OFF-LABEL USE OF THE CARTWRIGHT ACT: WILL *CIPRO* REQUIRE STATE COURTS TO ASSESS FEDERAL PATENT VALIDITY IN PAY-FOR-DELAY CASES?

By Dylan M. Carson and Avril G. Love, Tucker Ellis LLP[1]

I. INTRODUCTION

In *FTC v. Actavis, Inc.,* the United States Supreme Court subjected so-called reverse payment settlements in pharmaceutical patent litigation to rule of reason antitrust analysis under Section 1 of the Sherman Act.[2] The *Actavis* decision, however, left it to lower courts to determine how best to perform that analysis. In May 2015, the California Supreme Court stepped into the breach with its decision in *In re Cipro Cases I & II*.[3] The *Cipro* Court held that reverse payment settlements may be challenged under California's primary antitrust statute, the Cartwright Act. In doing so, it attempted to fill in some of the blanks left by the *Actavis* decision on how to conduct a rule of reason analysis of reverse payment settlements.

The *Cipro* Court established (i) a four-part test for plaintiffs to present a prima facie case, (ii) how defendants can rebut that prima facie showing, and (iii) what plaintiffs must ultimately demonstrate to carry their burden of persuasion. Given the discretion left by the United States Supreme Court's *Actavis* decision to formulate the applicable rule of reason test, it would not be surprising to see other courts use the *Cipro* decision to model their analysis in so-called pay-for-delay litigation under either federal or state antitrust law. What is more, given the relatively low burdens of proof and persuasion *Cipro* places on plaintiffs and the significant burdens it places on defendants, California courts are likely to become even more of a hotbed for antitrust litigation arising from disputes around pharmaceutical patents and generic market entry.

In *Cipro,* the California Supreme Court became the first state high court to apply to state antitrust law the *Actavis* Court's resolution of the developing conflict between patent and antitrust law in the pharmaceutical arena.[4] In the process, the *Cipro* Court created new challenges for state courts analyzing reverse payment settlements. On its face, the *Cipro* decision requires fact finders to assess the strength of a federal patent—an invitation that further expands the growing scope of patent-related state law claims.[5] Whether this is the proper role of a state court judge or jury in a Cartwright Act case will likely be the subject of dispute in the trial and appellate courts in the near future. How California state court judges and juries will apply the new rules articulated in *Cipro* is unclear. What is clear is that *Cipro* continued California's long history as a pioneer in expanding the boundaries of antitrust jurisprudence.[6]

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1 Dylan M. Carson is a partner in the Antitrust and Competition Law Group of Tucker Ellis LLP. Avril G. Love is a counsel in the Antitrust and Competition Law Group of Tucker Ellis LLP. This article reflects the views of the authors and not necessarily those of Tucker Ellis LLP, its attorneys, or its clients.

2 133 S. Ct. 2223 (2013).

3 61 Cal. 4th 116 (2015), *reh'g denied* (July 8, 2015) ("*Cipro*").

4 The court noted that while "*Actavis* is not dispositive on matters of state law" under the Cartwright Act, it was the "latest word" from the United States Supreme Court on "the extent to which antitrust law—whether state or federal—must accommodate patent law's requirements." *Cipro*, 61 Cal. 4th at 141–42.

5 *Gunn v. Minton*, 133 S. Ct. 1059 (2013) (state law claim for legal malpractice in handling patent case does not implicate exclusive jurisdiction of federal courts over cases arising under patent laws).

6 *See, e.g. Cal. v. ARC Am. Corp.*, 490 U.S. 93 (1989) (upholding California state antitrust law allowing indirect purchasers to recover for overcharges).

II. THE CONFLICT BETWEEN ANTITRUST LAW AND PATENT LAW

At the heart of pay-for-delay lawsuits is the tension between antitrust law and patent law. Antitrust and patent law are intended to coexist.[7] Both are intended to promote innovation and competition. The patent laws provide an incentive to innovate by granting a limited right to exclude others from making, using, or selling a useful new product or invention.[8] The antitrust laws, among other things, prohibit artificial barriers to competition and innovation. As a result, courts grapple with the tension between a patent's grant of the lawful right to exclude and antitrust law's proscription on exclusionary conduct.[9]

It is worth noting that the patent laws do not grant a monopoly in the antitrust sense.[10] Monopoly power is the power to exclude competition or control prices in a relevant market. A patent grants the right to exclude some competition for a limited period of time and can provide a patent holder with a significant barrier to entry against potential competition.[11] But exclusion does not necessarily result in market power.[12] For example, reasonably interchangeable substitutes may exist for the patented invention.[13]

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7 *U.S. v. Line Materials Co.*, 333 U.S. 287, 339 (1948) (Burton, J., dissenting) ("[S]ince the first anti-trust legislation in 1890, the patent laws and the anti-trust laws have coexisted without any irreconcilable conflicts between them.").

