#### 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

# APPLICATION OF 49 PROFESSORS FOR PERMISSION TO FILE AN AMICI CURIAE BRIEF; [PROPOSED] BRIEF OF AMICI CURIAE 49 PROFESSORS IN SUPPORT OF PETITIONERS

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## APPLICATION OF 49 PROFESSORS FOR PERMISSION TO FILE AN AMICI CURIAE BRIEF

Pursuant to Rule 8.520(f) of the California Rules of Court, 49
Professors respectfully request permission to file the attached brief of *amici curiae* in support of Plaintiffs, Appellants, and Petitioners Karyn McGaughey, Barbara Cohen, Deborah Patane, Donna Moore, IUOE Stationary Engineers Local 39 Health and Welfare Plan, and Sheet Metal Workers Health and Welfare Plan of Southern California, Arizona, and Nevada.

#### STATEMENT OF INTEREST

The *amici* are professors of economics, business, innovation, antitrust law, and intellectual property law. (A list of signatories is attached as Appendix A.) Their sole interest in this case is to ensure that antitrust and patent law develop in a way that serves the public interest and public health by promoting both innovation and competition.

The *amici* have filed this brief because they believe that the ruling of the court below is inconsistent with the U.S. Supreme Court's ruling in *FTC v. Actavis* (2013) 133 S. Ct. 2223, and with California law, and seriously threatens to undermine competition in the pharmaceutical industry. If allowed to stand, the opinion would result in severe anticompetitive harm to California consumers.

#### HOW THE PROPOSED BRIEFING WILL ASSIST THE COURT

The purpose of this brief is to provide legal and economic analysis to assist this Court in understanding the anticompetitive effects of exclusion-payment settlements. The *amici* are experts in economics, business, innovation, antitrust, and intellectual property (IP) law.

Because the issues in this case require the analysis of antitrust and patent law, as well as complex regulatory issues, *amici* offer this brief to

assist the Court. Each of the three main sections of this brief is designed to do so. The first explains the weaknesses of the six pillars of the Court of Appeal's decision below and how they were knocked down in *Actavis*. The second explains how California law reaches beyond federal law and describes three statutory frameworks this Court can rely on to apply robust scrutiny to these concerning settlements. And the third makes clear that preemption does not prevent this Court from addressing any of these issues.

#### **DISCLOSURE**

No party, or counsel for any party, in the matter pending before this Court has either authored the proposed *amici curiae* brief in whole or in part or made any monetary contribution intended to fund its preparation or submission. No person or entity has made any monetary contribution intended to fund the preparation or submission of the *amici curiae* brief, other than counsel in the pending matter.

#### **CONCLUSION**

For the foregoing reasons, 49 Professors respectfully request that the Court accept the accompanying brief for filing and consideration in this case.

Dated: March 18, 2014

Respectfully submitted,

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3

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# **TABLE OF CONTENTS**

INTRODUC	CTION	AND SUMMARY OF ARGUMENT	1
ARGUMEN	T		2
I.	ACTAVIS DECIMATES THE SIX PILLARS UNDERLYING THE DECISION BELOW		2
	A.	Pillar 1: Lack of Anticompetitive Effects	3
	B.	Pillar 2: Scope of Patent	5
	C.	Pillar 3: Settlement Policy	7
	D.	Pillar 4: Patent Policy	9
	E.	Pillar 5: Need for Exclusion Payments	11
	F.	Pillar 6: Natural By-Product	14
II.	MUS THA	T- <i>ACTAVIS</i> CALIFORNIA ANTITRUST LAW ST APPLY A MORE ROBUST ANALYSIS THAN AT ARTICULATED IN THE PRE- <i>ACTAVIS</i> SISION BELOW	15
	A.	California Antitrust Law Reaches Beyond Federal Law	15
	В.	Actavis Dramatically Restricts the Range of Permissible State-Law Analyses	20
	C.	This Court Can Apply a Constrained Rule-of- Reason or Per-Se Illegality	22
III.	STA	ERAL LAW DOES NOT PREEMPT A TE CAUSE OF ACTION FOR EXCLUSION-	24
		MENT SETTLEMENTS	
CONCLUSI	()N		27

# **TABLE OF AUTHORITIES**

# <u>Cases</u>

Blonder-Tongue Labs. v. Univ. of Illinois Found., (1971) 402 U.S. 313	10
California v. ARC America Corp., (1989) 490 U.S. 932	25
California ex rel. Van de Kamp v. Texaco, Inc., (1988) 46 Cal.3d 1147	16
Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co., (1999) 20 Cal. 4th 163	19
Cianci v. Super. Ct., (1985) 40 Cal. 3d 90316, 1	17
In re Cipro Cases I & II, (2011) 200 Cal.App.4th 442 passi	m
Clayworth v. Pfizer, Inc., (2010) 49 Cal.4th 758	16
Comedy Club, Inc. v. Improv W. Assocs., (9th Cir. 2009) 553 F.3d 127	18
Dow Chemical Co. v. Exxon Corp., (Fed.Cir. 1998) 139 F.3d 14702	26
Edwards v. Arthur Andersen LLP, (2008) 44 Cal. 4th 93718, 1	19
Egyptian Goddess, Inc. v. Swisa, Inc., (Fed.Cir. 2008) 543 F.3d 665	6
Freeman v. San Diego Ass'n of Realtors, (1999) 77 Cal.App.4th 171	16
Fruit Machinery Co. v. F.M. Ball & Co., (1953) 118 Ca. App. 2d 748	7

FTC v. Actavis, (2013) 133 S.Ct. 2223	sim
Gunn v. Minton, (2013) 133 S.Ct. 1059	26
Hathorn v. Lovorn, (1982) 457 U.S. 255	26
Hines v. Davidowitz, (1941) 312 U.S. 52	24
Hunter Douglas, Inc. v. Harmonic Design, (Fed.Cir. 1998) 153 F.3d 1318	24
Kewanee Oil Co. v. Bicron Corp., (1974) 416 U.S. 470	24
Knevelbaard Dairies v. Kraft Foods, Inc., (9th Cir. 2000) 232 F.3d 979	16
Lear, Inc. v. Adkins, (1969) 395 U.S. 653	10
Marin County Bd. of Realtors v. Palsson, (1976) 16 Cal.3d 920	17
Mars, Inc. v. Kabushiki-Kaisha Nippon Conlux, (Fed.Cir. 1994) 24 F.3d 1368	24
McAdams v. Monier, Inc., (2010) 182 Cal.App.4th 174	19
Oakland-Alameda County Builders' Exchange v. F.P. Lathrop Constr. Co., (1971) 4 Cal.3d 354	17
Rubin v. Green, (1993) 4 Cal.4th 1187	
In re Schering-Plough Corp., No. 9297 (F.T.C. Dec. 8, 2003) 2003 WL 22989651	
Speegle v. Board of Fire Underwriters, (1946) 29 Cal.2d 34	

