No. 14-2071, 15-1250

IN THE

United States Court of Appeals

FOR THE FIRST CIRCUIT

In Re: Loestrin 24 FE Antitrust Litigation

No. 14-2071
IN RE: LOESTRIN 24 FE ANTITRUST LITIGATION

AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated; ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly situated

Plaintiffs-Appellants

CITY OF PROVIDENCE, RHODE ISLAND, individually and on behalf of all others similarly situated; UNITED FOOD AND COMMERCIAL WORKERS LOCAL 1776 & PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated; NEW YORK HOTEL TRADES COUNSEL & HOTEL ASSOCIATION OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated; FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FIND, individually and on behalf of all others similarly situated; ELECTRICAL WORKERS 242 & 294 HEALTHCARE & WELFARE FUND, individually and on behalf of all others similarly situated; DENISE LOY, a resident citizen of the State of Florida, individually and on behalf of all others similarly situated; MELISA CHRESTMAN, a resident citizen of the State of Tennessee, individually and on behalf of all others similarly situated; MARY ALEXANDER, a resident citizen of the State of North Carolina, individually and on behalf of all others similarly situated; PAINTERS DISTRICT COUNCIL NO. 30 HEALTH & WELFARE FUND, individually and on behalf of all others similarly situated; TEAMSTERS LOCAL 237 WELFARE BENEFITS

FUND, individually and on behalf of all others similarly situated; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 35 HEALTH CARE FUND, individually and on behalf of all others similarly situated; ALLIED SERVICES DIVISION WELFARE FUND, individually and on behalf of all others similarly situated; WALGREEN CO,; THE KROGER CO.; SAFEWAY, INC.; ALBERTSON'S, LLC; HEB GROCERY COMPANY L.P.

Plaintiffs

v.

WARNER CHILCOTT COMPANY, LLC; WARNER CHILCOTT PUBLIC LIMITED COMPANY; WARNER CHILCOTT HOLDINGS COMPANY III, LTD.; WARNER CHILCOTT CORPORATION , LLC, f/k/a WARNER CHILCOTT COMPANY, INC.; WARNER CHILCOTT (US) LLC; WARNER CHILCOTT SALES (US), LLC; WARNER CHILCOTT LABORATORIES IRELAND LIMITED; WARNER CHILCOTT COMPANY; ACTAVIS INC., f//k/a WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; LUPIN LTD.; LUPIN PHARMACEUTICALS, INC.,

Defendants – Appellees

No. 15-1250
IN RE: LOESTRIN 24 FE ANTITRUST LITIGATION

CITY OF PROVIDENCE, RHODE ISLAND, individually and on behalf of all others similarly situated; END PAYOR PLAINTIFFS; UNITED FOOD AND COMMERCIAL WORKERS LOCAL 1776 & PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated; NEW YORK HOTEL TRADES COUNSEL & HOTEL ASSOC. OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated; FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FIND, individually and on behalf of all others similarly situated; ELECTRICAL WORKERS 242 & 294 HEALTHCARE & WELFARE FUND, individually and on behalf of all others similarly situated; DENISE LOY, a resident citizen of the State of Florida, individually and on behalf of all others similarly situated; MELISA CHRESTMAN, a resident citizen of the State of Tennessee, individually and on behalf of all others similarly situated; MARY ALEXANDER, a resident citizen of

the State of North Carolina, individually and on behalf of all others similarly situated; PAINTERS DISTRICT COUNCIL NO. 30 HEALTH & WELFARE FUND, individually and on behalf of all others similarly situated; TEAMSTERS LOCAL 237 WELFARE BENEFITS FUND, individually and on behalf of all others similarly situated; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 35 HEALTH CARE FUND, individually and on behalf of all others similarly situated; ALLIED SERVICES DIVISION WELFARE FUND, individually and on behalf of all others similarly situated; A.F OF L. BUILDING TRADES WELFARE PLAN; NEW YORK HOTEL TRADES COUNCIL AND HOTEL ASSOCIATION OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated

Plaintiffs – Appellants

AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated; ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly situated; WALGREEN CO,; THE KROGER CO.; SAFEWAY, INC.; ALBERTSON'S, LLC; HEB GROCERY COMPANY L.P.

Plaintiffs

v.

