No. S198616

IN THE SUPREME COURT
OF THE STATE OF CALIFORNIA

IN RE CIPRO CASES I & II

CALIFORNIA COURT OF APPEAL, FOURTH APPELLATE DISTRICT NO. D056361
SUPERIOR COURT OF SAN DIEGO, THE HONORABLE RICHARD E.L. STRAUSS
JUDICIAL COUNCIL COORDINATION PROCEEDING NOS. 4154 & 4220

[PROPOSED] BRIEF OF AMICUS CURIAE AMERICAN ANTITRUST INSTITUTE IN SUPPORT OF PETITIONERS

Richard M. Brunell (*pro hac vice* admission pending)
General Counsel
AMERICAN ANTITRUST INSTITUTE
2919 Ellicott St., N.W.
Washington, DC 20008
Telephone: (202) 600-9640

Judith A. Zahid (SBN 215418)
ZELLE HOFMANN VOELBEL & MASON LLP
44 Montgomery St., Suite 3400
San Francisco, CA 94104
Telephone: (415) 693-0700
Facsimile: (415) 693-0770

Attorneys for Amicus Curiae American Antitrust Institute

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INTEREST OF AMICUS CURIAE

AAI is an independent and non-profit educational, research, and advocacy organization devoted to advancing the role of competition in the economy, protecting consumers, and sustaining the vitality of the antitrust laws. AAI is managed by its Board of Directors, with the guidance of an Advisory Board that consists of more than 125 prominent antitrust lawyers, law professors, economists, and business leaders.[1] *See* http://www.antitrustinstitute.org. AAI frequently appears as amicus curiae in cases raising important antitrust issues, including, for example, in *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438 (2009), in which it participated in oral argument before the United States Supreme Court. AAI has been deeply concerned about the problem of "pay for delay" settlements, which cost consumers and governments billions of dollars, and has submitted amicus briefs in numerous federal cases addressing the issue, including *FTC v. Actavis*, 133 S. Ct. 2223 (2013).[2] AAI previously submitted a letter brief in this matter urging this Court to review the ruling of the Court of Appeal.[3] It submits this amicus brief in response to the

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[1] AAI's Board of Directors alone has approved the filing of this brief. The individual views of members of the Board of Directors and the Advisory Board may differ from the positions taken by AAI. Some of the attorneys for the plaintiffs are members of the Advisory Board. However, they played no role in the directors' deliberations over this brief, and no party or any counsel for a party authored this brief in whole or in part. Moreover, no person other than amicus curiae or its counsel made a monetary contribution intended to fund the preparation or submission of the brief.

[2] *See* Brief Amici Curiae of 118 Law, Economics, and Business Professors, and the American Antitrust Institute, http://www.antitrustinstitute.org/sites/default/files/SC%20Watson%20academic%20AAI%20brief.pdf.

[3] Letter of American Antitrust Institute to Frederick K. Ohlrich, Jan. 18, 2012, http://www.antitrustinstitute.org/sites/default/files/Final%20Letter%20Brief %201%2018%202011.pdf.

Court's Dec. 11, 2013 Order requesting supplemental briefing addressing the relevance of *Actavis* to this case.

ARGUMENT

REVERSE-PAYMENT SETTLEMENTS SHOULD BE SUBJECT TO A STRUCTURED RULE OF REASON BASED ON A LIMITED NUMBER OF FACTORS, NOT INCLUDING PATENT MERITS

Actavis obviously requires reversal of the lower courts' decisions in this action because, as explained by the appellants and their other amici, those decisions rested on the "scope of the patent" test rejected by *Actavis*, and California antitrust law is at least as protective of consumers as federal law. In addition, as we shall explain, *Actavis* suggests that this Court should establish a "structured" rule of reason for reverse-payment settlements based on a limited number of factors identified by the U.S. Supreme Court, which do not include the patent merits.