(Fed.Cir. 1983) 713 F.2d 1530	6
United States v. Glaxo Group, Ltd., (1973) 410 U.S. 52	10
Vulcan Powder Co. v. Hercules Powder Co., (1892) 96 Cal. 510	18
Statutes	
21 U.S.C. § 355(j)(2)(A)(vii)	4, 8
Federal Trade Commission Act, Section 5	19, 20
Cal. Antitrust and Unfair Competition Law § 2.04	23
Cal. Antitrust and Unfair Competition Law § 12.05	25
Cal. Antitrust and Unfair Competition Law § 12.06	18
Cal. Bus. & Prof. Code § 16600	passim
Cal. Bus. & Prof. Code § 16720	17
Cal. Bus. & Prof. Code § 16720(a)	17
Cal. Bus. & Prof. Code § 16720(b)	17
Cal. Bus. & Prof. Code § 16720(c)	17
Cal. Bus. & Prof. Code § 16720(e)(4)	17
Cal. Bus. & Prof. Code § 16726	17
Cal. Bus. & Prof. Code § 17200	22
Cartwright Act	passim
Other Authorities	
Aaron Edlin et al., Activating Actavis (2013) 28 Antitrust 16	4, 20, 21, 23

Antitrust and Unfair Competition Law Section, The State Bar of California, California Antitrust and Unfair Competition Law Revised Edition, Introduction (Cheryl Lee Johnson, ed., Matthew Bender & Co., 2013)
C. Scott Hemphill, An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition (2009) 109  Colum. L. Rev. 629
Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984)
Einer Elhauge & Alex Krueger, Solving the Patent Settlement Puzzle (2012) 91 Tex. L. Rev. 283
Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, An FTC Staff Study (2010)1
FTC Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012 (2013)
FTC Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005 (2006)
FTC Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2012 (2013)
Herbert Hovenkamp et al., Anticompetitive Settlement of Intellectual Property Disputes (2003) 87 Minn. L. Rev. 171914
Herbert Hovenkamp et al., IP and Antitrust (2d ed. Supp. 2011) § 5.3
John R. Allison & Mark A. Lemley, Empirical Evidence on the Validity of Litigated Patents (1998) 26 AIPLA L.Q. 185
Kimberly A. Moore, Judges, Juries, and Patent Cases – An Empirical Peek Inside the Black Box (2000) 99 Mich. L. Rev. 365

Michael A. Carrier, Actavis and Large and Unjustified Payments, SCOTUSblog, July 25, 2013	12
Michael A. Carrier, Five Arguments Laid to Rest after Actavis (October 2013) 13 Antitrust Source 1	9, 21
Michael A. Carrier, Why the 'Scope of the Patent' Test Cannot Solve the Drug Patent Settlement Problem (2012) 16 Stan. Tech. L. Rev. 1	5
Paul M. Janicke & LiLan Ren, Who Wins Patent Infringement Cases? (2006) 34 AIPLA Q.J. 1	5
RBC Capital Mkts., Pharmaceuticals: Analyzing Litigation Success Rates (2010)	6
Thomas F. Cotter, FTC v. Actavis, Inc.: When is the Rule of Reason Not the Rule of Reason? (2013)	23
Thomas Rice & Karen Y. Matsuoka, The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors (2004) 61 Med. Care Res. & Rev. 415	1
University of Houston Law Center, Decisions for 2000-2004, Issue Codes 01-16, 23, 24	6

#### INTRODUCTION AND SUMMARY OF ARGUMENT

Few competition problems are as critical as those raised by settlements such as the one involving Cipro. Agreements by which brandname drug companies pay generics to delay entering the market cost consumers billions of dollars each year.<sup>1</sup>

Beyond the financial costs, these agreements (known as reverse-payment, exclusion-payment, or pay-for-delay settlements) have severe effects on public health. Artificially inflated drug costs lead to high out-of-pocket costs that force uninsured patients to split pills in half or skip taking their medications. Such consumer-coping strategies expose patients to worsening symptoms, escalating medical conditions, and even death.<sup>2</sup>

Effects like these were on full display in this case. As the plaintiffs explained, Bayer used the settlement here to "raise[] Cipro prices at rates among the highest in the entire pharmaceutical industry." (Supplemental Letter Brief of Appellants, at p. 6.) In particular, "Bayer increased the prices for the three major [Cipro] dosages 4.56%, 4.85%, and 4.33% annually in the five years prior to the settlement agreements and 10.53%, 11.66%, and 74.83% respectively for the seven years after the settlement agreements." (*Id.*)

Back in 2011, the Court of Appeal in this case looked around and—despite California's more aggressive antitrust analysis—cast its lot with the

<sup>&</sup>lt;sup>1</sup> (See Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, An FTC Staff Study* (2010) at 2, <a href="http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf">http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf</a>; C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition* (2009) 109 Colum. L. Rev. 629, 649.)

<sup>&</sup>lt;sup>2</sup> (See Thomas Rice & Karen Y. Matsuoka, *The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors* (2004) 61 Med. Care Res. & Rev. 415, 420, 427-28.)

federal courts that had essentially immunized exclusion-payment settlements under the "scope of the patent" test. The court concluded that an agreement involving a \$398 million payment for delayed generic entry fell within the "scope" of the patent without undertaking the slightest inquiry into whether the agreement had unjustified anticompetitive effects or provided more exclusion than was warranted by the patent itself.

Times have changed. The scope-of-the-patent test is done. No court will ever apply such a narrow test again. Accordingly, the *Cipro* decision cannot stand.

Nor are any of the pillars of federal support relied on by the court below still standing. Each, based on antitrust law, patent law, settlements, or exclusion payments themselves, collapsed in the U.S. Supreme Court's landmark decision in *FTC v. Actavis* (2013) 133 S.Ct. 2223 (*Actavis*). There is literally nothing left of the *Cipro* decision. Given that California antitrust law reaches beyond federal law, and that the floor provided by federal law was dramatically raised in *Actavis*, this Court should reverse the decision below and articulate a more appropriate analysis for these anticompetitive settlements.

#### **ARGUMENT**

# I. ACTAVIS DECIMATES THE SIX PILLARS UNDERLYING THE DECISION BELOW

Faulty as they were, six rickety pillars supported the Court of Appeal's decision below. The court aligned itself with pre-*Actavis* federal courts that had adhered to the toothless "scope of the patent" test, borrowing themes such as deference to settlements, neglect of the Hatch-Waxman Act, and emasculation of antitrust law. In fact, the court "agree[d] with the reasoning of these cases and conclude[d] that it applies equally to antitrust claims under the Cartwright Act." (*In re Cipro Cases I & II* (2011) 200 Cal.App.4th 442, 467 (*Cipro*).)

In *Actavis*, the Supreme Court knocked out each and every one of the pillars, which were based on (1) exclusion payments' supposed lack of anticompetitive effects, (2) the toothless "scope of the patent" test, (3) a dispositive public policy favoring settlement, (4) the public policy (or at least one strand) underlying patent law, (5) the alleged need for exclusion payments to attain settlements, and (6) the "natural" status of exclusion payments.