WARNER CHILCOTT COMPANY, LLC, f/k/a Warner Chilcott Company, Inc.; WARNER CHILCOTT PUBLIC LIMITED COMPANY; WARNER CHILCOTT HOLDINGS COMPANY III, LTD.; WARNER CHILCOTT CORPORATION; WARNER CHILCOTT (US), LLC; WARNER CHILCOTT SALES (US), LLC; WARNER CHILCOTT LABORATORIES IRELAND LIMITED; ACTAVIS, INC.; WATSON PHARMACEUTICALS, INC.; LUPIN LTD.; LUPIN PHARMACEUTICALS, INC.

Defendants – Appellees

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND
Civil Action Nos. MDL No. 13-2472-S-PAS; 1:13-MD-2472-S-PAS

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

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STATEMENT OF INTEREST[1]

Amici curiae are economists at leading colleges and universities throughout the United States, and consultants who specialize in the economics of the pharmaceutical industry. (A list of the *amici curiae* is attached as Addendum A.) *Amici* have written extensively in the field of economics, including competition, antitrust economics and policy. They seek to bring to the Court's attention economic analysis relevant to assessing the treatment under the antitrust laws of terms reached as part of a settlement that resolves patent infringement litigation. In particular, *amici* address the economics of two features of the Loestrin settlement that, to date, have not been addressed by courts reviewing alleged reverse payment settlements post-*Actavis*.

SUMMARY OF THE ARGUMENT

Plaintiffs-Appellants attempt to subject routine patent settlement agreement provisions to antitrust scrutiny, even when doing so requires plaintiffs to ignore economic realities of the operation of the Hatch-Waxman Act and incentives involved in negotiating patent settlements. The reasons why courts should decline to adopt the view that all alleged reverse payment settlements exchanging something of value deserve antitrust scrutiny under *Actavis* have been

[1] The parties 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.

extensively briefed, including by the parties here. *Amici* focus on two economic issues that, to date, have garnered less attention but are before the Court. First, Indirect Purchaser Plaintiffs-Appellants (IPP-Appellants) challenge an acceleration provision of the settlement between Warner Chilcott and Watson as an improper reverse payment. Such provisions, however, do not present the anticompetitive risk complained of by plaintiffs and, in fact, allow for more generic competition, not less. Second, *amici* for plaintiffs propose that even a settlement that reflects a fair value exchange of goods or services should be suspect from an antitrust perspective. (Retailer Br. at 29 "Evidence of fair value for services in the relevant market does not mean that defendants win") Yet this view is economically unsound and, in the particular context of patent infringement lawsuits in the pharmaceutical industry, reduces the incentives to innovate and thereby disrupts the balance of incentives established by the Hatch-Waxman regulatory framework.

ARGUMENT

Two important economic issues that have received less attention in the reverse payment settlement arena include: (i) the treatment of acceleration clauses in settlements and (ii) the antitrust treatment of settlements that exchange fair value. [2]

[2] Although *amici* do not focus here on the question whether exclusive licenses warrant antitrust scrutiny, that issue also has important economic implications. Exclusive license agreements such as the one included in the Warner Chilcott

Acceleration clauses are common in patent settlements. They are necessary to achieving the settling parties' expectations, and they promote generic competition because they result in competition from multiple firms prior to a brand company's patent expiration. Plaintiffs challenge acceleration clauses as anticompetitive by analogizing them to most favored nation provisions. This

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settlement should not be viewed as anticompetitive and treated with suspicion under the antitrust laws. From an economic perspective, exclusive licenses granted to generic patent challengers are identical to another agreement common in the pharmaceutical industry – the agreement between a patent holder and another company to exclusively market the patented drug. According to a 2009 survey of 184 industry participants conducted by the Licensing Executives Society, 82 percent of the licensing deals in the biotechnology and pharmaceutical industries were exclusive. Licensing Executives Society (USA & Canada), Inc., 2009 *Global BioPharmaceutical Royalty Rates & Deal Terms Survey*, 7 (Sept. 2010). When a patent settlement agreement involves a provision that the brand will not launch an authorized generic during the exclusivity period granted to the first generic filer by the FDA under Hatch-Waxman, the brand is allowing the generic company to have complete marketing exclusivity over the generic drug for the period of the agreement. This type of marketing exclusivity is essentially no different than that granted by a patent holder any time it strikes an exclusive licensing deal with a marketing partner.