8 *See DVD Copy Control Ass'n, Inc. v. Bunner*, 31 Cal. 4th 864, 880 (2003) (discussing how patent law prompts "the independent innovator to proceed with the discovery and exploitation of his invention.") (quoting *Kewanee Oil Co. v. Bicron Corp.,* 416 U.S. 470, 485 (1974)); *Farmland Irrigation Co. v. Dopplmaier,* 48 Cal. 2d 208, 220 (1957) ("The purpose in granting a patent monopoly is to promote progress in science and the useful arts by stimulating invention and encouraging disclosure.").

9 *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) ("The patent laws which give a 17-year monopoly on 'making, using or selling the invention' are *in pari materia* with the antitrust laws and modify them *pro tanto*."); *U.S. v. Westinghouse Elec. Corp.,* 648 F.2d 642, 646 (9th Cir. 1981) ("There is an obvious tension between the patent laws and antitrust laws. One body of law creates and protects monopoly power while the other seeks to proscribe it.").

10 *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510 (1917) ("The patent law simply protects [the patent holder] in the monopoly of that which he has invented and has described in the claims of his patent."); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1367 (Fed. Cir. 1984) ("The patent system, which antedated the Sherman Act by a century, is not an 'exception' to the antitrust laws, and patent rights are not *legal monopolies* in the antitrust sense of that word.") (emphasis in original).

11 *Blonder-Tongue Labs., Inc. v. Univ. of Ill.* Found., 402 U.S. 313, 347 (1971) ("invalid patents [may] serve almost as effectively as . . . valid patents as barriers to the entry of new firms—particularly small firms."); *Lear, Inc. v. Adkins*, 395 U.S. 653, 669 n.16 (1969) ("royalty charged by the patentee serves as a barrier to entry."). *See generally* Richard A. Posner, An Economic Analysis of Law 282 (7th ed. 2007) (discussing effect of patent as barrier to entry).

12 *Ill. Tool Works, Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 45-46 (2006) ("Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee. Today, we reach the same conclusion"); *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1325-26 (Fed. Cir. 2000) ("A patent alone does not demonstrate market power."); *USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 511 (7th Cir. 1982) (Posner, J.) ("[O]f course, not every patent confers market power.").

13 *Jefferson Parish v. Hyde*, 466 U.S. 2, 37 n.7 (1984) (O'Connor, J., concurring) ("a patent holder has no market power in any relevant sense if there are close substitutes for the patented product."); *N. Pac. Ry. Co. v. U.S.,* 356 U.S. 1, 10 n.8 (1958) ("Of course it is common knowledge that a patent does not always confer market power over a particular commodity. Often the patent is limited to a unique form or improvement of the product and the economic power resulting from the patent privileges is slight."); *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 872 (Fed. Cir. 1997) ("Violation of the antitrust laws always requires . . . market power in a defined relevant market (which may be broader than that defined by the patent . . .").

A wide array of patent law activity implicates the antitrust laws, from industry standard setting[14] and patent pools,[15] to fighting patent assertion entities[16] and settling patent infringement lawsuits.[17] Recently, the latter category has created a veritable cottage industry of pay-for-delay litigation for government antitrust enforcers and both the plaintiff class action and defense bar in the pharmaceutical industry.

III. HATCH-WAXMAN AND THE RISE OF PARAGRAPH IV LITIGATION

An explosion of antitrust litigation has grown out of the settlements entered into between branded and generic manufacturers to resolve infringement litigation involving pharmaceutical patents. Such settlements grew rapidly since the 1984 passage of the Hatch-Waxman Act.[18] The Hatch-Waxman Act seeks to expedite and encourage the entry of lower-cost generic pharmaceuticals into the market through a streamlined process for generic manufacturers whereby they are permitted to submit Abbreviated New Drug Applications ("ANDAs") to the Food and Drug Administration, which rely of the applications and information already filed by the branded companies.[19]

One type of ANDA certification permitted under Hatch-Waxman is a Paragraph IV certification, whereby the generic applicant assures the FDA that the branded manufacturer's patent is either invalid or will not be infringed by the proposed generic pharmaceutical.[20] Because the generic manufacturer's submission is considered itself an act of patent infringement, patent litigation is all but certain to follow most Paragraph IV certifications filed before a pharmaceutical patent has expired.[21]

To incentivize generic manufacturers to file such ANDAs and certifications (thereby committing infringement and inviting litigation), Hatch-Waxman provides a 180-day period during which the first ANDA filer has market exclusivity as the only approved generic.[22] This exclusivity period can be very lucrative for a generic manufacturer when a branded drug reaches the "patent cliff," especially in states that have generic substitution laws requiring that prescriptions be filled with generic versions of branded pharmaceuticals.[23]

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14 *See* U.S. Dept. of Justice, Business Review Letter re: IEEE proposed update of its Standards Association's Patent Policy (Feb. 2, 2015), http://www.justice.gov/file/338591/download.