### A. Pillar 1: Lack of Anticompetitive Effects

The first pillar underlying the Court of Appeal's decision was a refusal to find that exclusion-payment settlements had anticompetitive effects. The court held that it was not appropriate to apply per se illegality under the Cartwright Act since the agreements did not "have a pernicious effect on competition" or "lack any redeeming virtue." (*Cipro*, *supra*, 200 Cal.App.4th at p. 467.)

This nonchalance was mistaken. Brand-name drug companies have used exclusion-payment settlements to pay generics as much as \$398 million to drop challenges to patents (many of which are invalid) and delay entering the market. When one company pays a second not to enter the market, the antitrust harm resembles that presented by market division, which restricts *all* competition between the parties on all grounds. But instead of allocating geographic space, the settlements allocate time, with the brand blocking all competition for a period of time. (See *In re Schering-Plough Corp.*, No. 9297 (F.T.C. Dec. 8, 2003) 2003 WL 22989651, at \*\*10-12, *vacated by Schering-Plough Corp. v. FTC* (11th Cir. 2005) 402 F.3d 1056, 1058.)

Before the Supreme Court threw cold water on the idea of paying competitors not to compete, such payments were common between drug companies. A central reason can be traced to the overlapping incentives of

brands and the first generic to challenge a brand firm's patent (thereby receiving a 180-day period of marketing exclusivity, 21 U.S.C. § 355(j)(2)(A)(vii)). Because the brand made more by keeping the generic out of the market than the two parties would have received by competing in the market, the parties had an incentive to split the monopoly profits, making each better off than if the generic had entered. The brand then could use a portion of these millions, if not billions, of dollars of additional profit from delayed competition to pay the generic. In fact, as happened in this case, the brand could even pay more than the generic would have received from winning its patent challenge and entering the market. (See Supplemental Letter Brief of Appellants, at p. 9 n.7 [explaining that \$398 million payment "constitutes more than twice the profits the [generics] would have earned had they defeated the patent and competed with Cipro"].)

Given these economic realities, the Supreme Court in *Actavis* explained that exclusion-payment settlements "tend to have significant adverse effects on competition." (*Actavis*, *supra*, 133 S.Ct. at p. 2231.) The Court pointed to the concern that "a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." (*Id.* at p. 2236.<sup>3</sup>) In particular, the settlement "simply keeps prices at patentee-set levels," which results in "[t]he patentee and the challenger gain[ing]" while "the consumer loses." (*Id.* at p. 2235.) In short, the first pillar of the Court of Appeal's analysis, based on a lack of exclusion payments' anticompetitive effects, tumbled.

<sup>&</sup>lt;sup>3</sup> (See also Aaron Edlin et al., *Activating Actavis* (2013) 28 Antitrust 16, 22 [demonstrating that settlement is anticompetitive if the payment "exceeds the patent holder's avoided litigation costs"]; Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle* (2012) 91 Tex. L. Rev. 283, 303, emphasis in original [exclusion payment "exceed[ing] the patent holder's anticipated litigation costs is never necessary to secure a *desirable* settlement"].)

#### B. Pillar 2: Scope of Patent

Second, the court below based its finding of no liability on the scope-of-the-patent test. It contended that "the Cipro agreements did not restrain competition outside the exclusionary zone" of the patent. (*Cipro*, supra, 200 Cal.App.4th at p. 467.) "[B]ecause a patent is presumed to be valid" and "gives the patent holder the right to exclude," a settlement is "not unlawful if it serves to protect that to which the patent holder is legally entitled—a monopoly over the manufacture and distribution of the patented invention." (*Id.*) The court "conclude[d] that because the Cipro agreements undisputedly did not restrain competition beyond the scope of the '444 patent, they do not violate the Cartwright Act." (*Id.* at p. 470.)

The court's reliance on the "scope" test to immunize the Cipro settlement was not appropriate. One reason is that a patent that is invalid or not infringed has no scope whatsoever in relation to the generic product. The scope test thus devolves to an inquiry that assumes the validity and infringement at issue in the case.<sup>4</sup>

The only way to avoid the conclusion that not every patent is valid (with empirical studies showing at least 40% of litigated patents invalid<sup>5</sup>) is

<sup>&</sup>lt;sup>4</sup> (See Michael A. Carrier, Why the 'Scope of the Patent' Test Cannot Solve the Drug Patent Settlement Problem (2012) 16 Stan. Tech. L. Rev. 1, 5-6.) The mere assertion that the patent is valid and infringed is not sufficient to prove these contested points. And, in fact, they are contested. Before the parties settle, generics vigorously claim that the patent is not valid and that its product does not infringe. But after settlement, the generic has every incentive to switch sides and trumpet the patent's validity and infringement.

<sup>&</sup>lt;sup>5</sup> (See John R. Allison & Mark A. Lemley, Empirical Evidence on the Validity of Litigated Patents (1998) 26 AIPLA L.Q. 185, 205 [courts invalidated 46% of patents between 1989 and 1996]; Paul M. Janicke & LiLan Ren, Who Wins Patent Infringement Cases? (2006) 34 AIPLA Q.J. 1, 20 [generics won 70% of Federal Circuit decisions from 2002 through 2004]; Kimberly A. Moore, Judges, Juries, and Patent Cases – An Empirical Peek Inside the Black Box (2000) 99 Mich. L. Rev. 365, 385

to hijack the procedural presumption of Section 282 of the Patent Act, which states that patents "shall be presumed valid," and, as the court below did (*id.* at p. 467), imbue it with dispositive influence. But a presumption of validity is only a procedural presumption governing the order in which proof is presented. It is not substantive evidence of validity. (See *Stratoflex, Inc. v. Aeroquip Corp.* (Fed.Cir. 1983) 713 F.2d 1530, 1534.<sup>6</sup>)

For these reasons, the Court in *Actavis* concluded that just because a payment might be within the asserted scope of a valid and infringed patent does not mean that "that fact, or characterization, can immunize the agreement from antitrust attack." (*Actavis, supra*, 133 S.Ct. at p. 2230.) The Court correctly explained that the patent "may or may not be valid, and may or may not be infringed." (*Id.* at p. 2231.) It understood that the owner of "an invalidated patent" and "even a valid patent" employed against "products . . . that do not actually infringe" cannot refuse to license it and cannot "charge a higher-than-competitive price." (*Id.*) And it recognized that exclusion-payment settlements end the litigation that "put the patent's validity at issue." (*Id.*)

Given these observations, the *Actavis* Court found it "incongruous" to "determine antitrust legality by measuring [a] settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well." (*Id.*)

<sup>[</sup>alleged infringer prevailed in 42% of patent cases that reached trial between 1983 and 1999]; RBC Capital Mkts., *Pharmaceuticals: Analyzing Litigation Success Rates* (2010), at p. 4 [generics won 48% of "Paragraph IV" Hatch-Waxman cases from 2000 to 2009]; University of Houston Law Center, Decisions for 2000-2004, Issue Codes 01-16, 23, 24, *available* at http://www.patstats.org/2000-04.htm [in patent cases between 2000 and 2004, courts found 43% of patents invalid and 75% not infringed].)