Moreover, exclusive licenses are a far cry from the harm that the Supreme Court focused on in *Actavis*. In *Actavis*, the Supreme Court decried agreements that involved a "patentee paying the challenger to stay out." 133 S. Ct. at 2237. In an exclusive license agreement with a brand company agreeing not to launch an authorized generic, the generic will only realize value from the agreement if it enters the market prior to patent expiration, which is procompetitive. An agreement not to launch an authorized generic incentivizes patent challengers to earn sales by challenging the patent prior to expiration. This procompetitive dynamic was not present in the settlement at issue in *Actavis*, which instead involved a cash payment. As settlements involving an exclusive license have important procompetitive distinctions from a cash payment, they should not be regarded with suspicion under *Actavis*.

analogy is flawed because it ignores the relevance of the economic position of the firm requesting the provision. Plaintiffs' argument that acceleration clauses create insurmountable disincentives for additional generic companies to enter, if correct, asks consumers to forgo assured procompetitive benefits from accelerated entry in favor of the possibility of other benefits in the future, benefits that might not materialize.

The settlement here also raises the question whether a settlement between pharmaceutical companies that exchanges fair value should draw antitrust scrutiny under *Actavis*. To subject parties to antitrust liability under those circumstances ignores the economic realities of the negotiation process and undermines the goal of promoting settlements, particularly in the context of the balance established by the Hatch-Waxman framework. This is especially true when considering the social benefits from innovation in the pharmaceutical industry, the high costs associated with developing new drug products, and the significant costs of patent litigation.

I. The Hatch-Waxman Regulatory Framework

The Hatch-Waxman Act[3] ("Hatch-Waxman") includes a complex set of provisions setting forth Congress's balancing of enhanced access to generic

[3] Drug Price Competition and Patent Restoration Act, 21 U.S.C. § 355.

drugs and consumer cost savings (static efficiency) with incentives for innovation that result in new drugs (dynamic efficiency).[4]

Under Hatch-Waxman, generic manufacturers file Abbreviated New Drug Applications ("ANDAs") for approval of their products. ANDAs reduce the level of scientific data required for drug approval by the Food and Drug Administration ("FDA") before a generic company distributes and markets a generic drug. In contrast to New Drug Applications ("NDAs"), which require that the drugs undergo costly and lengthy studies to demonstrate that they are safe and effective for its intended uses, ANDA filers need only show that their generic version of a drug is "bioequivalent" to its branded counterpart. *See* 21 U.S.C. §§ 355(b)(1), (d), (j)(2)(A)(ii)-(iv).

In addition, Hatch-Waxman establishes strong incentives for generic manufacturers to challenge patents associated with branded drugs. In contrast to typical patent litigation standing requirements, Hatch-Waxman permits generic manufacturers to challenge a brand's patent before the generic places its product

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4 *See* William J. Kolasky, *The Merger Guidelines and the Integration of Efficiencies Into Antitrust Review of Horizontal Mergers*, 71 ANTITRUST L.J. 207, 247-48 (2003). ("The dynamic efficiency principle, most closely associated with Austrian economist Joseph Schumpeter, suggests that the short run costs associated with allocative and productive inefficiencies stemming from market power can more than be offset by benefits from encouraging dynamic efficiencies through 'creative destruction.'") 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.

on the market (21 U.S.C. § 355(j)(2)(A)(vii)(IV)), meaning that generic drug companies may challenge patents before incurring any liability for sale of infringing products. This incentive applies equally to all generic manufacturers that seek to market a given product, not just the first to file an ANDA.

If a generic company's ANDA references a branded drug that has an unexpired patent listed in the FDA's Orange Book, which lists drug products approved by the FDA for safety and effectiveness, the generic company must certify that it will not seek final FDA approval until after the patent expires on the branded drug (Paragraph III certification), or certify that the patent listed in the Orange Book is invalid or will not be infringed by the generic version of the drug described in the ANDA (Paragraph IV certification). *See* 21 U.S.C. § 355(j)(2)(A)(vii).

