfare.

An important implication of how patent races work is that Petitioner's choice of market for conducting its market exclusion analysis is incorrect. Petitioner asks the Court to examine exclusion in the market for a drug *once it is patented*. It admits that market exclusion (and profits) afforded by a valid patent is legally protected from antitrust scrutiny by patent law. Petitioner argues that market exclusion afforded by a patent covered by a reverse payment settlement is not protected from antitrust scrutiny because such settlements potentially extend the duration of patents that might have been judged in valid at trial. FTC Br. at 16 and 21.

But the fact that patent races may dissipate the profits obtained from a patent—whether that patent is involved in a reverse payment settlements or

not—suggests that the profits obtained from a patent is not truly producer welfare and the market for a drug once it is patented is the wrong market to search for exclusion. The correct market is the market for a drug patent, *i.e.*, the race for a patent. If that race is not competitive, then the ultimate patent holder's profits are evidence of actual producer welfare. But if the race is competitive, then profits from a patent, even one extended by a reverse payment settlement, are not evidence of producer welfare.

One piece of empirical evidence suggesting that the market for drug patents is competitive is that pioneer drug companies do not appear to make a supra-competitive return on assets even after accounting for the additional profits they obtain from reverse payment settlements. When calculating a company's return on assets, one must normalize for risk, especially scientific and regulatory risk involved in a patent race. Once that is done, the rate of return for pharmaceutical firms is only 2-3% higher than non-pharmaceutical companies. U.S. Congress, Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards at 23,* OTA-H-522 (1993).

Other estimates suggest even worse performance, with pharmaceutical company returns only one-half percent above their cost of capital. Henry Grabowski, John M. Vernon, Joseph DiMasi, *Returns on research and development for 1990s new drug introductions*, 20 PharmacoEconomics 16 (2002). *See also* G.P. Pisano, *Science Business: The Promise, the Reality, and the Future of Biotech* 112-118 (2006) (finding negative profits in bio-

pharmaceutical companies). These data "tend[] to reduce substantially, if not to eliminate altogether, the inference that pharmaceutical companies are on average achieving supranormal profit returns." F.M. Scherer, *Chapter 12 - Pharmaceutical Innovation*, in H. H. Bronwyn & R. Nathan, eds., 1 Handbook of the Economics of Innovation 539, 564 (2010).

Not only might Petitioner overestimate the producer welfare that pioneer drug companies obtain from reverse payment settlements, Petitioner does not appear to take into account that the manner in which drug companies finance R&D expenditures determines how reverse payment settlements affect consumer welfare. Specifically, pioneer drug companies' use of retained earnings to finance R&D implies that reverse payment settlements may not convert consumer welfare into producer welfare. Rather, reverse payment settlements may convert the welfare of existing consumers—who provide retained earning—into welfare for future consumers, who benefit from the R&D financed by the retained earnings.

Drug companies tend to use profits from one patented drug to finance R&D for future drugs. They do not appear to rely very much on external financing, perhaps because it is hard to convince banks and outside investors that an as-yet-undeveloped drug will be clinically successful. Uwe Reinhardt, *Perspectives on The Pharmaceutical Industry*, 20 Health Aff. 136, 142 (2001). Because drug patents have such variable profits, drug companies also typically hold a portfolio of drugs to ensure a relatively stable flow of revenue to finance

R&D for future products. OTA, *Pharmaceutical R&D* at 8.

This reliance on retained profits for financing means that, at any point in time, a drug company's profits from patents on existing drugs sold to existing consumers are applied to R&D expenditures for future drugs sold to future consumers. F.M. Scherer, *The Link Between Gross Profitability And Pharmaceutical R&D Spending*, 20 Health Aff. 216 (2001). And this holds whether the profits are attributable to a patent covered by a reverse payment settlement or not. Figure 4 provides evidence for this. It shows that R&D expenditures track the gross margins of pioneer drug companies over time.