<sup>&</sup>lt;sup>6</sup> In addition, it is the patentee that "bears the ultimate burden of proof" to "demonstrate infringement by a preponderance of the evidence." (*Egyptian Goddess, Inc. v. Swisa, Inc.* (Fed.Cir. 2008) 543 F.3d 665, 679.)

Both patent and antitrust policies are "relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent." (*Id.*) In short, the Court made it crystal clear that settling parties are no longer able to effectively immunize their agreements by claiming that brand payments to generics lie within the "scope of the patent." Perhaps no pillar was as central to courts' excessive deference to anticompetitive settlements, but this foundation has collapsed.<sup>7</sup>

### C. Pillar 3: Settlement Policy

The third pillar of the court's decision below was "the important public polic[y]" that "favor[s] the settlement of patent litigation." (*Cipro*, *supra*, 200 Cal. App. 4th at p. 467.) Such an assertion was central to its conclusion that per-se treatment was inappropriate. (*Id*.)

But any general policy favoring settlements is subordinate to an industry-specific resolution that encourages patent challenges. Drug patent agreements with exclusion payments are not typical settlements. They are agreements that align the interests of the settling parties (at the expense of unrepresented consumers) while disposing of the validity and infringement challenges central to the regulatory scheme. As a result, any general preference in the law for settlement was displaced—or at least significantly weakened—by the specific framework of the Drug Price Competition and

<sup>&</sup>lt;sup>7</sup> The case of *Fruit Machinery Co. v. F.M. Ball & Co.* (1953) 118 Ca. App. 2d 748, relied on by the court below, *Cipro, supra*, 200 Cal.App.4th at pp. 467-68, uses the words "scope of the patent," but in an entirely different setting. The relevant question in that case focused on the rights that the defendant sublicensee received from the plaintiff, an exclusive licensee of the patent holder. The court found that the plaintiff did not act outside the scope of the patent in that it did not grant rights it itself lacked based on its license with the patent holder. That finding has little to do with the issue of whether a brand drug company can immunize its patent from challenge by paying its generic rival not to compete.

Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act.

In passing the Hatch-Waxman Act, Congress enacted a complex regulatory regime to solve urgent problems. One central concern was sparse generic entry. Congress increased competition by creating a 180-day period of marketing exclusivity, reserved for the first generic to certify that the brand firm's patent was invalid or not infringed. This period is not available to other generics that certify (1) no patent on the drug, (2) an expired patent, or (3) a promise to wait until the patent expires. (21 U.S.C. § 355(j)(2)(A)(vii).) Only the "Paragraph IV" certification, by which the generic claims that the patent is invalid or not infringed, leads to 180 days of marketing exclusivity. (*Id.*)

A 180-day period of exclusivity for the first generic to challenge a patent only makes sense in the context of encouraging patent challenges. In addition, the bounty itself demonstrates the unique nature of these agreements. General patent settlements do not prevent other competitors from challenging patents. In cases outside the Hatch-Waxman context, even if the settling defendant agrees not to challenge the patent, many others wait in the wings to do so. In contrast, the 180-day bounty creates a regulatory barrier to entry that can significantly delay other patent challenges.

The Court in *Actavis* recognized "the value of settlements and the patent litigation problem." (*Actavis*, *supra*, 133 S.Ct. at p. 2234.) But it then parted ways from the court below in "nonetheless conclud[ing] that this patent-related factor should not determine the result." (*Id.*) Instead, "five sets of considerations" led the Court to "conclude that the [Federal Trade Commission (FTC)] should have been given the opportunity to prove its antitrust claim." (*Id.*) In the Court's own words, those five considerations emphasized that:

- "[T]he specific restraint at issue has the 'potential for genuine adverse effects on competition.'"
- "[T]hese anticompetitive consequences will at least sometimes prove unjustified."
- "[W]here a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice."
- "[A]n antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed."
- "[T]he fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit." (*Actavis*, *supra*, 133. S.Ct. at pp. 2234-37.)

In a nutshell, these considerations reveal the antitrust concern with exclusion-payment settlements. They recognize the agreements' unjustified antitrust harm and reflection of market power, courts' ability to analyze the agreements, and parties' ability to settle cases without exclusion payments. As a result, the Court of Appeal's exhortation to rely on the general policy in favor of settlements cannot be considered apart from these competing public policies. Given the significance of these five considerations and their lack of direct connection to the policy supporting settlements, the most natural interpretation is that the pro-settlement policy has been subordinated to the facts and antitrust analysis of specific cases. (Michael A. Carrier, *Five Arguments Laid to Rest after Actavis* (October 2013) 13 Antitrust Source 1, 5.) So goes the third foundation of the *Cipro* court's ruling.

### D. Pillar 4: Patent Policy

The fourth pillar of the court's decision below was "the important public polic[y] underlying patent law." (*Cipro*, *supra*, 200 Cal.App.4th at p. 467.) Like the settlement policy, this also was central to the court's

conclusion that it would be inappropriate to apply per-se treatment to exclusion-payment settlements. (*Id.*)

Patent law, however, is supported by multiple policies. And one of the most important is the policy of testing weak patents and protecting the public from monopolies based on invalid patents. The U.S. Supreme Court has repeatedly emphasized the importance of encouraging challenges to weak patents. (See, e.g., *United States v. Glaxo Group, Ltd.* (1973) 410 U.S. 52, 57; *Blonder-Tongue Labs. v. Univ. of Illinois Found.* (1971) 402 U.S. 313, 345; *Lear, Inc. v. Adkins* (1969) 395 U.S. 653, 670 (*Lear*).<sup>8</sup>)

The grant of a patent reflects an initial judgment by the U.S. Patent and Trademark Office (PTO), made after limited scrutiny, that an invention is patentable. But when a patent is asserted in litigation, accused infringers are entitled to demonstrate that the patent should not have issued. As the Court explained in *Lear*, a patent "simply represents a legal conclusion reached by the Patent Office" that is "predicated on factors as to which reasonable men can differ widely." (*Lear*, *supra*, 395 U.S. at p. 670.) The Patent Office "is often obliged to reach its decision in an ex parte proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity." (*Id*.) As a result, it did not seem "unfair" to the Court "to require a patentee to defend the Patent Office's judgment when his licensee places the question in issue." (*Id*.)

The Actavis Court continued this long line of analysis in highlighting the benefits of patent challenges. In fact, it cited Lear to emphasize "the patent-related policy of eliminating unwarranted patent grants so the public

<sup>&</sup>lt;sup>8</sup> For an argument that exclusion-payment settlements actually *reduce* innovation, see Elhauge & Krueger, *supra*, at p. 295 ("[B]y reducing the net reward for investing in stronger patents rather than weaker patents, settlements that provide excessive exclusion periods distort investment choices away from the stronger patents that are more likely to reflect real innovation.").

will not 'continually be required to pay tribute to would-be monopolists without need or justification.'" (*Actavis*, *supra*, 133 S.Ct. at p. 2233.)

