Nos. 15-3559 & 15-3681

IN THE

United States Court of Appeals

FOR THE THIRD CIRCUIT

In Re: Wellbutrin XL Antitrust Litigation

AETNA HEALTH OF CALIFORNIA, INC., *et al.*,

Plaintiffs-Appellants/Cross-Appellees,

v.

SMITHKLINE BEECHAM CORPORATION, *et al.*,

Defendants-Appellees/Cross Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PENNSYLVANIA

BRIEF OF ANTITRUST ECONOMISTS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES

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STATEMENT OF INTEREST[1]

Amici curiae, listed in Appendix A, are professors and scholars who specialize in evaluating the "economic realities" that the Supreme Court has repeatedly held "must govern review of antitrust activity."[2] *Amici* submit this brief to share with the Court their expertise regarding those economic realities in the fields of industrial organization, competition, and antitrust policy, particularly as those fields help explain the workings of the pharmaceutical industry. Specifically, *amici* write to bring to the Court's attention economic analyses relevant to measuring the market effects of patent infringement litigation settlements that contain large payments from the patent holder to the patent challenger.

SUMMARY OF THE ARGUMENT

In *FTC v. Actavis*, the Supreme Court for the first time established that patent infringement settlements with "large" and "unexplained" payments made by the patent holder to the infringer would be subject to antitrust scrutiny under the rule of reason.[3] The Court did not, however, provide a road map for what in

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[1] The parties to Case Nos. 15-3559 & 15-3681 have consented to the filing of this brief. No one other than *amici curiae* and their counsel authored this brief or contributed money that was intended to fund preparing or submitting this brief.

[2] *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005) (citing *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466-67 (1992)).

[3] 133 S. Ct. 2223, 2236 (2013). *Amici* understand that the lower court did not consider whether the settlement under consideration involved a large payment;

particular that rule of reason inquiry should look like, instead "leav[ing] to the lower courts the structuring" of the appropriate analysis.[4]

For the same reasons that the Supreme Court rejected the truncated analytical approaches presented by the parties in *Actavis* and held that the rule of reason applies, the truncated rule of reason approach urged by the Appellants and FTC in this appeal also should be rejected. Neither the courts nor economists are equipped with the breadth of experience or empirical evidence to determine what analytical shortcuts, if any, would yield conclusions regarding the effects of a particular reverse payment settlement that matched economic realities.[5]

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the court instead skipped the threshold inquiry under *Actavis* and applied the rule of reason inquiry that follows after the threshold is met. *See United Food & Commerce Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc. (Lidoderm)*, 74 F. Supp. 3d 1052, 1066 (N.D. Cal. 2014) ("Most district courts read *Actavis* to hold that it is the 'large and unjustified reverse payment' that creates the anticompetitive concerns, and only after finding such a payment in the settlement may courts engage in the traditional rule of reason analysis."). This brief therefore covers only the economic realities associated with the scope and nuances of the antitrust scrutiny that applies post threshold inquiry.

[4] *Id.* at 2238.

[5] *E.g.*, *California Dental Ass'n v. FTC*, 526 U.S. 756, 781 (1999) ("What is required . . . is an enquiry [designed] for the case, looking to the circumstances, details, and logic of a restraint. The object is to see whether the experience of the market has been so clear, or necessarily will be, that a confident conclusion about the principal tendency of a restriction will follow from a quick (or at least quicker) look, in place of a more sedulous one."); *Northwest Wholesale Stationers, Inc. v. Pac. Stationery & Printing Co.*, 472 U.S. 284, 294 (1985) (noting the appropriateness of a *per se* rule only where "the likelihood of anticompetitive

As this Court evaluates the proper scope of the rule of reason inquiry, *amici* offer three economic arguments against a truncated approach. First, a payment from the patent holder to the patent challenger as part of the settlement of a patent infringement case brought under the Hatch-Waxman Act[6] is not an accurate proxy for the anticompetitive effects of that settlement. Such an approach assumes that a payment would only have been provided by the patent holder in the context of settling a patent infringement case if the patent holder sought to purchase delayed generic entry. However, economic principles illuminate many reasons other than delay as to why a patent holder might provide consideration to a patent challenger as part of a settlement agreement, including risk aversion, litigation cost, and the benefits a company derives from increased certainty.