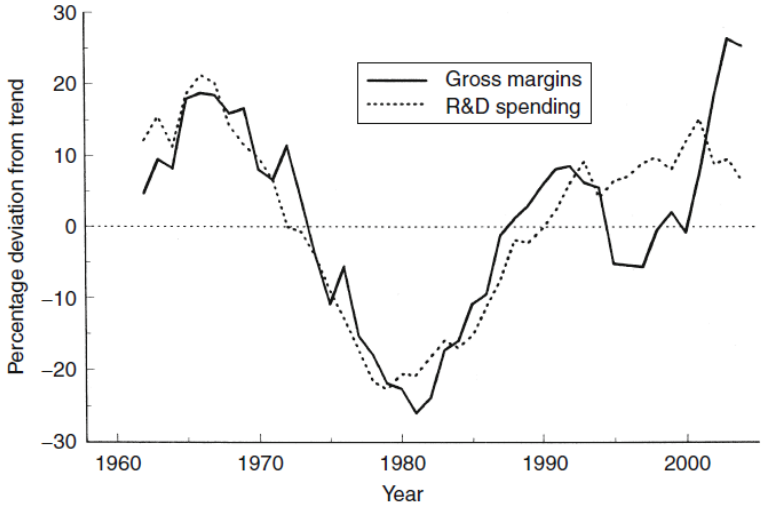


Figure 4. Trend-adjusted changes in pharmaceutical company margins and R&D spending. Source: Scherer, *Pharmaceutical Innovation* at 563 (Figure 5).

From this perspective, attempts to reduce patent duration—*e.g.*, by barring reverse payment settlements—are really attempts to shift consumer welfare from future consumers, the beneficiaries of current R&D expenditures, to current consumers. Once patent duration is understood to be a tradeoff between current and future consumers, it is not at all obvious what position antitrust law should take in the matter. Certainly, the economics of pharmaceuticals provide many reasons to doubt the claim that extending a drug patent, even one associated with a reverse payment settlement, is likely to harm consumers.

B. Petitioner Underestimates the Benefits Of Drug Patents To Consumers

Petitioner contends that a pioneer drug company is likely to enjoy a longer period of exclusivity for a patent if the litigation is settled than if the patent's validity were litigated to judgment.

Implicit in Petitioner's antitrust claim, which must make reference to the loss of consumer welfare from a patent, are two assumptions. First, the standards used to judge whether a patent is valid under patent law discriminates between those innovations that promote consumer welfare—and should enjoy a 20-year patent life—from those that do not and should not enjoy any further patent protection. Second, patents that are not actually held invalid by a court but are involved in a settlement also do not promote consumer welfare.

Amici agree with Respondent Solvay Pharmaceuticals that a reverse payment settlement does not imply that the associated patent would have been found invalid by a court, Br. for Resp. Solvay

Pharm. at 30. That undermines the second assumption. We go further and question the first assumption as well.

If the pioneer drug company's patent were litigated to judgment, then the patent's validity would be judged by the traditional patent standards of non-obviousness, novelty, and utility. These standards may measure the social value of non-drug patents, but they fail to capture the full social value from a drug patent.

First, the traditional standards for patent validity do not appreciate that all drug patents—whether valid or not—are necessary to compensate drug companies for conducting clinical trials. Moreover, clinical trials of a drug are socially valuable even if the patent covering that drug is associated with a reverse payment settlement.

Second, profits from a drug patent—even if the patent is involved in a reverse payment settlement—sustain research on a large number of other drugs, the patents on which may never be challenged or would be held valid if were challenged and litigated to judgment. This cross-subsidization implies that antitrust law should judge the consumer welfare created by a pioneer drug company by the consumer welfare from its portfolio of patents and not just from any individual patent it holds. Petitioner's position, implicitly applying traditional standards for patent validity to individual patents, fails to do that.

Our contention is not that traditional standards for judging patent validity must be perfect in order for antitrust law to rely on them in cases involving abuse of patents. Rather, our contention is that

there is a worse fit between patent validity standards and social value of innovation in the pharmaceutical industry than in other industries. As a result, in antitrust inquiries judging the value of pharmaceutical patents to consumers, courts should not rely as heavily as Petitioner contends on traditional patent validity standards and judgments upholding patent validity.

1. Drug patents associated with reverse payment settlements encourage socially valuable clinical trials

Nearly all drug patents encourage production of useful public goods, specifically information about whether a drug works. One reason is that, unlike patents for other products, a patent for a drug is typically obtained before research on the drug is completed. Specifically, drug companies obtain patents on molecules after lab and animal testing, but before clinical test, *i.e.*, testing on humans. Yet human testing is roughly half the cost of all drug R&D. Joseph A. DiMasi, Ronald W. Hansen and Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs,* 22 J. Health Econ. 151 (2003).