15 *See* Thomas D. Jeitschko & Nanyun Zhang, *Adverse Effects of Patent Pooling on Prod. Dev. & Comm.*, 14 The B.E. J. of Theoretical Econ., 27-57 (2014), http://www.justice.gov/atr/public/eag/283557a.html.

16 *See* Mark S. Popofsky & Michael D. Laufert, *Patent Assertion Entities and Antitrust: Operating Company Patent Transfers*, Antitrust Source (Apr. 1, 2013).

17 *See generally* Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (2003); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747 (2002); *U.S. v. Singer Mfg.* Co., 374 U.S. 174 (1963).

18 The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

19 *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990); 21 U.S.C. § 355(j).

20 *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012); 21 U.S.C. § 355(j)(2)(A)(viii)(IV).

21 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent").

22 21 U.S.C. § 355(j)(5)(B)(iv).

23 *New York. v. Actavis PLC*, 787 F.3d 638, 644–47 (2d Cir. 2015) (discussing substitution laws and the patent cliff).

Once a potentially infringing ANDA and Paragraph IV certification is filed by a generic manufacturer, if the branded manufacturer files an infringement lawsuit within 45 days, the FDA must withhold approval of the application for two and a half years (unless the litigation resolves sooner than 30 months).[24]

IV. A BRIEF HISTORY OF REVERSE PAYMENT PATENT LITIGATION

Given the competing incentives of branded and generic manufacturers, further spurred by the Hatch-Waxman Act and state substitution laws, significant patent litigation has arisen as generics have sought to take advantage of the six month exclusivity period. Pharmaceutical patent holders have the right to "enforce [their] patent rights against infringement or contributory infringement,"[25] and have done so often against would-be generic entrants. And, given the high cost of patent litigation, it was inevitable that the branded and generic manufacturers looked for ways to settle these lawsuits.

Some of those settlement agreements have prohibited the generics from entering the market for some agreed period of time.[26] These settlements have also included a payment or transfer of some other value from the branded company to the generic. In the view of some enforcers and judges, the payment to resolve the litigation flowed counterintuitively: from the branded plaintiff to the allegedly infringing generic defendant.[27] As a result, they gained the moniker "reverse payments."[28]

These settlements ultimately attracted the attention of both the Federal Trade Commission and the plaintiffs antitrust bar.[29] In the late 1990s, the FTC began investigating what it called "pay-for-delay" agreements whereby branded manufacturers paid generics

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24 21 U.S.C. § 355(j)(5)(B)(iii).

25 35 U.S.C. § 271(d)(3).

26 *See*, *e.g.*, *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1300 (11th Cir. 2003) (agreement not to market an infringing generic drug terminated when either another generic manufacturer marketed a generic product and any exclusivity period expired or patent expired); *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 125 (E.D.N.Y. 2003), *aff'd*, 466 F.3d 187 (2d Cir. 2006) (under parties' patent settlement, generic amended its ANDA application to certify that it would not seek to market its generic version of tamoxifen until the patent expired); *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 707 (E.D. Pa. 2014) (reverse payment settlement agreements included promises not enter the market until the expiration of the subject patents); *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 185 (D.R.I. 2014) (agreement not to market Loestrin 24 generic until time patent set to expire).

27 *In re Nexium Antitrust Litig.*, 777 F.3d 9, 16 (1st Cir. 2015) ("Unlike traditional settlements, where a party with a claim for damages receives a sum equal to or less than the value of its claim, in reverse payment settlements a party with no claim for damages walks away with money simply so it will stay away from the patentee's market.") (internal quotations omitted); David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 Food & Drug L.J. 321, 335 (2000) ("Typically, in patent infringement cases the payment flows from the alleged infringer to the patent holder.").

28 *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) ("Reverse payments are a natural by-product of the Hatch-Waxman process.").