In addition to highlighting the benefits of patent challenges, the Supreme Court made clear that nothing in the Patent Act allows a patentee to pay off a potential competitor. (*Id.* at p. 2231.) The Court accordingly explained that it would be "incongruous" to "determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well." (*Id.*)

The Court in *Actavis* considered not just antitrust and patent law, but also the Hatch-Waxman Act, Congress's calibration of the antitrust and patent laws in the pharmaceutical industry. The Court found that the Act "does not embody a statutory policy that supports" the scope-of-the-patent test. (*Id.* at p. 2233.) Instead, "the general procompetitive thrust of the statute, its specific provisions facilitating challenges to a patent's validity, . . . and its later-added provisions requiring parties to a patent dispute triggered by a paragraph IV filing to report settlement terms" to the antitrust agencies "suggest the contrary." (*Id.* at p. 2234.) In short, patent law does not provide the foundation to apply excessively deferential analysis to exclusion-payment settlements.

### E. Pillar 5: Need for Exclusion Payments

The fifth pillar of the decision below centered on the parties' claimed need to use exclusion payments to reach settlements. The California court worried that aggressive treatment of settlements involving payment "would obviously chill such settlements," which would have the effect of "increasing the cost of patent enforcement and decreasing the value of patent protection generally." (*Cipro*, *supra*, 200 Cal.App.4th at p. 468.) The court also believed that "a rule prohibiting" exclusion payments

"could harm competition by reducing the incentive to challenge patents by reducing the challenger's settlement options in a suit for infringement." (*Id.* at pp. 468-69.)

But historical evidence casts doubt on the need for exclusion payments to achieve settlement. Brands and generics can and do settle patent cases without these payments, for example in dividing the remaining patent term by selecting a time for generic entry. From 2000 to 2004, after the FTC announced it would challenge exclusion-payment settlements, but before federal appellate courts deferred to the agreements, not one of twenty reported agreements involved a brand paying a generic to delay entering the market. In 2005, however, after several appellate courts took a lenient view of these agreements, the exclusion-payment floodgates opened, with the number of such settlements increasing each year from 3 to 40 in just seven years. But such settlements are not needed. In its most recent report, the FTC observed that more than 70% of settlements between

<sup>&</sup>lt;sup>9</sup> FTC Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005 (2006) at p. 4, available at <a href="http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf">http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf</a>; see also Michael A. Carrier, Actavis and Large and Unjustified Payments, SCOTUSblog, July 25, 2013, <a href="http://www.scotusblog.com/2013/07/actavis-and-large-and-unjustified-payments/">http://www.scotusblog.com/2013/07/actavis-and-large-and-unjustified-payments/</a> [discussing similar evidence from Europe].)

<sup>&</sup>lt;sup>10</sup> (FTC Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012 (2013) at p. 2, available at http://www.ftc.gov/os/2013/01/130117mmareport.pdf.)

brands and generics did not involve payment for delay, with 58% not involving payment and 14% not involving delay.<sup>11</sup>

For all these reasons, the *Actavis* Court explained that "the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit." (*Actavis*, *supra*, 133 S.Ct. at p. 2237.) The parties "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." (*Id.*)

The Court also recognized that "the parties may have reasons to prefer settlements that include reverse payments." (*Actavis*, *supra*, 133 S.Ct. at p. 2237.) But of course, a central reason for concern in this setting is the parties' aligned incentives, with brands and generics sharing monopoly profits while consumers are left paying higher drug prices. That is why the Court kept its eye on the ball in seeking to determine the reason for the payments. If "the basic reason is a desire to maintain and to share patent-generated monopoly profits," then "in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." (*Id.*) With numerous ways to settle cases not involving exclusion payments (and not offering such anticompetitive harm), the fifth pillar of the opinion below crumbles.

<sup>&</sup>lt;sup>11</sup> (FTC Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2012 (2013), at p. 1, available at

http://www.ftc.gov/os/2013/01/130117mmareport.pdf. See Elhauge & Krieger, *supra*, at p. 303, emphasis omitted [showing that an exclusion payment in excess of the patentee's anticipated litigation costs "is never necessary to secure a desirable settlement"].)

#### F. Pillar 6: Natural By-Product

The sixth pillar was the alleged natural status of exclusion payments. The court below stated that they were a "natural by-product of patent litigation under the Hatch-Waxman Act." (*Cipro*, *supra*, 200 Cal.App.4th at p. 468.) The court relied on an earlier federal case to conclude that "[s]imply because a brand-name pharmaceutical company . . . paid its generic competitor money cannot be the sole basis for a violation of antitrust law." (*Id.* at p. 469.)

The court was correct that exclusion payments have often accompanied settlements under the Hatch-Waxman Act. But that is a far cry from a conclusion that such a development is beneficial. (See, e.g., Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes* (2003) 87 Minn. L. Rev. 1719, 1758.)

In allowing the brand firm to prolong its monopoly and provide the generic with the certainty of receiving profits for not entering the market, settlements serve the interests of both sides. But that does not provide cover for the agreements, which threaten collusion and harm to consumers. To consider the point more broadly, courts would not justify collusion in an industry based on rivals' effortlessly engaging in it.

Looking across the universe of patent settlements, the *Actavis* Court found that it was "unusual" for parties to enter into exclusion-payment settlements in which "in substance the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for damages." (*Actavis*, *supra*, 133 S.Ct. at p. 2231.) Citing the leading treatise on antitrust and intellectual property law, the Court recognized that "where only one party owns a patent, it is virtually unheard of outside of pharmaceuticals for that party to pay an accused infringer to settle the

lawsuit." (Id. at p. 2235 [quoting II. Hovenkamp et al., IP and Antitrust (2d ed. Supp. 2011) § 15.3, at 15-45 n.161].)

In short, the frequency of exclusion payments in the setting of the Hatch-Waxman Act in no way justifies them, demolishing the sixth pillar of the opinion below.

\* \* \*

In the famous Roadrunner cartoon, Wile E. Coyote runs off a cliff and finds himself suspended in midair before looking down and plunging into the chasm below. Post-*Actavis*, the California Court of Appeal is now the sole court in this country that still has these six excessively deferential pillars on the books. But just like Wile E. Coyote knew it was only a matter of time until he plummeted, so too are we at the moment when we look down and know that these pillars (and the decision below) will meet their demise. The result will be clear: savings for consumers, dramatic effects for public health, and a resuscitated California antitrust regime.

# II. POST-ACTAVIS CALIFORNIA ANTITRUST LAW MUST APPLY A MORE ROBUST ANALYSIS THAN THAT ARTICULATED IN THE PRE-ACTAVIS DECISION BELOW

As shown in the previous section, each of the pillars underlying the court's decision below was toppled by *Actavis*. The floor provided by federal law thus has been raised significantly. And given the expansive reach of California antitrust law, the ceiling is even higher, requiring a far more robust antitrust analysis than the one applied by the court below.