In addition to providing this framework for challenging the validity of Orange Book patents in order to facilitate the launch of generic drugs, Hatch-Waxman incentivizes patent challenges by providing the first company to file an ANDA pertaining to a given brand drug product ("Reference Listed Drug") that includes a Paragraph IV certification, 180 days of exclusivity before the FDA will approve another generic for sales and marketing. The Supreme Court has recognized the 180-day exclusivity period as an important incentive to generic companies. *FTC v. Actavis*, 133 S. Ct. 222, 2229 (2013) (citing Hemphill, *Paying*

for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. REV. 1553, 1579 (2006)).

Overall, Hatch-Waxman creates strong incentives for generic companies to challenge brand companies' patents, while at the same time ANDA filers face little or no damage exposure in patent infringement litigation. *See* Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAGERIAL & DECISION ECON. 491, 495-96, 501 (2007); *see also* Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, 9 CPI ANTITRUST CHRON. at 6 (Sept. 2012). As such, challenges to a brand's patents have the potential to benefit consumers because they can lead to competition from generic versions prior to a patent's expiration.

II. Acceleration Clauses are Procompetitive

IPP-Appellants ignore the Hatch-Waxman regulatory and economic context, arguing that acceleration clauses – and the specific clause contained in the Warner Chilcott Settlement – are anticompetitive. *See* IPP Br. at 25-36. The Warner Chilcott Settlement acceleration clause provided that if a generic manufacturer other than Watson entered the market before the date agreed upon in the Warner-Watson settlement, then Watson could enter immediately. *Id.* at 25

(citing JA-000151; JA-000273-274). The provision further stipulated that if Warner Chilcott provided a license to a generic company other than Watson that allowed generic entry prior to the date agreed to with Watson, Watson could enter 180 days prior to that date. *Id*. Rather than impede competition, an acceleration provision with such terms enhances competition by facilitating settlement and entry by *more* competing generic firms. Indeed, although acceleration clauses have been utilized in numerous patent settlements that have come under court scrutiny (including the settlement at issue in *Actavis*), no court has treated an acceleration clause as a reverse payment. This court should decline to subject acceleration clauses to unprecedented antitrust scrutiny and instead recognize the procompetitive effects of these clauses.

A. Acceleration Clauses Facilitate Settlement and Are Therefore Routine in Pharmaceutical Patent Settlements

Acceleration clauses are routine in settlement agreements when multiple generic firms seek entry. Such provisions allow an individual patent challenger to enter prior to an agreed upon date in the event of earlier entry by another generic company. According to the FTC, provisions allowing a settling generic to launch its product at the time of another generic company's launch are "typical" in Hatch-Waxman settlements. *See* Br. of Pet'r at 52, *FTC v. Actavis, Inc.*, 133 S. Ct. 2233 (2013), 2013 WL 267027.

Whenever a brand manufacturer negotiates a settlement involving a specific entry date with a generic company, such settlement is subject to the threat that another patent challenger could launch its generic product earlier than the specified entry date, either by (1) negotiating a settlement involving an earlier entry date; (2) launching its product at risk of patent infringement; or (3) obtaining a ruling of noninfringement or invalidity in the patent litigation.

A generic company negotiating a settlement with a brand manufacturer has far less incentive to enter a settlement without an acceleration provision as compared to one with such a provision due to the risk of being disadvantaged by earlier entry of another generic. This is true even in a settlement whose only terms include a license agreement between the brand and the generic that specifies a negotiated entry date earlier than patent expiration, a settlement construct specifically endorsed by the Supreme Court in *Actavis*. *Actavis*, 133 S. Ct. at 2237. The omission of an acceleration clause would disadvantage the first generic company to settle with a brand and would upset the expectations of both sides (brand and generic) of a settlement. And in some circumstances, settlement without an acceleration provision would be impossible. But when the effect of a settlement, through inclusion of an acceleration clause, is to permit competition by multiple generics once any generic company enters, such settlement should be encouraged.

B. Plaintiffs' Most Favored Nation Analogy Fails

Plaintiffs attempt to analogize acceleration clauses included in patent settlements with "most favored nation" provisions that are sometimes included in agreements among trading partners and may be anticompetitive under certain circumstances. This comparison is inapt.[5] Unlike most favored nation clauses, which have the potential to *prevent* price competition, acceleration clauses further the settlement of litigation *and* increase competition in the relevant market (*see* II.A and II.C *infra*), thereby creating assured gains. Discouraging acceleration clauses asks the public to forgo these certain gains for potential gains in the future that are speculative at best.