Second, courts should not overlook procompetitive settlement terms merely because those terms are stated separately from the term that the plaintiffs

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effects is clear and the possibility of countervailing procompetitive effects is remote."); *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 317-18 (3d Cir. 2010) (explaining that truncated approaches are only appropriate where market effects are undisputed); Timothy J. Muris & Brady P.P. Cummins, *Tools of Reason: Truncation Through Judicial Experience and Economic Learning*, ANTITRUST, Vol. 28, at 46, 47 (Summer 2014) (explaining that truncation is appropriate only when supported by "past judicial experience and current economic learning").

[6] The Hatch-Waxman Act is formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

characterize as a "payment." A settlement agreement may not have been reached at all without the inclusion of all terms, and the effect of all settlement terms, taken together, must be evaluated when measuring the settlement's market impact.

Third, the truncated inquiry advocated by Appellants and the FTC would have substantial long-term welfare costs. The error risks associated with application of such a limited approach all tend toward exposing benign settlements to unwarranted antitrust liability. That liability would substantially undercut the value of patent rights—a result antithetical to the purposes of the antitrust laws and the patent laws.

Given these economic realities, courts should employ a traditional rule of reason analysis to evaluate the market effects of reverse payment settlements once the fact of a large payment is established.

ARGUMENT

I. *Actavis* Rejected Truncated Analytical Approaches Like the Approach Proposed by Appellants and the FTC Here

The default method for evaluating conduct under the antitrust laws is the rule of reason, which involves a comprehensive weighing of the procompetitive and anticompetitive effects of the challenged conduct. Truncated antitrust analyses—that is, analyses short of the traditional rule of reason, including quick looks, presumptions, and *per se* rules—are shorthand tools that courts adopt when extensive judicial and market experience with the restraint at issue supports the

conclusion that particular conduct is so likely to harm competition that a traditional rule of reason analysis is not necessary.[7]

To determine whether a truncated analysis is appropriate from an economic perspective, the costs associated with adopting a model that does not yield accurate results—*i.e.*, error costs—must be weighed against the costs associated with engaging in the analysis—*i.e.*, application costs. Under the standard error cost approach, the appropriate analytical tool must strike the right balance between error costs and application costs.[8] As the extent of the inquiry narrows, error costs typically increase, while application costs increase as the extent of the inquiry broadens. Where a truncated analysis results in application cost savings without substantially increasing error costs, engaging in that limited analysis may make sense. Frequently, however, the increased error costs associated with truncated approaches reveal that more analysis is required to ensure that the antitrust inquiry

[7] *See supra* note 5.

[8] *See* Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 751-52 (2002); *see generally* Isaac Ehrlich & Richard A. Posner, *An Economic Analysis of Legal Rulemaking*, 3 J. LEGAL STUD. 257 (1974) (setting out the general error cost approach); Richard A. Posner, *An Economic Approach to Legal Procedure and Judicial Administration*, 2 J. LEGAL STUD. 399 (1973) (same); Frank H. Easterbrook, *The Limits of Antitrust*, 63 TEX. L. REV 1, 9-17 (1984) (applying the error cost framework to antitrust law).

matches economic realities. Courts routinely strike down efficient rules that do not produce consistently accurate results.[9]

The *Actavis* Court rejected two proposed truncated approaches to evaluating reverse payment settlements, the scope-of-the-patent test and the quick look test. Even though the application costs associated with these truncated approaches were low, the error costs were too high. The scope-of-the patent test, the Court concluded, would yield a correct outcome for valid patents while protecting against the costs associated with the erroneous invalidation of valid patents, known as Type I error costs.[10] However, the scope-of-the-patent test also produces error costs associated with allowing invalid patents to remain on the books and in force, known as Type II error costs. Out of concern for Type II error costs, the Supreme Court held that the scope-of-the patent test was not appropriate because it did not account for the important "patent-related policy of eliminating unwarranted patents

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[9] *E.g.*, *California Dental Ass'n*, 526 U.S. at 781; *Northwest Wholesale Stationers, Inc.*, 472 U.S. at 294; *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d at 317-18.