### A. California Antitrust Law Reaches Beyond Federal Law

In analyzing Bayer's \$398 million payment for delayed generic entry, this Court can look to three strands of California antitrust law that reach beyond federal law: the Cartwright Act, section 16600 of the Business and Professions Code, and the Unfair Competition Act.

First is the Cartwright Act, California's general antitrust statute. This Court has made clear that its interpretation of antitrust law under the Act is "broader in range and deeper in reach than the Sherman Act." (Cianci v. Super. Ct. (1985) 40 Cal.3d 903, 920 (Cianci).) The Cartwright Act "was patterned after the 1889 Texas act and the 1899 Michigan act, and not the Sherman Act." (California ex rel. Van de Kamp v. Texaco, Inc. (1988) 46 Cal.3d 1147, 1162 n.14, 1164 (Texaco), overruled on other grounds by statute.) As the leading California competition-law treatise proclaims: "Now more than one hundred years old, our Cartwright Act has its own unique language, history and intent, which differs from, and is often more expansive than federal antitrust law." (Antitrust and Unfair Competition Law Section, The State Bar of California, California Antitrust and Unfair Competition Law Revised Edition, Introduction (Cheryl Lee Johnson, ed., Matthew Bender & Co., 2013) [California Antitrust and Unfair Competition Law].)

For these reasons, while "federal antitrust precedents are properly included in a Cartwright analysis, . . . their role is limited." (*Knevelbaard Dairies v. Kraft Foods, Inc.* (9th Cir. 2000) 232 F.3d 979, 985.) These precedents "are 'often helpful' but not necessarily decisive." (*Id.*; see also *Texaco*, 46 Cal.3d at p. 1164 ["judicial interpretation of the Sherman Act, while often helpful, is not directly probative of the Cartwright drafters' intent, given the different genesis of the provision under review"]; *Freeman v. San Diego Ass'n of Realtors* (1999) 77 Cal.App.4th 171, 183 ["federal precedents must be used with caution because the acts, although similar, are not coextensive"].)

One "primary concern" of the Cartwright Act is to "eliminat[e] restraints of trade and impairments of the free market." (*Clayworth v. Pfizer, Inc.* (2010) 49 Cal.4th 758, 783.) In fact, in allowing indirect purchasers to recover from antitrust violators under California law, the state

cast its lot in favor of stronger enforcement, "maximiz[ing] deterrence" even at the expense of "overcompensat[ing] injured plaintiffs." (Id.)

Moreover, the Cartwright Act treats consumer welfare as "a principal, if not the sole, goal of antitrust laws." (*Cianci, supra*, 40 Cal.3d at p. 918; see *Marin County Bd. of Realtors v. Palsson* (1976) 16 Cal.3d 920, 935 ["Antitrust laws are designed primarily to aid the consumer."]; *Speegle v. Board of Fire Underwriters* (1946) 29 Cal.2d 34, 44 [explaining that the "public interest requires free competition so that prices be not dependent upon an understanding among suppliers of any given commodity, but upon the interplay of the economic forces of supply and demand"].) The exclusion-payment settlement in this case is a classic example of collusion that, as the Supreme Court explained in *Actavis*, results in "[t]he patentee and the challenger gain[ing]" while "the consumer loses." (*Actavis, supra*, 133 S.Ct. at p. 2235.)

Under the Cartwright Act, "every" trust is "unlawful, against public policy, and void." (Cal. Bus. & Prof. Code § 16726; see, e.g., Oakland-Alameda County Builders' Exchange v. F.P. Lathrop Constr. Co. (1971) 4 Cal.3d 354, 361 [finding violations of § 16720 and § 16726 where agreements had "pernicious effect on competition" and lacked "redeeming virtue"].) The parties' settlement in this case fits comfortably within multiple definitions of "trust" under the Act. It "carr[ied] out restrictions in trade." (Cal. Bus. & Prof. Code § 16720(a).) It "limit[ed] or reduce[d] production, or increase[d] price." (Id. § 16720(b).) It "prevent[ed] competition in manufacturing." (Id. § 16720(c).) And obviously it "[a]gree[d] to pool, combine, or directly or indirectly unite any interests . . . connected with the sale" of the product in a way "that its price might in any manner be affected." (Id. § 16720(e)(4).)

The second mode of potential analysis is Business and Professions Code section 16600, which has no equivalent in federal law and reaches

well beyond it in invalidating "every contract by which anyone is restrained from engaging in a lawful profession, trade, or business of any kind." This provision "evinces a settled legislative policy in favor of open competition." (*Edwards v. Arthur Andersen LLP* (2008) 44 Cal.4th 937, 945.) Dating to the nineteenth century, the provision is an important component of California's antitrust laws, serving as "independent of and supplemental to the Cartwright Act." (*Comedy Club, Inc. v. Improv W. Assocs.* (9th Cir. 2009) 553 F.3d 1277, 1293 n.17.) Section 16600 derives from the California common law, making it relevant for the complaint in this case which (even though it does not assert a section 16600 claim) alleges a common-law monopolization claim.

Although most cases applying section 16600 have addressed "postagreement or post-employment covenants not to compete," the provision "has been applied to licensing and settlement agreements involving patent and trademarks which restrain competitors or competition." (California Antitrust and Unfair Competition Law, supra, § 12.06.) For example, in Vulcan Powder Co. v. Hercules Powder Co. (1892) 96 Cal. 510, 514, this Court applied the predecessor to section 16600 to strike down a patent license on the grounds that the parties to the contract divided the market. This Court refused to accept a defense that "several persons or companies can legally enter into a business combination to control the manufacture, or sale, or price of a staple of commerce merely because some of the contracting parties have letters patent for certain grades of that staple." (Id. at 516.) Despite this unambiguous line of jurisprudence, the remaining drug companies in this case offer just such a defense. (See Generics' Answering Br. at 20 [contending that "the statutory monopoly conferred by a patent . . . entitles the owner to exclude others from producing the patented invention, and to settle patent litigation on flexible terms"].)

More recently, this Court has made clear that section 16600 is not subject to a general reasonableness defense. In *Edwards v. Arthur Andersen LLP* (2008) 44 Cal.4th 937, 949, citation omitted, the Court explained that "California courts 'have been clear in their expression that section 16600 represents a strong public policy of the state which should not be diluted by judicial fiat." This Court noted that "Section 16600 is unambiguous" and that "if the Legislature intended the statute to apply only to restraints that were unreasonable or overbroad, it could have included language to that effect." (*Id.* at p. 950.)

Finally, California antitrust law, of course, includes the Unfair Competition Law (UCL), which prohibits "any unlawful, unfair or fraudulent business act or practice." (Bus. & Prof. Code, § 17200.) The scope of the UCL is "quite broad," and because the statute "is framed in the disjunctive, a business practice need only meet one of the three criteria [unlawful, unfair or fraudulent] to be considered unfair competition." (McAdams v. Monier, Inc. (2010) 182 Cal.App.4th 174, 187-88.) The coverage of the UCL is "sweeping, embracing 'anything that can properly be called a business practice and that at the same time is forbidden by law." (Rubin v. Green (1993) 4 Cal.4th 1187, 1200, citation omitted.)

In Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Company (1999) 20 Cal.4th 163, this Court "turn[ed] for guidance" to the "parallel" Section 5 of the Federal Trade Commission Act. (Id. at p. 185.) It found that "[i]n view of the similarity of language and obvious identity of purpose of the two statutes, decisions of the federal court on the subject are more than ordinarily persuasive." (Id.) And the Court adopted a definition of unfair competition as "conduct that threatens an incipient violation of an antitrust law, or violates the policy or spirit of one of those laws because its effects are comparable to or the same as a violation of the law, or otherwise significantly threatens or harms

competition." (*Id.* at p. 187.) Such a definition, similar to Section 5 of the FTC Act, reaches beyond traditional federal antitrust law in providing another route to prohibit unfair and anticompetitive settlements that inflict significant harms on California consumers.

The three avenues under California law provide tools by which this Court can emphasize consumer welfare and condemn trusts beyond federal law. Violations under these laws are not saved by a general reasonableness defense. And the UCL draws on Section 5 of the FTC Act, perhaps the most expansive competition-related statute in the federal constellation.

In short, based on the Cartwright Act, section 16600, and the Unfair Competition Law, California courts should apply searching scrutiny to agreements like the one here, in which Bayer paid generics nearly \$400 million to avoid competition, maintain higher prices, and restrain trade.

# **B.** Actavis Dramatically Restricts the Range of Permissible State-Law Analyses

Even if the settling parties were able to justify their agreements under California law, the more-lenient federal law just removed from their arsenal justifications related to patents and the elimination of risk. In fact, as a practical matter, defendants are left with only two allowed justifications: that their payment (1) does not exceed future litigation costs or (2) is for unrelated generic services. (*Actavis*, *supra*, 133 S.Ct. at 2236.<sup>12</sup>)

After *Actavis*, defendants typically will not be able to introduce the patent merits to defend their payment. The Court in *Actavis* made clear that

<sup>&</sup>lt;sup>12</sup> The Court lobbed a half-hearted reference to possible "other justifications," but showed no interest in exploring what those might be. (*Actavis, supra*, 133 S.Ct. at p. 2236. See Edlin et al., *Activating Actavis, supra*, at p. 18 ["The Court leaves the door open to other 'justifications' for a reverse payment, but is skeptical, and does not explicitly identify any."].)

the "size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." (*Id.* at pp. 2236-37.) And it stated that an "unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." (*Id.* at p. 2236; see also Carrier, *Five Arguments Laid to Rest after Actavis, supra*, at p. 6 ["Rather than viewing [large payments] as natural and plunging into the inadministrability of the patent merits with only a procedural presumption to grasp onto, the *Actavis* Court reinjected a healthy dose of common sense into the analysis."].) As leading antitrust commentators have concluded, allowing the defendants to litigate patent validity and infringement "would defeat the Court's stated purpose of cutting to the chase in these cases." (Edlin et al., *Activating Actavis, supra*, at p. 19.)

In addition, the settling parties' justification based on avoiding risk through exclusion-payment settlements is now off limits. Drug companies are fond of the argument that a payment to eliminate the chance of losing litigation on strong patents is a reasonable way to manage risk. And the court below cited federal case law to conclude that "[d]ue to the 'asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent may pay a potential infringer a substantial sum in settlement.'" (Cipro, supra, 200 Cal.App.4th at p. 468, citation omitted.) The remaining defendants in this appeal raised this same argument in their prior briefing in this Court. (See Generics' Answering Br. at pp. 42, 48-50 [arguing for deference on the grounds that "the primary purpose of settling litigation, including Hatch-Waxman patent litigation, is to eliminate the risk and uncertainty of litigation"].) That argument, however, met its match in Actavis.

The Court made clear that unlike "traditional settlement considerations, such as avoided litigation costs or fair value for services," there is significantly greater concern where "a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." (*Actavis, supra*, 133 S.Ct. at p. 2236.) In fact, exclusion payments "in effect amount[] to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed." (*Id.* at p. 2234.)

Lest there be any doubt, the Court made clear that even strong patents are not immune from the concern with payments. The Court clarified that an unexplained payment on a "particularly valuable patent . . . likely seeks to prevent the risk of competition." (*Id.* at p. 2236.) And, crucially, the avoidance of this risk "constitutes the relevant anticompetitive harm." (*Id.*) The Court's focus on avoiding risk reveals an antitrust analysis emphasizing the restraint itself rather than the results of subsequent litigation involving the patent. (*Id.*; see also Elhauge & Krueger, *supra*, at pp. 311-12 [offering reasons for not allowing defense based on risk aversion].)

So much for the *Cipro* court's reliance on risk avoidance as a legitimate justification. No longer is there support for the court's assertion that "even a patentee confident in the validity of its patent may pay a potential infringer a substantial sum in settlement." (*Cipro*, *supra*, 200 Cal.App.4th at p. 468.)

# C. This Court Can Apply a Constrained Rule-of-Reason or Per-Se Illegality

Considering federal case law as a floor, the settling parties have at most two justifications they can introduce to explain their settlement: that their payment (1) was less than the patentee's future litigation costs or (2)

constituted fair value for other services. An open-ended kitchen-sink Rule-of-Reason approach is not appropriate. This is not a garden-variety business arrangement bursting with procompetitive justifications. It is a private settlement that eliminates challenges to patents of questionable validity shielding high prices for vital prescription drugs. Even under more defendant-friendly federal law, the Supreme Court articulated only two justifications for such troubling payoffs.

Not only is there a limited menu of justifications the settling parties can offer, but the plaintiff's showings under federal law are streamlined as well. The *Actavis* Court made clear that exclusion-payment settlements have the "potential for genuine adverse effects on competition." (*Actavis, supra*, 133 S.Ct. at p. 2234, citation omitted.) And the key step of showing market power—which plaintiffs often cannot demonstrate—received a significant shortcut since the "size of the payment" serves as "a strong indicator of power." (*Id.* at p. 2236. 13)

In effectuating California's robust antitrust framework under the Cartwright Act, section 16600, and the Unfair Competition Law, this Court thus must apply an analysis more searching than a full-blown Rule of Reason. The Court faces a choice of adopting a constrained Rule-of-Reason

<sup>(</sup>See also California Antitrust and Unfair Competition Law, *supra*, § 2.04 ["Although the Actavis Court did not extend the quick look umbrella, it signaled a willingness to infer anticompetitive effects from large unexplained reverse settlement payments."]; Thomas F. Cotter, *FTC v. Actavis, Inc.: When is the Rule of Reason Not the Rule of Reason?* (2013) at p. 2, <a href="http://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2281291">http://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2281291</a> ["In reality, the Court appears to have all but in name adopted the presumptive illegality approach it purported to reject."]; Edlin et al., *Activating Actavis, supra*, at p. 17 [noting that Court "made clear that a 'long form' rule of reason was not necessary" and that "both anticompetitive effect and market power could be inferred from large reverse payments themselves"]; Elhauge & Krueger, *supra*, at p. 311 [a payment exceeding exclusion costs "itself proves market power"].)

that would allow the settling parties to introduce justifications based on litigation costs or unrelated services, or one of per se illegality for payments not justified under *Actavis*. To be clear, this would not be a general approach of per se illegality that would apply to all patent settlements, or even all settlements involving payment. Rather, the analysis would be targeted to payments that cannot be explained by the two justifications accepted in *Actavis*.