In addition, most favored nation provisions raise concerns when they are demanded by a dominant market player seeking the best price for goods or services in an effort to prevent competitors from obtaining a better deal. For acceleration clauses included in patent settlements, the parties seeking entry on par with the earliest generic entrant are instead the *non-dominant* parties – the generic challengers to a patent held by a brand company. For this reason alone, the analogy to most favored nation provisions is of little import because a firm's position in the market (dominant vs. non-dominant) impacts what conduct it may

[5] In its *amicus* brief, the FTC notes that the End-Payor Appellants "incorrectly state[] that the FTC has described acceleration clauses in pharmaceutical settlements as analogous to 'unlawful [most favored nation clauses.]'" FTC Br. at 24-25, n.13.

insist on from other entities. ABA Section of Antitrust Law, MONOPOLIZATION AND DOMINANCE HANDBOOK 92 (2011) ("concerted action taken by a monopolist may be unlawful in some circumstances even though that same action may be lawful when undertaken by a firm without monopoly power"). Further, most favored nation clauses involve a party imposing a restriction on a trading partner. The acceleration clause here, allowing Watson to launch its generic if another generic entered the market, imposes no such restriction on Warner Chilcott.

C. The Use of Acceleration Clauses Can Promote Competition

IPP-Appellants contend that acceleration clauses delay generic competition because once a generic manufacturer enters into a settlement containing an acceleration clause, other generic manufacturers will not wage their own challenge to a brand's patent. IPP Br. at 26. Plaintiffs argue that unless a generic company has the ability to be the first and only generic on the market, its incentive to launch a generic product is "very substantially diminished, if not altogether eliminated." *Id.* That position is refuted by the economic evidence. Firms regularly make the decision to enter with a generic even knowing that they will face competition from a generic already on the market. The same holds true for a generic manufacturer that knows a rival generic manufacturer has entered into

a settlement that contains an acceleration clause.[6] Contrary to the claims of the plaintiffs, competition among generic companies supplying the same drug will occur as long as new suppliers can obtain sufficient sales to be profitable, including gaining sales by underpricing the existing suppliers.

Indeed, acceleration clauses can create the potential for *earlier* entry by *multiple generics*. If an acceleration clause is triggered by generic entry from a non- or later-settling generic company, the immediate effect is *more* competition and, as a result, lower prices for consumers. Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. OF ECON. & MGMT. STRATEGY 89 (1997) ("[I]t appears that more competition among generic drug producers is linked to price reductions for those drugs.").

III. Exchanging Fair Value to Settle Is Procompetitive

In plaintiffs' sweeping efforts to paint nearly all settlements between a brand pharmaceutical company and a generic company as anticompetitive, *amici* for plaintiffs go so far as to suggest that even settlements that reflect a fair value exchange raise competitiveness concerns. Retailer Br. at 21-22. There is no basis in economics for this position. Instead, as *Actavis* emphasizes, compensation for

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[6] Here, the Warner-Watson settlement, with the inclusion of the acceleration clause, was announced publicly on January 12, 2009. Thereafter, both Lupin and Mylan filed ANDAs seeking approval of their own generic versions of Loestrin. DPP-Appellant Compl. ¶¶ 175, 188; IPP-Appellant Compl. ¶ 109. At the time these ANDAs were filed, it was public knowledge that generic entry would result in entry by Watson as well.

fair value in a settlement is not an antitrust concern. *Actavis*, 133 S. Ct. at 226 ("Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.").

A. The Exchange of Fair Value Facilitates Settlements

Plaintiffs wrongly assume that the conveyance of consideration by a patent holder to the challenger is necessarily tied to a delay in generic entry beyond what would be expected under litigation (or, put differently, beyond the date that is consistent with the parties' assessment of the strength of the brand company's patent case).[7] Against the backdrop of the high cost of uncertainty, there are

[7] 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. This brief assumes *arguendo* that parties to pharmaceutical patent infringement litigation have precise and accurate assessments of the strength of the patent holder's patent case, and further that they are the same across the parties. This, of course, is not necessarily the case.

numerous reasons why a brand company might provide consideration while still accepting a generic entry date consistent with the expected entry date were the case fully litigated.