[10] Michael I. Meyerson & William Meyerson, *Significant Statistics: The Unwitting Policy Making of Mathematically Ignorant Judges*, 37 PEPP. L. REV. 771, 811 (2010) (defining Type I and Type II errors).

so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification.'"[11]

Actavis also rejected the quick look approach advocated by the FTC. Under that approach, "reverse payment settlement agreements [would be] presumptively unlawful," although defendants would be permitted some leeway to challenge that presumption.[12] A quick look test would have protected against Type II errors by making it more likely that invalid patents would not prevent generic entry. That said, applying the quick look test would increase the risk of Type I errors by creating a presumption of unlawful conduct, even when valid patents were challenged, if the settlement involved any type of consideration flowing from the patent holder to the patent challenger. The *Actavis* Court recognized the drawbacks associated with this type of truncated analysis, too, noting quick look tests should apply "only where 'an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets'"—*i.e.*, when the risk of Type I errors was extremely low, and not in the reverse payment context.[13]

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[11] 133 S. Ct. at 2233 (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).

[12] *Id*. at 2237.

[13] *Id.* (quoting *California Dental*, 526 U.S. at 770).

To avoid the error costs associated with the truncated approaches to antitrust scrutiny advocated by the parties in *Actavis*, the Supreme Court held that lower courts should apply the rule of reason to determine the competitive effects of settlements with large reverse payments. Structuring an appropriate rule of reason inquiry involves taking into account not just error costs, but also the costs associated with the model's application. As economists, we believe the challenge is to fashion a procedure that minimizes both error costs and, to the extent feasible, application costs. As the Supreme Court explained in *Actavis*, lower courts must "structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis."[14] On the other hand, "consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences"—would be equally ill-advised.[15]

II. An Analysis Focused Only on the Consideration Provided Will Yield Higher-Than-Acceptable Error Costs

Appellants and the FTC effectively ignore the Supreme Court's instruction in *Actavis* to apply the rule of reason and urge this Court to adopt a truncated analysis similar those already rejected by the high court. The primary feature of

[14] *Id.* at 2238.

[15] *Id.*

the truncated analysis that Appellants and the FTC champion relates to a plaintiff's prima facie burden under the rule of reason to establish that particular challenged conduct has anticompetitive effects.[16] Rather than meet that burden directly, Appellants and the FTC propose that plaintiffs in reverse payment cases should be permitted to present evidence regarding the consideration provided by the patent holder to the patent challenger as a proxy for the settlement's anticompetitive effects. Put differently, whereas *Actavis* explained that "a reverse payment, where large and unjustified, *can* bring with it the *risk* of significant anticompetitive effects,"[17] Appellants and the FTC insist that a settlement that includes such a payment is necessarily anticompetitive.

In fact, the presence of a large payment as part of a settlement neither predictably results in observed anticompetitive effects nor has been empirically established to yield those effects.[18] To the contrary, the inclusion of a payment in a patent litigation settlement does not necessarily result in a delay in generic entry beyond what might be expected under litigation (or, put differently, beyond the

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[16] *Id.* (To prevail on its claims, a plaintiff carries the initial burden under the rule of reason to demonstrate "significant unjustified anticompetitive consequences."); *see also Tose v. First Penn. Bank, N.A.*, 648 F.2d 879, 892 (3d Cir. 1981) ("[P]roof of anticompetitive impact or intent is a necessary element of a prima facie case under the rule of reason.").

[17] *Id.* at 2237 (emphasis added).

[18] *See supra* note 5 and accompanying text.

date that is consistent with the parties' assessment of the strength of the brand company's patent case).[19]

A. Brand Companies Are Willing to Provide Consideration to Patent Challengers for Reasons Other Than Delay

Brand companies are willing to provide consideration to settle patent infringement litigation even when that settlement results in generic entry at a time consistent with what would be expected under litigation for several reasons. Chief among them is the brand companies' risk aversion.[20] The risks associated with

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[19] The generic entry date expected under litigation is equal to the remaining patent life multiplied by the probability the brand company will win the case, plus the amount of time remaining until trial multiplied by the probability the brand company will lose the litigation (assuming no at-risk entry). For example, if (1) trial is scheduled for a year from now, (2) there are five years remaining until patent expiration, and (3) the brand company has a 75% probability of winning the patent litigation, then the expected generic entry date under litigation is in four years: 25%* 1 year + 75%*5 years = 0.25 years + 3.75 years = 4 years. Note that the probability of winning the patent litigation and the expected entry date under litigation are unobservable. If a case is fully litigated, one side either wins or loses, and which side wins provides no information on the *ex ante* probability of that outcome. In other words, a party with only a 5% *ex ante* probability of winning can still be observed to win, so observing a win does not indicate that the *ex ante* probability of winning was high.