In *Actavis*, the Supreme Court rejected the FTC's proposed "quick look" approach to reverse payments, or a rule of presumptive illegality, "because the likelihood of a reverse payment bringing about anticompetitive effects depends upon" several factors, namely, "[1] its size, [2] its scale in relation to the payor's anticipated future litigation costs, [3] its independence from other services for which it might represent payment, and [4] the lack of any other convincing justification." *Actavis,* 133 S. Ct. at 2237. At the same time, the Court rejected a "full blown" rule of reason, in favor of "structuring" the rule of reason to focus "on the basic question—that of the presence of significant unjustified anticompetitive consequences." *Id.* at 2238; *cf. Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 898-99 (2007) ("Courts can . . . devise rules over time for offering proof, or even presumptions where justified, to make the rule of reason a fair and efficient way to prohibit anticompetitive restraints and to promote procompetitive ones."). The four factors cited by the Court in rejecting a "quick look" approach provide an ample basis for a structured rule of reason.

Specifically, the factors cited in *Actavis* suggest that a plaintiff can establish a prima facie case by producing evidence showing: (1) a "large" reverse payment, *i.e.*, one that is likely to exceed the brand manufacturer's anticipated future litigation costs and that is independent from any other services received from the generic firm; and (2) an agreement by the generic firm to refrain from entering the market for any period of time. In these circumstances, it can be inferred that the payment is for "delay." *See* Aaron Edlin et al., *Activating* Actavis, 28 ANTITRUST, No. 1, at 16, 16 (Fall 2013) ("Whenever the reverse payment exceeds the patent holder's prospective litigation costs plus the value to the patent holder of any other goods and services provided by the allegedly infringing firm, . . . the settlement diminishes the expected period of competition and harms consumers.").[4]

A defendant can rebut the prima facie case by disproving it—*i.e.* by showing that the payment is less than reasonably anticipated future litigation costs or is less than the value of bona fide services provided by the generic—or by showing some other procompetitive justification for the payment. *See Actavis,* 133 S. Ct. at 2236 ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.").[5]

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[4] The Court made clear that independent proof of market power is not required because the "'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power.'" 133 S. Ct. at 2236 (quoting 12 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW, ¶ 2046, at 351 (3d ed. 2012)).

[5] The Court stated, "There may be other justifications," without indicating what those might be. The Third Circuit has suggested that a reverse

Importantly, and contrary to the arguments of the generic defendants, patent invalidity or non-infringement is *not* a necessary element of antitrust plaintiffs' liability case, nor is patent validity and infringement a proper defense.[6] The Court was emphatic that "it is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham)."[7] *Id.* at 2236 (citation omitted); *see also id.* at 2237 ("this is not to require . . . that the Commission need litigate the patent's validity"). And this makes perfect sense in light of the theory of anticompetitive harm adopted by the Court.

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payment to a "cash starved" generic that allows it to avoid bankruptcy might qualify. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012), *vacated on other grounds*, 133 S.Ct. 2849 (2013). As appellants and other amici argue, this Court is free, especially under California law, to reject any additional justifications because they are unrealistic.

[6] This does not mean that patent merits will always be irrelevant in a private action. In order to establish causation and damages, plaintiffs may seek to prove that the generic would have won the infringement litigation. While this may be difficult in many cases, it is not necessarily speculative, as malpractice cases involving patent litigation demonstrate. *See Gunn v. Minton*, 133 S. Ct. 1059, 1065 (2013). Also, there are other ways to prove causation and damages. For example, plaintiffs may show that without a payment, the parties likely would have settled on an earlier entry date, as economics and common sense would suggest. This may not be difficult to prove, given that most Hatch-Waxman litigation is settled without a payment. *See* FTC, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, at 2 (FY 2012), http://www.ftc.gov/os/2013/01/130117mmareport.pdf. Indeed, the parties' own internal documents may show the entry date that would have been agreeable to all parties absent the payment, as in *Actavis* itself. *See* Second Amended Complaint, Ex. A, *FTC v. Watson Pharms., Inc.*, No. 1:09-CV-00955-TWT, http://www.ftc.gov/sites/default/files/documents/cases/2013/01/130122watsonappendix2.pdf (Project Tulip document).