# III. FEDERAL LAW DOES NOT PREEMPT A STATE CAUSE OF ACTION FOR EXCLUSION-PAYMENT SETTLEMENTS

Federal preemption under the Patent Act does not deprive this Court of the leeway to adopt a robust, post-*Actavis* framework to apply to anticompetitive exclusion-payment settlements.

First, there is no express preemption of California antitrust law, and federal patent law does not occupy the field. As the Federal Circuit has explained, "there is no reason to believe that the clear and manifest purpose of Congress was for federal patent law to occupy exclusively the field pertaining to state unfair competition law." (*Hunter Douglas, Inc. v. Harmonic Design* (Fed.Cir. 1998) 153 F.3d 1318, 1333.) Similarly, "[u]nfair competition law and patent law have long existed as distinct and independent bodies of law, each with different origins and each protecting different rights." (*Mars, Inc. v. Kabushiki-Kaisha Nippon Conlux* (Fed.Cir. 1994) 24 F.3d 1368, 1373.)

In addition, there is no conflict between federal and state law, and state law does not create an obstacle to the accomplishment of federal objectives. (*Kewanee Oil Co. v. Bicron Corp.* (1974) 416 U.S. 470, 480; *Hines v. Davidowitz* (1941) 312 U.S. 52, 67.) To the contrary, robust enforcement will further the patent law policy, recognized in *Actavis*, of weeding out weak patents for the benefit of consumers. (*Actavis, supra*, 133 S.Ct. at p. 2233.) And it is hard to see how state antitrust law could create

an obstacle to the accomplishment of federal patent law objectives when the Supreme Court recognized that federal antitrust restrictions on exclusion payments do not conflict with the Patent Act. (*Id.* at p. 2231.)

Where "state law regulates an area of historic state power such as antitrust and consumer protection, there is a strong presumption against preemption." (California Antitrust and Unfair Competition Law, *supra*, § 12.05.) As the U.S. Supreme Court has explained, the "long history of state common-law and statutory remedies against monopolies and unfair business practices" ensures that "this is an area traditionally regulated by the States." (*California v. ARC America Corp.* (1989) 490 U.S. 93, 101.) And "[w]hen Congress legislates in a field traditionally occupied by the States, . . . the assumption [is] that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." (*Id.*) California's antitrust and unfair competition laws "represent areas of long-standing and historic state power and regulation." (*Id.*)

And again, application of state law in this setting would not frustrate the purposes of a federal statute. To the contrary, enforcement would be completely consistent with a U.S. Supreme Court decision that highlighted the "significant anticompetitive effects" of exclusion payments and that carved out a crucial role not just for patent but also for antitrust analysis. (*Actavis*, *supra*, 133 S.Ct. at pp. 2231, 2237.)

In addition, the appellate court's decision that plaintiffs' shamlitigation claim was preempted makes even less sense now. (Cipro, supra, 200 Cal.App.4th at p. 473.) The court found that "[b]ecause the Cipro settlement did not restrain competition beyond the exclusionary scope of the [] patent, plaintiffs' claims . . . necessarily turn on the patent law issue of whether Bayer's infringement suit was objectively baseless due to inequitable conduct." (Id. at 475.) With the demise of the scope-of-the-

patent test, however, plaintiffs no longer must rely on sham-litigation claims as one of the two paths (along with fraudulent patent procurement) to a viable claim. As discussed above, plaintiffs need only show a payment for delayed entry (subject to a defendant's explanation based on two justifications). In one fell swoop, then, a plaintiff's need to show sham litigation to prove an exclusion-payment claim went from critical to tangential.

Even if it were more central to the antitrust assessment of exclusion payments (which *Actavis* made clear it was not), the existence of a patent-law issue does not strip the state courts of jurisdiction. Just last year, in *Gunn v. Minton* (2013) 133 S.Ct. 1059, 1065, the U.S. Supreme Court found that state courts had jurisdiction over a malpractice claim based on a patent case even though "such cases may necessarily raise disputed questions of patent law" and the "causation element requires a 'case within a case' analysis" that "will necessarily require application of patent law." The Court found that these cases were "unlikely to have the sort of significance for the federal system necessary to establish jurisdiction" and that the state courts' answer to the patent-law question "will have no broader effects." (*Id.* at pp. 1065, 1068.)

To similar effect, the Federal Circuit has explained that "it is well established that a state court has authority to adjudicate patent questions so long as the action itself does not arise under the patent laws." (Dow Chemical Co. v. Exxon Corp. (Fed.Cir. 1998) 139 F.3d 1470, 1475 (Dow); see, e.g., Hathorn v. Lovorn (1982) 457 U.S. 255, 266 n.18 [citing courts reaching this conclusion as early as 1897].) In the Dow case, for example, the Federal Circuit, a court as aware as any of effective patent enforcement, found that a state cause of action for unfair competition was not preempted by federal law since the action did not arise under patent law and the

determination of patent law would be "ancillary to [the] central purpose" of the state action. (*Dow*, *supra*, 139 F.3d at p. 1475.)

The court in *Dow* made clear that "commercial agreements traditionally are the domain of state law" and that "[s]tate law is not displaced merely because the contract relates to intellectual property which may or may not be patentable." (*Id.* at p. 1474.) The court further reasoned that the state-law cause of action, like plaintiffs' antitrust claims here, "include[d] additional elements not found in the federal patent law cause of action" and were "not an impermissible attempt to offer patent-like protection to subject matter addressed by federal law." (*Id.* at p. 1473.)

Similarly, this antitrust action challenging exclusion-payment settlements does not arise under the patent laws. The operative question under not only *Actavis* but also California law is whether a brand makes a payment to a generic to delay entering the market. And again, because the exclusion results from the payment and not the patent, adjudication of the patent is "not necessary," further reducing the likelihood of conflict between federal and state law. (*Actavis*, *supra*, 133 S.Ct. at p. 2236.)

#### **CONCLUSION**

For the reasons articulated in this brief, this Court should reverse and remand the decision of the Court of Appeal affirming summary judgment

// // // // // for the defendants and articulate a more robust standard for antitrust analysis of exclusion-payment settlements.

Dated: March 18, 2014

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#### **CERTIFICATE OF WORD COUNT**

The foregoing [Proposed] Brief of Amici Curiae 49 Professors in Support of Petitioners contains 8,223 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.

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# APPLICATION OF 49 PROFESSORS FOR PERMISSION TO FILE AN AMICI CURIAE BRIEF; [PROPOSED] BRIEF OF AMICI CURIAE 49 PROFESSORS 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.

Signed Poly Mainman

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

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