In assessing settlements of this nature, courts must be mindful of the complexities of negotiation. Negotiating on only one element is a zero-sum game and can make it difficult for the parties to reach agreement. For example, when the element is patent life, negotiations will result in only less profit for the generic or less profit for the patent holder. Yet, a number of factors complicate negotiations of patent settlements. These include asymmetries of information, differences in beliefs as to the strength of the parties' respective litigation positions, and differing discount rates. *See* Barry C. Harris et al., *Activating* Actavis: *A More Complete Story*, 28 ANTITRUST 83, 86 (2014); Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements That Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 667-77 (Fall 2004); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004). These factors can render it impossible for the parties to reach a settlement that does not include ancillary terms and the corresponding payment of consideration.

To facilitate settlement, it is not uncommon for a patent challenger to agree to provide the patent holder with ancillary products, services, or benefits such as exclusive licenses for products either on the market or in development,

backup product supply, and joint marketing or development commitments. William O. Kerr & Cleve B. Tyler, *Measuring Reverse Payments in the Wake of* Actavis, 28 ANTITRUST 1 (2013). These types of settlements enlarge the economic "pie" being divided among the parties and make settlement more likely.

In particular, settlements involving exchanges of items to which the parties attribute differing relative valuations can be particularly meaningful in facilitating settlements. *See* Robert H. Mnookin, Scott R. Peppet & Andrew S. Tulumello, *Beyond Winning: Negotiating to Create Value in Deals and Disputes* at 123-25 (2000). When a party is able to give something that is of greater relative value to the receiver that to the party itself, overall value is increased and settlement is more likely to occur.

B. Courts Should Encourage the Procompetitive Benefits from Settlements

Plaintiffs' effort to target compensation for fair value directly conflicts with courts' repeated recognition that settlement should be promoted. *See, e.g.*, *See Fidelity & Guar. Ins. Co. v. Star Equip. Corp.*, 541 F.3d 1, 5 (1st Cir. 2008) ("Settlement agreements enjoy great favor with the courts 'as a preferred alternative to costly, time-consuming litigation.'") (internal citation omitted); *Conservation Law Found. of New England, Inc. v. Franklin*, 989 F.2d 54, 59 (1st Cir. 1993) ("recogniz[ing] a strong and clear policy in favor of encouraging settlements, especially in complicated regulatory settings") (internal quotations and

citation omitted); *Nelson v. Mead Johnson & Johnson Co.*, 484 F. App'x 429, 443 (11th Cir. 2012) ("There is a strong judicial policy favoring settlement as a realization that compromise is the essence of settlement."); *In re Sony Corp. SXRD*, 448 F. App'x 85, 87 (2d Cir. 2011) ("Public policy favors settlements."); *Enriquez v. Estelle*, 427 F. App'x 305, 306 (5th Cir. 2011) ("Due to the strong public policy encouraging the settlement of cases, we prefer upholding settlements rather than overturning them.") (citation omitted); *In re Gen. Motors Corp. Pick-Up Truck Fuel Tank Products Liab. Litig.*, 55 F.3d 768, 784 (3d Cir. 1995) ("The law favors settlement, particularly in class actions and other complex cases where substantial judicial resources can be conserved by avoiding formal litigation.").

Relative to continued litigation, settlements are a more reliable and lower-cost mechanism for achieving generic entry before patent expiration. First, the social benefits of innovation in the pharmaceutical arena are impossible to deny. Yet achieving those benefits requires substantial investment by brand manufacturers. Settlements that preserve brand companies' incentives to innovate and, at the same time, permit generic entry prior to patent expiration are cost-effective *and* benefit consumers. Second, litigation, and in particular patent litigation, presents uncertainty that makes efficient investment of resources by brand manufacturers difficult and costly. Settlements reduce uncertainty and allow

for efficient allocation of resources. Third, the cost of patent litigation itself can be significant; settlements mitigate those costs.

As the Hatch-Waxman Act recognized, preserving a brand company's incentive to continue to invest in the development of new products is critical because these investments result in significant social benefits. Economic studies have shown that social returns from pharmaceutical development are exponentially larger than the cost of innovation. *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. & POL'Y, iss. 2, art. 3 at 1-2 (2006) (each dollar spend on HIV drug research and development benefits society by about $18); Frank R. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS*, 20 HEALTH AFF. 241-245 (2001). Economists have estimated that improvements in life expectancy and quality of life, which are related to higher rates of prescription drug consumption, have enormous monetary value. A widely cited study concluded: "Gains in life expectancy over the century were worth over $1.2 million per person to the current population. From 1970 to 2000, gains in life expectancy added about $3.2 trillion per year to national wealth." Kevin Murphy & Robert Topel, *The Value of Health and Longevity*, 114 J. OF POL. ECON. 871, 872 (2006).