[20] Risk aversion as discussed here is not an aversion to the risk associated with generic entry at the time when the strength of the patent suggests that a generic version of a particular product should be on the market. Rather, it is the risk associated with earlier-than-appropriate generic entry given the brand company's patent rights. That risk is all the more acute because of the inherent uncertainty in the litigated outcomes of patent infringement disputes. *See, e.g.*, PricewaterhouseCoopers, *2015 Patent Litigation Study* 18-19 (May 2015), *available at* https://www.pwc.com/us/en/forensic-services/publications/assets/2015-pwc-patent-litigation-study.pdf (noting that overall success rate of patent

litigation may lead a company to prefer a certain outcome associated with settlement even if the certain outcome ultimately appears to yield less for the company than would be likely under the uncertain outcome of litigation.

To explore why risk aversion could lead to the exchange of consideration having nothing to do with delayed entry, consider a lottery ticket with a 50% chance of a $0 payoff and a 50% chance of a $100 million payoff—*i.e.,* the lottery ticket has an expected payoff of $50 million. Most people holding such a ticket would be willing to accept less than the expected payoff amount to achieve certainty.[21] If a person would trade the aforementioned lottery ticket for a certain outcome of $20 million dollars, he or she would essentially be willing to pay $30 million dollars to eliminate the risk of holding the lottery ticket that might result in the $0 payoff. Accepting the certain outcome of $20 million dollars, however, does not reflect a belief that a $0 payoff is anything more than 50%.

As the lottery ticket example makes clear, in the context of a patent litigation settlement, risk aversion could lead a brand company to accept a generic entry date consistent with the strength of its patent case (*i.e.*, no anticompetitive delay) while

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litigation challenges varied between 9 percent and 73 percent in cases heard by the ten federal judges deciding the greatest number of patent litigations between 1995 and 2014 and that more than half of appealed cases were modified in some way on appeal).

[21] *See* Charles A. Holt & Susan K. Laury, *Risk Aversion and Incentive Effects,* 92 AM. ECON. REV. 1644, 1655 (2002).

still providing consideration to the generic company. It is worth noting that one would expect that the more important the drug is to the brand company, the more consideration the brand company would be willing to provide while still accepting an entry date consistent with the strength of its patent case.

Consideration from a brand company to a generic company can also be explained by the benefit brand companies might receive from having more certainty as to when generic entry will occur. For example, the level of investment in research and development and in marketing that a brand company undertakes when the company knows that the remaining patent life for a given drug is five years may differ substantially from the level it would make when facing a 50-50 chance of immediate entry on the one hand, or ten years of remaining patent life on the other. Removing the uncertainty can provide value to the brand company by allowing it to make more optimal investment decisions, *e.g.*, to avoid the costs of delaying investment decisions until more certainty is gained.[22] For example, decisions regarding research and development of new drug candidates could be made more optimally if a brand company had a high degree of certainty regarding the generic entry dates for its existing drugs. In this situation, too, the brand company would be willing to provide consideration to the generic company to gain

[22] *See* AVINASH K. DIXIT & ROBERT S. PINDYCK, INVESTMENT UNDER UNCERTAINTY 6-9 (1994).

more certainty as to when generic entry will occur, without delaying generic entry beyond the expected generic entry date under litigation.[23]

A brand company also might be willing to provide consideration to a patent challenger while still accepting an entry date consistent with its expected entry date under litigation if the company will incur costs from losing the patent litigation other than lost drug sales. For example, there may be costs associated with idling or laying off part of its sales force if it loses the patent case that the company would not face if generic entry occurs at a date consistent with the strength of the brand company's patent case.[24] There also could be costs related to existing drug supply contracts that were entered assuming later generic entry, as well as costs related to returns of the branded product if generic entry occurs suddenly and unexpectedly. These costs are non-trivial and a brand company might be willing to pay to avoid the possibility of facing these costs. In this situation again, the

[23] To the extent the increased certainty incentivizes the brand company to make additional investments in a drug due to the expectation that it could ultimately recoup its investment, the settlement could also increase consumer welfare even though the agreed-upon generic entry date is identical to the expected entry date under litigation. For example, consumers would benefit because additional research and development may provide information on whether or not a drug is effective for new indications, information on the optimal dosing for new indications, and information on how the drug performs in pediatric populations.

