Appeal Nos. 15-1184, 15-1185, 15-1186,
15-1187, 15-1274, 15-1323, & 15-1342 (Consolidated)

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

IN RE: EFFEXOR XR ANTITRUST
LITIGATION

On Appeal from the United States District Court
for the District of New Jersey

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

JONATHAN D. HACKER
EDWARD HASSI
O'MELVENY & MYERS LLP
jhacker@omm.com
1625 Eye Street, N.W.
Washington, DC 20006
Telephone: (202) 383-5300
Facsimile: (202) 383-5414

Counsel for Amici Antitrust Economists

February 23, 2016

TABLE OF CONTENTS

Page

STATEMENT OF INTEREST 1

SUMMARY OF ARGUMENT 1

ARGUMENT 3

I. PLAINTIFFS CANNOT DEMONSTRATE A "LARGE AND UNEXPLAINED" REVERSE PAYMENT WITHOUT CONSIDERING THE VALUE OF THE ROYALTIES TEVA AGREED TO PAY WYETH. 3

CONCLUSION 9

TABLE OF AUTHORITIES

Page(s)

CASES

FTC v. Actavis, Inc.,
133 S. Ct. 2223 (2013) ..... passim

In re Effexor XR Antitrust Litig.,
No. 11-5479, 2014 WL 4988410 (D.N.J. Oct. 6, 2014) 5

King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.,
791 F.3d 388 (3d Cir. 2015) 4, 5, 7

OTHER AUTHORITIES

Barry C. Harris, et al., Activating Actavis*: A More Complete Story*,
28 Antitrust 83, 86 (2014).....6

FTC and DOJ, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.3 (Apr. 6, 1995) 7

James McCarthy & Ben Bonifant, *A Review of the Global BioPharmaceutical Royalty Rates & Deal Terms Survey*, *Les Nouvelles*, Sept. 2011, at 251.....8

William O. Kerr & Cleve B. Tyler, *Measuring Reverse Payments in the Wake of* Actavis, 28 Antitrust 29 (2013) 6

STATEMENT OF INTEREST[1]

Amici curiae are economists who conduct research and teach 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 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 importance of a feature understood to be part of the Effexor settlement—royalty payments promised by the generic manufacturer (here, Teva) to the brand manufacturer (here, Wyeth) derived from profits earned during the generic's statutorily provided exclusivity period—that, to date, has not been addressed by courts reviewing alleged reverse payment settlement post-*Actavis*.

SUMMARY OF ARGUMENT

Amici file this brief to make a basic, but crucial economic point—settlements involve an exchange of consideration and there is no basis for claiming that a so-called "reverse payment" is "large and unexplained" without examining

[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 the preparation or submission of this brief.

all of the consideration exchanged as part of the transaction. *Amici*'s understanding is that to challenge a settlement agreement between a brand pharmaceutical company and a generic company in the course of Hatch-Waxman patent litigation, a plaintiff must plead, with sufficient specificity, that the challenged settlement includes a "large and unexplained" reverse payment from the brand to the generic. As a matter of simple arithmetic, that burden cannot be met where the complaint accounts for only one element of the transaction and ignores the others.

Such is the case here. Plaintiffs have failed to consider the royalty payments Teva agreed to pay Wyeth in exchange for the license to the patents at issue and Wyeth's agreement not to market an authorized generic ("AG") of its own during Teva's regulatory exclusivity period. Thus, Plaintiffs cannot demonstrate that the "reverse payment" Plaintiffs allege is either "large," or "unexplained," or even a "reverse payment" at all.

Moreover, permitting a plaintiff to initiate costly litigation by focusing on a single term of a settlement agreement (here, the No-AG agreement) while ignoring other elements of the same settlement (here, the exclusive license that Wyeth provided to the patents at issue or the royalty that Teva provided in exchange for this license) could result in negative economic outcomes. When viewed in isolation, *any* individual settlement term can appear "large" or "unexplained," and

thus potentially anticompetitive. Allowing a suit to proceed that myopically focuses on a single settlement term (to the exclusion of other terms) thus would expose a wide range of settlement terms to challenge under antitrust laws.

From an economic perspective, this would be a bad outcome. It could incentivize patent holders to forego mutually beneficial settlement arrangements, or indeed any mutually beneficial exchanges, to avoid potential antitrust litigation risk. And it threatens to eliminate the important economic benefits associated with such mutually beneficial arrangements (not to mention the saved litigation costs). *Amici* strongly urge this Court to avoid this outcome.

ARGUMENT

I. PLAINTIFFS CANNOT DEMONSTRATE A "LARGE AND UNEXPLAINED" REVERSE PAYMENT WITHOUT CONSIDERING THE VALUE OF THE ROYALTIES TEVA AGREED TO PAY WYETH.