[7] Sham litigation is no longer at issue here. *See* Supplemental Letter Br. of Appellants Addressing the Relevance of FTC v. Actavis, Inc. at 13 (Jan. 24, 2014).

Reverse payments are anticompetitive when "a patentee is using its monopoly profits *to avoid the risk* of patent invalidation or a finding of non-infringement." *Id.* (emphasis added). The Court explained,

> The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.

Id.

Even where the generic is permitted into the market "early," *i.e.*, before the expiration of the patent, an otherwise unexplained reverse payment is anticompetitive because it purchases more protection from the risk of patent invalidation or non-infringement than warranted by the parties' own assessment of the merits of the patent litigation. Thus, as the Court explained, parties may freely settle patent litigation "by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, *without the patentee paying the challenger*." *Id.* at 2237 (emphasis added). Any such settlement will likely be based on the settling parties' views of the likelihood that the brand drug manufacturer will prevail. If, for example, the patent has ten years of economic life remaining, and the parties believe there is a 50% chance that the brand drug manufacturer will prevail, they may be expected to agree the generic drug manufacturer will enter the market in five years. However, adding a "large" reverse payment to the settlement mix is anticompetitive because it skews the negotiation towards later entry; in this scenario, it means that the agreed entry date will be substantially later than five years.[8]

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[8] Sometimes, drug industry advocates argue that a payment is necessary to "bridge the gap" between the brand manufacturer's and generic's divergent assessment of the likelihood of success. For example, the brand manufacturer may believe that it has a 70% chance of success, while the

A delayed entry settlement without a reverse payment is lawful even if the patent is subsequently invalidated and, looked at retrospectively, the brand had "no right" to keep the generic out of the market at all. Likewise, subsequent validation of the patent provides no basis to exculpate a settlement with a reverse payment. Under *Actavis*, the crucial question is not the ultimate validity of the patent, which cannot be known at the time of the settlement. Rather, the key issue is whether the negotiated period of exclusion is based on arm's length bargaining likely to reflect the parties' expectations about the success of the patent lawsuit, or whether the period is collusively extended based on the payment. When the payment exceeds the brand manufacturer's reasonably anticipated litigation costs and the value of bona fide services provided by the generic, then *Actavis* holds the payment unlawful under federal law (absent some other convincing justification); so too should this Court hold under California law.

CONCLUSION

Because California antitrust law is at least as protective of consumers as federal law, *Actavis* requires the Court to reverse and remand the decision of the Court of Appeal affirming summary judgment for the defendants, and suggests that the Court establish a structured rule of reason

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generic may believe that the brand has only a 30% chance of success. It is important to recognize that a reverse payment in this context will not result in a settlement that splits the difference, say, allowing the generic into the market after five years if there are ten years of economic life remaining. In this scenario, a brand manufacturer will make a "large" payment to the generic only if the generic agrees to delay entry by *more* than seven years; otherwise the brand manufacturer would prefer to continue to litigate. Hence, "bridge the gap" settlements are more aptly characterized as bridges to monopoly extension.

for antitrust analysis of reverse-payment settlements based on a limited number of factors, not including the patent merits.

Dated: March 18, 2014

Respectfully submitted,

Richard M. Brunell (*pro hac vice* admission pending)
General Counsel
AMERICAN ANTITRUST INSTITUTE
2919 Ellicott St., N.W.
Washington, DC 20008
Telephone: (202) 600-9640

By: ________________________
Richard M. Brunell

Judith A. Zahid (SBN 215418)
ZELLE HOFMANN VOELBEL & MASON LLP
44 Montgomery St., Suite 3400
San Francisco, CA 94104
Telephone: (415) 693-0700
Facsimile: (415) 693-0770

Attorneys for Amicus Curiae American Antitrust Institute

CERTIFICATE OF WORD COUNT

The foregoing [Proposed] Brief of Amicus Curiae American Antitrust Institute in Support of Petitioners contains 1,976 words (including footnotes, but excluding tables and this certificate). In preparing this certificate, I have relied on the word count generated by the word processing software used to prepare this brief.