[24] Such costs have been shown to drive merger activity. *See* Patricia M. Danzon et al., *Mergers and Acquisitions in the Pharmaceutical and Biotech Industries*, 28 MANAGERIAL & DECISION ECON. 307, 325 (2007) [hereinafter Danzon, *Mergers & Acquisitions*].

agreed-upon generic entry date may still be entirely consistent with the strength of the brand company's patent case even though the brand company provides consideration to the generic company.

Uncertainty in future cash flows and the concomitant increase in a company's borrowing costs may further explain why a brand company would be willing to provide consideration to settle patent infringement litigation.[25] Increased borrowing costs, in turn, increase the discount rate used in valuations of the company's possible research projects and the company itself. As a result, more certainty in cash flows even with no change in expected cash flows (*i.e.,* no change in the expected date of generic entry) can reduce borrowing costs, increase research and development investment, and increase market value. This is yet another reason a brand company might be willing to provide consideration while still accepting a generic entry date consistent with the strength of its patent case.[26]

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[25] *See* STEVEN A. ROSS ET AL., CORPORATE FINANCE 392-420 (9th ed. 2010); RICHARD A. BREALEY, STEWART C. MYERS & FRANKLIN ALLEN, PRINCIPLES OF CORPORATE FINANCE 160-183 (11th ed. 2014); ASWATH DAMODARAN, INVESTMENT VALUATION 383-422 (2nd ed. 2002).

[26] Research suggests that risk in the form of potential government intervention has led the market to demand higher returns for medical research and development firms (*i.e.*, increased financing costs for such firms), which in turn has substantially reduced medical research and development investments. *See* Ralph S.J. Koijen et al., *Financial Health Economics* 41 (Nat'l Bureau of Econ. Research, Working Paper No. 20075, 2014).

B. Differences in Bargaining Position Explain Patent Challengers' Ability To Extract Consideration from Patent Holders Regardless of the Strength of the Patent

The existence of a payment from the patent holder to the patent challenger can also be explained by the substantially better bargaining position in which patent challengers find themselves in patent infringement litigation under the Hatch-Waxman Act. As a result, generic companies are able to extract consideration and obtain a better outcome than what would be expected under litigation (while the brand obtains a worse outcome).

Generic companies are generally not at risk for damages, having been able to challenge the patents without entering the market under the Hatch-Waxman Act.[27] Even when the odds of winning are low, generic companies have an incentive to challenge patents given the substantial benefits from a six-month exclusivity award relative to the costs of mounting a challenge. Indeed the FTC estimated in a 2011 study that "for a drug with brand sales of $130 million, a generic that does not anticipate [competition from an authorized generic] will expect a patent challenge

[27] *See* 21 U.S.C. § 355(j); Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. CORP. L. 309, 316-17 (2005). In other industries, many potential patent infringers may never choose to challenge a patent because of the risk of damages.

to be profitable if it has at least a 4 percent chance of winning."[28] In contrast, brand companies may lose many profitable years from successful challenges and therefore are often inclined to settle on terms favorable to the generic company even when they believe they have a strong case on the merits. Brand companies also tend to rely on a smaller number of products for the bulk of their revenue so a single drug can be extremely important to brand company profits.[29] As a result, generic companies will be able to extract consideration even in situations where the parties agree on the strength of the brand's patent case.

At bottom, a large payment from the brand company to the generic company as part of a patent infringement litigation settlement provides little information about the competitive effects of that settlement. As a result, a truncated rule of reason analysis keyed to the payment does not always provide a reliable proxy for anticompetitive effects. As economists, we find that the error costs are too high to justify eschewing a traditional rule of reason analysis in favor of analyzing only the payment.

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[28] FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT, iii n.7 (2011), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

[29] Danzon, *Mergers & Acquisitions, supra* note 24, at 309.