Moreover, the results from clinical trials, which are made public as part of the drug approval process, are a public good. Once a drug is shown to be effective, generics would know whether it is effective and enter the market in the absence of a patent. If a company did not have a patent that could prevent that entry, it would never recoup the costs of conducting clinical trials. Anticipating that, it would not conduct trials in the first place.

A second feature that distinguishes drug R&D, specifically clinical trials, from R&D for other products is that clinical trials are socially valuable even if the patents covering a drug were associated with a reverse payment settlement. It is socially valuable to learn whether a drug is safe and effective and that value is positive whether the relevant patent is litigated to judgment and upheld or settled. Professor Roin notes that a large number of molecules in the public domain—either because they were not patentable or their patents expired—may be valuable but are untested and unexploited because no company can recoup the costs of doing research on them. Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability,* 87 Texas L. Rev. 503, 505-506 (2008-2009).

Further evidence comes from the Orphan Drug Act, which rewards drug companies that demonstrate via trials that a molecule is safe and effective at treating an orphan disease—a disease that afflicts 200,000 individuals or less per year—with up to 7 years of market exclusivity, even if the molecule is already in the public domain. 21 U.S.C. § 360cc(a). The Orphan Drug Act is thought to have successfully increased the number of treatments for orphan diseases. *See, e.g.,* Wesley Yin, *Market Incentives and Pharmaceutical Innovation*, 27 J. Health Econ. 1060, 1073 (2008); Alan M. Garber, *Benefits Versus Profits: Has the Orphan Drug Act Gone Too Far?*, 5 Pharmacoeconomics 88, 91 (1994). If market exclusivity for drugs that are in the public domain have social value, so too does market exclusivity for drugs that are associated with reverse

payment settlements rather than litigated to judgment and upheld.

Admittedly, information that a drug works may be more valuable than knowing a drug does not work. But the manner in which generic drug companies select patents for Paragraph IV challenges suggests that reverse payment settlements largely cover drugs that work—thus drugs for which trials are particularly valuable. All Paragraph IV challenges are filed against drugs approved by the FDA, *i.e.*, those already found to be safe and effective. Moreover, Professors Hemphill and Sampat have demonstrated that sales are an important predictor of Paragraph IV challenges. Hemphill and Sampat, *When Do Generics Challenge Drug Patents* at 613, 630, 632. And sales tend to follow drugs that work well rather than drugs that do not work well. This should not be surprising: generics companies also care about profits. Drugs that give the greatest value from Hatch-Waxman's 180-day market exclusivity period for the first-filing generic are exactly those drugs that are most profitable to the pioneer drug company.

One criticism of this line of argument is that patents may reward drugs companies "too much" for trials, *i.e.*, give them more money than is required to get them to do trials on the drug in question. Average sales for drugs that are subject to Paragraph IV challenges are $200 million. Hemphill and Sampat, *When Do Generics Challenge Drug Patents* at 628 (Table 2). This amount is greater than the $100.4 million it takes on average to conduct the three phases of clinical trials required for drug approval by the FDA. DiMasi *et al.*, *The*

Price of Innovation at 165 (Table 4). Revenue must cover the cost of pre-clinical testing, but those costs are only $60.6 million, leaving $39 million in profits per challenged drug. *Id*. at 162 (Table 1).

But there are many drugs for which trials are conducted and the drug is not approved. Cost estimates that account for the fact that revenues from drugs that are approved must pay for trials for drugs not approved range from roughly $800 million to $2 billion per approved drug. *See* DiMasi *et al.*, *The Price of Innovation* at 166 (giving an estimate of $802 million per approved drug); Christopher P. Adams and Van Vu Brantner, *Spending on New Drug Development*, 19 Health Econ. 130, 131 (2010) (confirming the $802 million estimate); Christopher P. Adam and Van Vu Brantner, *Estimating the Cost of New Drug Development: Is It Really $802 Million?* 25 Health Aff. 420, 425-426 (2006) (finding that for some firms the costs may rise to $2.1 billion per approved drug and $1.1 billion for some diseases).

Likewise, there are many drugs that are approved, but the drug does not generate enough revenue to cover the costs of R&D for the drug. Cost estimates here are unknown. Because the median drug does not cover it cost of development, Henry G. Grabowski and John M. Vernon, *Returns to R&D on new drug introductions in the 1980s*, 13 J. Health Econ. 383, 399 (1994) (Figure 5), the estimated costs of developing a profitable drug could be double, or as high as $1.6 billion to $4 billion. From this perspective, the average revenues on drugs subject to Paragraph IV challenges do not seem excessive.