In *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), the Supreme Court decided that settlement agreements made by a brand pharmaceutical company and a generic company in the course of Hatch-Waxman patent litigation were not to be immunized from antitrust scrutiny. While "recogniz[ing] the value of settlements" to patent litigation, *id.* at 2234, the Court nevertheless decried settlements that involved a "patentee paying the [patent] challenger to stay out" of the market. *Id.* at 2237. The Court thus held that such agreements—commonly referred to as "reverse payments"—had the "potential for genuine adverse effects on

competition" and were therefore to be subjected to antitrust scrutiny. *Id.* at 2234 (internal quotation marks omitted).

However, the Court recognized that settlements with reverse payments reflecting "traditional settlement considerations" did not present "the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Id.* at 2236. The Court therefore concluded that only a payment which is "large and unjustified can bring with it the risk of significant anticompetitive effects." *Id.* at 2237. Thus, as we understand *Actavis* and this Court's recent *Lamictal* opinion interpreting it, a plaintiff must plead that the reverse payment is large and unexplained with sufficient specificity to subject a settlement agreement to antitrust scrutiny. *Id.*; *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015) (holding that the alleged reverse payment—a promise by a brand drug company not to launch an authorized generic—"falls under *Actavis*'s rule because it may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer").

It is *amici*'s understanding that as part of the settlement agreement between Teva and Wyeth, Teva agreed to pay royalties from the sale of its generic version of Effexor XR, Wyeth granted Teva a license to the patents at issue, and Wyeth agreed not to market an AG of its own during Teva's regulatory exclusivity period

obtained by being the first ANDA filer. Plaintiffs allege that the latter agreement—often referred to as a "No-AG" agreement—constitutes the type of "large and unexplained" reverse payment that concerned the *Actavis* Court.

But in labeling the challenged agreement a "reverse payment," Plaintiffs focus on only one element of the challenged agreement—*i.e.*, Wyeth's promise not to market an AG version of Effexor XR. As the district court in this case recognized, Plaintiffs' complaint fails to consider (or even mention) the royalties that Teva agreed to pay Wyeth in return. *See In re Effexor XR Antitrust Litig.*, No. 11-5479, 14 WL 4988410, at *22 (D.N.J. Oct. 6, 2014).

Of course, the mere *existence* of other contractual terms does not necessarily explain a challenged settlement term. But without analyzing the *magnitudes* and *rationales* of other contractual terms, *i.e.*, all of the consideration exchanged as part of an agreement, how can a plaintiff demonstrate that a challenged settlement term is unexplained, much less that it constitutes a "reverse payment"? For example, without attempting to value the royalties that Teva had to pay Wyeth for its license to the Effexor XR patents, Plaintiffs cannot establish that Wyeth's promise not to launch an AG is the type of "unusual, unexplained reverse transfer of considerable value" from brand to generic that warrants antitrust scrutiny. *King Drug Co.*, 791 F.3d at 394. Indeed, one obvious economic explanation for Wyeth's decision to promise Teva that it would not launch an AG is that it was

granting Teva a license to produce Effexor XR and would be compensated by Teva's promise to pay Wyeth royalties garnered from the sale of its generic.

Moreover, Plaintiffs' failure to account for all of the elements of the agreement between Teva and Wyeth also ignores the complexities of settlement negotiations. Negotiating on only one term—for example, the date of generic entry—is a zero sum game that may make it difficult for the parties to reach agreement. *Barry C. Harris, et al.*, *Activating* Actavis*: A More Complete Story*, 28 Antitrust 83, 86 (2014) ("Litigation can be more difficult to settle when the Brand and the Generic differ in their expectations of the likelihoods of different trial outcomes."). 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 the type of exclusive license Teva and Wyeth agreed to here. William O. Kerr & Cleve B. Tyler, *Measuring Reverse Payments in the Wake of* Actavis, 28 Antitrust 29 (2013). Thus, Plaintiffs' error in failing to account for the size of the royalty payments reflects a larger failure to account for the realities of complex settlement negotiations.

Finally, allowing a plaintiff to initiate costly litigation without consideration of the other terms found in settlement agreements could result in negative economic outcomes. When looked at in isolation, *any* piece of a complex negotiation can look "large," and thus suspicious under *Actavis*. Possible

justifications for the payment, including offsetting royalties promised in exchange for an exclusive license to market a product, therefore must be considered to avoid overextending antitrust scrutiny. Otherwise, the resulting increased risk of litigation may chill procompetitive licensing arrangements.

A patent holder's right to grant exclusive licenses is an important feature of our economic system. Indeed, in the *Lamictal* opinion, this Court expressly recognized that "a patent holder may generally have the right to grant licenses, exclusive or otherwise," *King Drug Co.*, 791 F.3d at 401. The FTC and the Department of Justice have also recognized the procompetitive benefits of "various forms of exclusivity," including "[f]ield of use, territorial, and other limitations on intellectual property licenses." FTC and DOJ, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.3 (Apr. 6, 1995).