III. An Analysis That Allows for Consideration of Only Part of the Settlement Will Yield Higher-Than-Acceptable Error Costs

In addition to seeking a truncated approach to the anticompetitive effects portion of the traditional rule of reason, Appellant and the FTC ask the Court to limit the facets of a settlement that can be evaluated under the rule of reason to determine its procompetitive benefits. Both Appellants and the FTC contend that unless a procompetitive benefit is articulated as part of whatever term they claim qualifies as a reverse payment, it should not be evaluated under the rule of reason.

This approach fails because it assumes that the procompetitive terms of a settlement would also exist in a but-for world settlement that did not include the challenged settlement term. But economic literature suggests to the contrary: Payments from patent holders to patent challenges make otherwise unobtainable settlements possible, including settlements that include procompetitive features. As a result, settlement terms cannot be evaluated in isolation.

There are several reasons why it might not be possible for the parties involved in a patent suit brought by a brand manufacturer against a generic manufacturer to settle without additional terms beyond an agreed upon entry date. Real-world complexities such as asymmetric information, differing beliefs regarding the likelihood of prevailing in litigation, and differing discount rates could all lead to situations in which the parties cannot successfully negotiate a

settlement without adding additional terms to the agreement.[30] For example, generic companies may be unwilling to simply wait the amount of time to enter that is consistent with the strength of the brand company's patent case because of its uncertainty regarding the future size of the market. In this situation, a settlement without other terms may not be possible.

In addition, depending on the circumstances, offering an earlier entry date than the agreed upon entry date may provide little or no additional compensation to the generic company. The first generic manufacturer to file an abbreviated new drug application is entitled, upon FDA approval, to six months of exclusivity before other generic firms may enter. This is when the vast majority of generic profits are earned.[31] But when precisely the exclusivity period occurs could have very little effect on the profits the first filer will earn. Indeed, later entry may be more profitable if the brand company has expanded the market in the interim or if

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[30] *See generally* Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements That Settle Patent Litigation,* 49 ANTITRUST BULL. 655, 667-77 (Fall 2004); *see also* Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 368, 368-400 (2010); Gregory K. Leonard & Rika Onishi Mortimer, *Antitrust Implications of Pharmaceutical Patent Litigation Settlements, in* ECONOMIC APPROACHES TO INTELLECTUAL PROPERTY POLICY 251, 261-264 (Gregory K. Leonard & Lauren Stiroh eds., 2005).

[31] *See* Generic Pharm. Assoc., Comment to Fed. Trade Comm'n on Authorized Generic Drug Study, 2 (June 27, 2006), *available at* http://www.ftc.gov/system/files/documents/publiccomments/2006/06/062806gpha.pdf. Note that this analysis presumes multiple patent challengers.

that later entry enables the generic company to prepare better to launch the product. In those circumstances, generic companies will not be encouraged toward settlement by earlier generic entry, and incorporating other settlement terms may be the only bargaining chip that brand companies have to incentivize generic companies to settle on a schedule consistent with expected litigated outcomes.

The fact that settlements might not occur at all without the provision of consideration by the patent holder to the patent challenger means that *all* terms of a settlement agreement must be evaluated to determine the settlement's overall economic effect. A single term of the settlement cannot be extracted and examined in isolation without distorting the "economic realities" that "must govern review of antitrust activity."[32]

In the instant case, the district court appropriately considered several procompetitive features of the underlying settlement agreement, including a back-up supply provision, which would have enabled generic market entry if certain conditions obtained, and a license regarding a different patent related to the same pharmaceutical product in the absence of which generic entry could not have occurred without substantial risk. These are exactly the type of procompetitive features that should be measured during a traditional rule of reason analysis.

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[32] *Dentsply Int'l*, 399 F.3d at 189 (citing *Eastman Kodak*, 504 U.S. at 466-67).

IV. The Truncated Analysis That Appellants and the FTC Propose Would Punish Benign Settlements and Have Long Term Effects at Odds With the Purposes of the Patent and Antitrust Laws

Embracing the mode of analysis that Appellants and the FTC urge will condemn otherwise competitively neutral or even beneficial settlements, and that will have far ranging consequences in the pharmaceutical industry. Importantly, the risks associated with over-inclusive antitrust liability will decrease the options available to patent holders regarding how to manage their intellectual property assets. This, in turn, decreases the value of brand companies' patent rights and reduces incentives to innovate.