Dated: March 18, 2014

By: ______________________________
Richard M. Brunell

Counsel for Amicus Curiae
American Antitrust Institute

PROOF OF SERVICE

I, Robert L. Newman, certify and declare under penalty of perjury that I: am a citizen of the United States; am over the age of 18 years; am employed by Zelle Hofmann Voelbel & Mason LLP, 44 Montgomery Street, Suite 3400, San Francisco, CA 94104, whose members are members of the State Bar of California and at least one of whose members is a member of the Bar of each Federal District Court within California; am not a party to or interested in the cause entitled upon the document to which this Proof of Service is affixed; and served a true and correct copy of the following document(s) in the manner indicated below:

APPLICATION OF AMERICAN ANTITRUST INSTITUTE FOR PERMISSION TO FILE AN AMICUS CURIAE BRIEF; [PROPOSED] BRIEF OF AMICUS CURIAE AMERICAN ANTITRUST INSTITUTE IN SUPPORT OF PETITIONERS

☒ **BY MAIL:** by today depositing, at San Francisco, California, the said document(s) in the United States mail in a sealed envelope, with first-class postage thereon fully prepaid, addressed to the parties listed on the attached service list.

Executed on March 18, 2014, in San Francisco, California.

Signed ______________________________

SERVICE LIST

Joseph R. Saveri, Esq.
JOSEPH SAVERI LAW FIRM
505 Montgomery Street, Suite 625
San Francisco, CA 94111

Eric B. Fastiff, Esq.
Brendan Glackin, Esq.
Jordan Elias, Esq.
Dean M. Harvey, Esq.
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339

Dan Drachler, Esq.
ZWERLING, SCHACHTER & ZWERLING, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101

Ralph B. Kalfayan, Esq.
KRAUSE KALFAYAN BENINK & SLAVENS, LLP
625 Broadway, Suite 635
San Diego, CA 92101

Counsel for Plaintiffs-Appellants

Charles A. Bird, Esq.
Christopher J. Healey, Esq.
Todd R. Kinnear, Esq.
MCKENNA LONG & ALDRIDGE LLP
600 West Broadway, Suite 2600
San Diego, CA 92101

Peter B. Bensinger, Jr., Esq.
BARLIT BECK HERMAN PALENCHAR & SCOTT LLP
54 West Hubbard Street, Suite 300
Chicago, IL 60654

Kevin D. McDonald, Esq.
JONES DAY
51 Louisiana Avenue, NW
Washington, DC 20001

Counsel for Defendant-Respondent Bayer Corporation

Joann F. Rezzo, Esq.
EDELSON & REZZO
402 West Broadway, Suite 2700
San Diego, CA 92101

Kathryn E. Karcher, Esq.
KARCHER HARMES PS
401 B Street, Suite 2450
San Diego, CA 92101

Counsel for Defendants-Respondents Hoechst Marion Roussel, Inc., The Rugby Group, Inc., Barr Laboratories, Inc., and Watson Pharmaceuticals, Inc.

David E. Everson, Esq.
Heather S. Woodson, Esq.,
Victoria Smith, Esq.
STINSON MORRISON HECKER LLP
1201 Walnut Street, Suite 2900
Kansas City, MO 64106

Counsel for Defendants-Respondents Hoechst Marion Roussel, Inc., The Rugby Group, Inc., and Watson Pharmaceuticals, Inc.

Jay P. Lefkowitz, Esq.
Karen N. Walker, Esq.
Edwin John U., Esq.
Gregory Skidmore, Esq.
KIRKLAND & ELLIS LLP
655 Fifteenth Street, N.W.
Washington, DC 20005-5793

Counsel for Defendant-Respondent Barr Laboratories, Inc.

State Bar of California
Pro Hac Vice Program
180 Howard Street
San Francisco, CA 94105

(with check in the amount of $50 made payable to the State Bar of California)