An outside check on whether drugs subject to Paragraph IV challenges make "excessive" profits is

to examine overall drug company profits. If the profits from drugs subject to Paragraph IV challenges were "too profitable," drug companies should be making supra-competitive profits across their portfolio. As amici previously pointed out above, the health economics literature suggests that drug companies barely cover their actual cost of capital. *Ibid.*

2. Patents associated with reverse payment settlements may sustain research on unchallenged and affirmatively valid patents

Drug companies typically conduct trials on a number of drugs and even sell multiple approved drugs on the market. Carrying a number of drugs reduces the variability of a drug company's profits. Scherer, *Pharmaceutical Innovation* at 559; F.M. Scherer and Dietmar Harhoff, *Technology policy for a world of skew-distributed outcomes*, 29 Research Policy 559, 564 (2000). This smoothing of profits reduces the cost of capital to a drug company. Investors demand a higher rate of return on more risky investments. Offering investors a portfolio of drugs offers lower risk investment than offering just one drug. Therefore, *ceteris paribus*, investors demand a lower return from a company with a portfolio of drugs than a company with an individual drug. As a result, holding portfolios of drugs enables drug companies to raise capital at a lower cost. OTA, *Pharmaceutical R&D* at 8.

Carrying a portfolio of drugs also allows drug companies to lower capital costs by partly self-financing investment in innovation. Raising capital for R&D is difficult because companies typically

have more information about the prospects of their R&D projects than lenders or investors. This asymmetry makes lenders and investors reluctant to offer capital except at high rates of return. Again, an alternative to paying those high rates is for the company to finance R&D through retained earnings. Holding a portfolio increases the odds that at least one drug generates positive profits that can be retained for financing purposes. Scherer, *Link Between Gross Profitability and Pharmaceutical R&D Spending* at 216.

Combining the fact that drug companies carry portfolios with the fact that, adjusting for risk, drug companies do not make substantially supra-competitive profits, one can infer that drug patents that generate high profits cross-subsidize R&D on unprofitable patents on approved drugs and also patents on unapproved drugs. Paragraph IV challenges place pressure on this financing system because they target drugs with high sales. *See* Hemphill and Sampat, *When Do Generics Challenge Drug Patents* at 615. The ability of a pioneer drug company and a first-filing generic to settle a Paragraph IV challenge substantially reduces the impact that such challenges have on the pioneer's financing of R&D.

Petitioner contends that patents associated with reverse payment settlements are relatively "weak" patents. FTC Br. 7, 44. Amici agree with Respondent Solvay Pharmaceuticals that it is difficult to identify which patents are "strong" or "weak." Resp. Br. at 28-30. Certainly sham patents cannot be enforced. But drugs involved in reverse settlements might have been held valid had the

matter been fully litigated. Moreover, this Court's precedents hold patents as presumed valid until held otherwise. Resp. Br. at 19.

Even if one were to assume for the sake of argument that it is possible to distinguish "weak" patents from "strong" or valid ones, the fact that patents associated with reverse payment settlements are "weak" does not negate the fact that they generate substantial sales. Otherwise they would not have been subjects to Paragraph IV challenges by generic companies. *See* Hemphill and Sampat, *When Do Generics Challenge Drug Patents* at 613, 630, 632. Because all profitable patents cross-subsidize unprofitable ones, whether or not they are "weak," declaring reverse settlements presumptively illegal undermines the manner in which pioneer drug companies finance R&D.

Admittedly, allowing what Petitioner calls "weak" patents into a drug company's portfolio reduces the overall "strength" of that portfolio. But the position taken by Petitioner is that reverse payment settlement should be presumptively illegal, *i.e.*, not even one "weak" drug patent should be tolerated under antitrust law. Such a stance rules out the possibility that a portfolio of drug may have some—but not all— "weak" patents, that the portfolio would not exist (or have as many "strong" patents) without the "weak" but profitable patents, and that the portfolio as a whole is socially valuable. This possibility counsels against a strong presumption against reverse payment settlements.

CONCLUSION

The Court should affirm the judgment of the court of appeals and reject Petitioner's proposed rule.

Respectfully Submitted,

Dated: February 2013

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APPENDIX

APPENDIX A — LIST OF ACADEMIC SIGNATORIES[2]

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[2] This brief presents the views of the individual signers. Institutions are listed for identification purposes only.

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