The benefits of pharmaceutical innovation are beyond dispute, but in the context of reverse payment discussions, those benefits are often subordinated to the importance of generic drug availability. Consumers benefit from improved access to lower priced versions of existing products (static efficiency), but they also benefit from efforts to develop new products (dynamic efficiency).[33] Dynamic efficiencies attributable to innovation in healthcare and pharmaceuticals are a major cause of improved standards of living over the last century.[34] Economic

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[33] Static efficiency concerns the optimal use of current resources (*e.g.*, drugs already developed) to maximize short-run welfare, while dynamic efficiency concerns incentives to develop new resources (*e.g.*, new drug development) over the long run.

[34] *See* Mark A. Lemley, *Industry-Specific Antitrust Policy for Innovation,* 2011 COLUM. BUS. L. REV. 637, 638-39 (2011) [hereinafter Lemley, *Antitrust*

studies of particular drug classes demonstrate that societal returns from pharmaceutical development are not only large, but often far outpace the cost of innovation.[35]

Research and development costs are abnormally high in the pharmaceutical industry.[36] That only a few initially promising experimental compounds—about one in 10,000[37]—meet safety and efficacy benchmarks and are ultimately approved

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Policy for Innovation]; *see also* Frank R. Lichtenberg, *Sources of the U.S. Longevity Increase, 1960-2001*, 44 Q. REV. ECON. & FIN. 369, 369 (2004); Frank R. Lichtenberg, *The Impact of New Drugs on US Longevity and Medical Expenditure*, 1990-2003: *Evidence from Longitudinal, Disease-Level Data*, 97 AM. ECON. REV. 438, 442 (2007); Pierre-Yves Cremieux et al., *Pharmaceutical Spending and Health Outcomes in the United States, in* INVESTING IN HEALTH: THE SOCIAL AND ECONOMIC BENEFITS OF HEALTH CARE INNOVATION 59, 68 (I. Farquar, K. Summers & A. Sorkin, eds., 2001).

[35] *See, e.g.*, Tomas Philipson & Anupam B. Jena, *Who Benefits from New Medical Technologies? Estimates of Consumer and Producer Surpluses for HIV/AIDS Drugs,* 9 FORUM FOR HEALTH ECON. & POLICY, issue 2, art. 3, at 1-2 (2006) ($1 spent on HIV/AIDS drugs benefits society by approximately $18); David C. Grabowski et al., *The Large Social Value Resulting From Use Of Statins Warrants Steps To Improve Adherence and Broaden Treatment*, 31 HEALTH AFF. 2276, 2280 (2012) (statins provide value at four times their cost); Frank R. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS*, 20 HEALTH AFF. 241, 241-245 (2001) (substituting new drugs for older drugs leads to significant improvements in patient health).

[36] THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY 2 (Patricia M. Danzon & Sean Nicholson eds., 2012) ("The US research-based pharmaceutical industry invests about 15 percent of its sales in research and development (R&D), compared with about 4 percent for US industry in general.").

[37] Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BOARD FAM. MED. 362, 364 (2001).

by the FDA drives a substantial portion of that cost. Just this year, economists estimated that, including the cost of development failures, the average cost to develop and bring to market a single FDA-approved prescription drug was over $2.5 billion.[38] And the cost is only expected to rise. One expert has noted that the number of new drugs invented per billion dollars of research and development investment has been cut in half every nine years.[39]

Innovator companies are able to recoup the high-risk investments in pharmaceutical products because of the patent protection their successful inventions receive.[40] Experts estimate "that innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection."[41] One

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[38] *See* Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 31 (2016).

[39] Jack W. Scannell et al., *Diagnosing the Decline in Pharmaceutical R&D Efficiency,* 11 NATURE REVIEWS DRUG DISCOVERY 191, 191-92 (2012).

[40] *See* Lemley, *Antitrust Policy for Innovation, supra* note 34*,* at 643.