Settlements help to preserve resources for drug development (by innovators) and dissemination (by generics) and therefore are pro-consumer in the long-run. Costly and unpredictable litigation only fuels higher drug prices in the long run. For example, differences in product liability costs between the U.S. and Canada have been shown to be an important factor in explaining the higher drug prices in the U.S. relative to Canada. Richard L. Manning, *Product Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. & ECON. 203 (Apr. 1997).

Uncertainties as to patent litigation outcomes and, consequently, patent life have a substantial impact on a brand company's research, development, and marketing efforts. A brand company that has better knowledge as to the patent life of its drug products can make more reliable decisions regarding investment in patented drugs. Avinash K. Dixit & Robert S. Pindyck, INVESTMENT UNDER UNCERTAINTY 6-9 (1994). Efficient investment by innovator companies in research and development promotes dynamic efficiency and benefits competition. William Kolasky, *The Merger Guidelines and Integration of Efficiencies into Antitrust Review of Horizontal Mergers*, 71 ANTITRUST L.J. 207, 247-448 (2008) ("The dynamic efficiency principle . . . suggests that the short run costs associated with allocative and productive inefficiencies stemming from market power can

more than be offset by benefits from encouraging dynamic efficiencies through 'creative destruction.'").

Patent litigation is particularly costly. In fact, in patent infringement litigation under Hatch-Waxman when the amount in controversy exceeds $25 million, the median cost to litigate a case through trial is $6 million. *See* Am. Intellectual Property Law Ass'n, Report of the Economic Survey 34 (2013). And, in its recent settlement with Cephalon, Inc., the FTC recognized that litigation costs for a patent holder could be as much as $7 million. *See FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go To Purchasers Affected By Anticompetitive Tactics*, Federal Trade Commission Press Release (May 28, 2015).[8] Recognizing the cost – and also extra duration – of patent litigation, courts have recognized the economic importance of settlement in patent cases:

> Public policy strongly favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming. Settlement agreements should therefore be upheld whenever equitable and policy considerations so permit. By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and to the citizens whose taxes support the latter. An amicable

[8] Available at https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill (last accessed Aug. 27, 2015).

> compromise provides the more speedy and reasonable remedy for the dispute.

Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976). This is of particular concern in the pharmaceutical industry. In 2013, pharmaceutical companies spent $51.6 billion on research and development. 2015 Profile Biopharmaceutical Research Industry (April 2015), Appendix Table 1. In 2007, economists estimated that the average cost to develop and bring to market a single FDA-approved prescription drug was over $1.3 billion (in 2005 dollars) including the cost of development failures. *See* Joseph A. DiMasi & Henry G. Grabowski, *The Costs of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469, 469 (2007). A recent update by the authors placed the cost estimate at $2.558 billion (2013 dollars). Tufts Center for the Study of Drug Development, *Briefing on Cost of Developing a New Drug* (Nov. 18, 2014). In addition, researchers have noted that the number of new drugs invented per billion dollars of research and development investment has been cut in half every nine years – that is, new drug development has become progressively more costly over time. Jack W. Scannell et al., *Diagnosing the Decline in Pharmaceutical R&D Efficiency*, 11 NATURE REVIEWS DRUG DISCOVERY 191, 191–92 (2012).

Settlement of patent disputes is a way of equipping innovator companies with greater certainty as to costs and revenue, allowing for efficient

planning and allocation of resources. In the realm of pharmaceuticals, where the up-front investment cost of developing each drug is high and the social value of an effective drug even higher, this concern with dynamic efficiency should be a key consideration in antitrust analysis.

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 treatment under the antitrust laws.

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Respectfully submitted,

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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 4,885 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: August 27, 2015

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CERTIFICATE OF SERVICE

I, Burt M. Rublin, certify that on this 27th day of August, 2015, I filed an electronic copy of the brief via CM/ECF, which will deliver notification of filing to all counsel of record.

Dated: August 27, 2015

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