These exclusive licenses provide economic benefit, as they allow for mutually beneficial agreements between patent holders and licensing partners when the patent holder believes there is more value available from licensing the rights compared to using the patent. This is especially true in the pharmaceutical industry where agreements between a patent holder and another company to exclusively market the patented drug are common. According to a 2009 survey of 132 industry participants conducted by the Licensing Executives Society, 82 percent of the licensing deals in biotechnology and pharmaceutical industries were

exclusive. *See* James McCarthy & Ben Bonifant, *A Review of the Global BioPharmaceutical Royalty Rates & Deal Terms Survey*, *Les Nouvelles*, Sept. 2011, at 251, 254. That same survey found that 153 of the 184 agreements (83%) involved some type of royalty payment, either flat or tiered. *Id.* at 256.

Permitting a challenge to an exclusive license (here, the No-AG agreement) to succeed without consideration of a payment made in exchange for that license (here, the royalties) would likely expose *all* licenses granted to a party challenging a patent under Hatch-Waxman to condemnation under antitrust laws. When viewed in a vacuum, *any* payment may appear to convey a "large" amount of value to the licensee and thus look potentially anticompetitive. Such a result may incentivize patent holders to forego mutually beneficial licensing arrangements, or indeed any mutually beneficial exchanges, to avoid potential antitrust litigation risk. This may remove the possibility of the firms finding a mutually agreeable settlement. This result potentially harms consumers, as it may prevent generic versions of drugs from reaching the market prior to patent expiration. Furthermore, to the extent the requirements needed to challenge a license are relaxed, courts may be saddled with the additional costs associated with litigation involving licensing agreements that are justified and procompetitive.

CONCLUSION

Amici urge the Court to consider the economic analyses above and evaluate both sides of the equation as it decides the instant case.

Respectfully Submitted,

Dated: February 23, 2016

O'MELVENY & MYERS LLP

By: /s/ Jonathan D. Hacker

Jonathan D. Hacker
Edward Hassi
1625 Eye Street, N.W.
Washington, D.C. 20005
Telephone: (202) 383-5300

Counsel for Amici Antitrust Economists

ADDENDUM A

List of Amici

Gregory Bell
Charles River Associates

Lisa Cameron
The Brattle Group, Inc.

Professor Iain Cockburn
Boston University School of Management

Joshua Gans
Rotman School of Management, University of Toronto

Paul E. Greenberg
Analysis Group, Inc.

Steven Herscovici
The Brattle Group, Inc.

Professor James W. Hughes
Bates College

Professor Keith N. Hylton
Boston University School of Law

Mark Lewis
Analysis Group, Inc.

Derrick Moore
Analysis Group, Inc.

Richard Mortimer
Analysis Group, Inc.

Professor Edward A. Snyder
Yale School of Management

Bruce E. Stangle
Analysis Group, Inc.

Andrew Tepperman
Charles River Associates

Professor Michael K. Wohlgenant
North Carolina State University

CERTIFICATE OF BAR MEMBERSHIP

In accordance with Local Rule of Appellate Procedure 28.3(d), I certify that I am a member of the bar of the United States Court of Appeals for the Third Circuit.

Dated: February 23, 2016

By: /s/ Jonathan D. Hacker
Jonathan D. Hacker

Counsel for Amici Antitrust Economists

CERTIFICATE OF COMPLIANCE

This brief complies with the length limitation of Fed. R. App. P. 29(d) because it contains 1,959 words, excluding the portions of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman. The text of the electronic pdf version of this brief filed via the CM/ECF system is identical to the text in the paper copies. Microsoft Forefront Endpoint Protection version 4.8.204.0 was used to scan the electronic pdf version of this brief and no virus was detected.

Dated: February 23, 2016 O'MELVENY & MYERS LLP

By: /s/ Jonathan D. Hacker

Jonathan D. Hacker
Edward Hassi
1625 Eye Street, N.W.
Washington, D.C. 20005
Telephone: (202) 383-5300

Counsel for Amici Antitrust Economists

CERTIFICATE OF SERVICE

I hereby certify that on February 23, 2015, I electronically filed the foregoing Brief of Antitrust Economists with the Clerk of the Court for the United States Court of Appeals for the Third Circuit via the appellate CM/ECF system and Federal Express. In addition, I certify that I have caused all interested parties to be served via the CM/ECF system and that all interested parties in these cases are registered CM/ECF system users.

Dated: February 23, 2016

O'MELVENY & MYERS LLP

By: /s/ Jonathan D. Hacker

Jonathan D. Hacker
Edward Hassi
1625 Eye Street, N.W.
Washington, D.C. 20005
Telephone: (202) 383-5300

Counsel for Amici Antitrust Economists