[41] *Id.*; *see also* Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 INT'L J. TECH. MGMT. 98, 98-99 (2000) (pharmaceutical industry particularly sensitive to patent incentives); Bronwyn H. Hall & Dietmar Harhoff, *Recent Research on the Economics of Patents*, 4 ANN. REV. ECON. 541, 548 (2012) (describing a survey that found that patents effectively increase innovation primarily in the pharmaceutical industry); B.N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 545–56 (2008) (describing the pharmaceutical industry's unique dependence on patent protection to spur research and development investment).

study concluded that about 65% of pharmaceutical inventions would not have been introduced into the market absent patent protection.[42]

Subjecting patent litigation settlements to a truncated antitrust analysis that presumes anticompetitive effect on the basis of a large payment would substantially decrease the value of patent rights. And when patent rights are not as valuable, brand firms have less incentive to innovate.[43] Importantly, these decreases in dynamic efficiency (innovation) could more than offset the efficiencies gained from a truncated antitrust analysis in reverse payment cases. Indeed, one economic study analyzed the effects of eliminating drug patents and

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[42] Edwin Mansfield, *Patents and Innovation: An Empirical Study,* 32 MGMT. SCI. 173, 173, 175 tbl. l, 175-76 n.8 (1986).

[43] *See* Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship,* 71 ANTITRUST L.J. 1069, 1087 (2004) ("Others, including me, fear that restricting the range of settlements in this fashion would decrease the value of some patents, because otherwise the patentee would have voluntarily licensed the defendant; and that reducing the value of patents in this manner may reduce patent owners' incentives to invent, disclose, and innovate."); Jonathan Orszag & Robert Willig, *A Preliminary Economic Analysis of FTC Chairman Leibowitz's June 23rd Speech*, at 4 (2009) ("The prospect of facing patent challenges and more frequent protracted litigation to defend patents may also discourage investments in innovation to develop new drugs in the first place."), *available at* http://compass-lexecon.s3.amazonaws.com/prod/cms-documents/fbd395eee3ef87b9/Orszag-Willig_Statement_Re_FTC_Reverse_Payment_Settlement_Study.pdf.

found that the reduced flow of new therapies would cause consumer losses *three times* the short-term gains from immediate generic competition on *all drugs*.[44]

"The intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare."[45] The long-term innovation-related costs associated with the errors likely to result from application of the truncated analysis that Appellants and the FTC urge will have the opposite effect. This, too, supports the application of a traditional rule of reason analysis that measures actual anticompetitive effects and all procompetitive benefits that a settlement produces.

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[44] James W. Hughes et al., *Napsterizing Pharmaceuticals: Access, Innovation, and Welfare* 3, 15-16 (National Bureau of Econ. Research, Working Paper No. 9229, 2011).

[45] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 1.0 (1995), *available at* https://www.justice.gov/atr/antitrust-guidelines-licensing-intellectual-property; *see also id.* ("The intellectual property laws provide incentives for innovation and its dissemination and commercialization by establishing enforceable property rights for the creators of new and useful products, more efficient processes, and original works of expression. In the absence of intellectual property rights, imitators could more rapidly exploit the efforts of innovators and investors without compensation. Rapid imitation would reduce the commercial value of innovation and erode incentives to invest, ultimately to the detriment of consumers. The antitrust laws promote innovation and consumer welfare by prohibiting certain actions that may harm competition with respect to either existing or new ways of serving consumers.").

CONCLUSION

As the Court evaluates the instant case, *amici* urge it to consider the economic analyses above, all of which are relevant to assessing the scope of rule of reason review that should apply to settlements that resolve patent infringement litigation and include a large payment from the patent holder to the patent challenger.

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6,188 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010, in 14 pt. Times New Roman.

Dated: May 10, 2016

/*s*/ Barbara W. Mather
Barbara W. Mather

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I, Barbara W. Mather, hereby certify that the electronic version of this brief is identical to the text version in the paper copies that were sent to the Clerk of the Court of the United States Court of Appeals for the Third Circuit.

Dated: May 10, 2016

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CERTIFICATION OF COUNSEL

I, Barbara W. Mather, hereby certify that I am a member of the bar of this court.

Dated: May 10, 2016

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CERTIFICATE OF SERVICE

I, Barbara W. Mather, certify that on this 10th day of May, 2016, I caused an original and six (6) copies of this Brief of Antitrust Economists as *Amici Curiae* in Support of Defendants-Appellees to be dispatched by hand delivery to the Clerk of the Court for the United States Court of Appeals for the Third Circuit, and filed an electronic copy of the brief via CM/ECF. I certify that counsel for the parties are filing users of the Court's CM/ECF system.

Dated: May 10, 2016

/*s*/ Barbara W. Mather
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