29 According to the FTC, "most pharmaceutical patent settlements do not raise antitrust concerns," but when settlements included compensation to the generic entrant, the FTC is committed to challenging them. Prepared Statement of the Federal Trade Commission on Pay-for-Delay Deals: Limiting Competition and Costing Consumers, at 2 n.8, U.S. Senate Committee on the Judiciary, July 23, 2013, https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-pay-delay-deals-limiting-competition-and-costing/130723payfordelay.pdf.

companies to settle patent litigation and refrain from entering the market with generic products.[30] The FTC Staff described these agreements as a "win-win" for the companies because "brand-name pharmaceutical prices stay high, and the brand and generic share the benefits of the brand's monopoly profits," but a loss for consumers who do not see the benefits of dramatically reduced pricing after generic entry.[31]

In 1998, the first of many antitrust lawsuits challenging an alleged pay-for-delay agreement was filed.[32] In consolidated cases involving the hypertension medication Cardizem CD, several states and various direct and indirect purchasers challenged an agreement between the branded manufacturer and a generic that filed its ANDA and Paragraph IV certification seeking 180-day exclusivity.[33] In 2003, the Sixth Circuit held that the agreement paying the generic $40 million per year not to enter the market after the generic had received FDA approval was "a horizontal market allocation agreement and . . . per se illegal under the Sherman Act."[34]

While litigation proliferated, several Courts of Appeal decisions changed the tenor of the debate towards one reflecting the general policy in both patent and antitrust law in favor of settlements. In 2005, the Eleventh Circuit ignored the Sixth Circuit's per se treatment and required an antitrust analysis reflecting "the need to evaluate the strength of the patent."[35] In *Schering-Plough Corp. v. FTC,* the court considered an appeal from an FTC order, which held that a Paragraph IV patent infringement litigation settlement involving a $60 million reverse payment to the generic defendant in exchange for a deferred entry date violated Section 1 of the Sherman Act and Section 5 of the FTC Act.[36] The court rejected the FTC's reliance on the rule of reason analysis and ruled that "[s]imply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law."[37] The court rejected "a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and, in an ancillary transaction, pays for other products licensed by the generic."[38] Instead, the

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30 Fed. Trade Comm., "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions" (January 2010), https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff ("Pay-for-Delay FTC Staff Study").

31 Pay-for-Delay FTC Staff Study at 1.

32 *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618 (E.D. Mich. 2000).

33 *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003). The FTC also filed an administrative complaint in 2000 and secured a consent decree. *See In re Hoechst Marion Roussel, Inc.*, No. 9293 (FTC 2000), https://www.ftc.gov/enforcement/cases-proceedings/9810368/hoechst-marion-roussel-inc-carderm-capital-lp-andrx.

34 332 F.3d at 900. In finding the agreement for delayed-entry in exchange for payment "a classic example of a *per se* illegal restraint of trade," the Sixth Circuit noted that "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." *Id.* at 908.

35 *Schering Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005); *see also Valley Drug*, 344 F.3d 1294.

36 402 F.3d at 1062.

37 *Id.* at 1076.

38 *Id.* at 1076.

Eleventh Circuit ruled that courts must evaluate the "scope of the patent" to determine whether a settlement violates antitrust law: "the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."[39] Under this "scope-of-the-patent" test, so long as a settlement did not extend beyond the temporal duration or subject matter of the patent (*i.e.,* exclude the generic from entering past the patent period), there was no antitrust violation.

In 2006, the Second Circuit followed the Eleventh Circuit by rejecting *per se* treatment of reverse payment settlements[40] and requiring an analysis of "whether the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection.'"[41] Two years later, the Federal Circuit chimed in, joining the other circuits in adopting a scope-of-the-patent test.[42] In 2012, the Third Circuit broke from the crowd, holding that reverse payments carried a presumption of illegality under the "quick look" rule of reason antitrust analysis.[43]

V. *ACTAVIS*: SOMETIMES YOU WIN, SOMETIMES. . . .

After passing on several certiorari petitions, the Supreme Court provided *some* guidance in *Actavis*.[44] Asked whether reverse payments can violate the Sherman Act, the Supreme Court firmly responded, "sometimes."[45]

In January 2009, the FTC filed a federal lawsuit under Section 5 of the FTC Act against several branded and generic manufacturers who settled patent litigation involving AndroGel. The patent litigation arose when the pioneer, Solvay, acquired a patent and FDA approval to market, followed by an ANDA filing by Actavis and certification under Paragraph IV that Solvay's patent was invalid and that the proposed generic medication would not be infringing. In 2006, the patent settlement provided Actavis with nine years of payments of between $19 and $30 million for agreeing not to enter the market until 2015, over five years *before* Solvay's patent expired.[46] The FTC contended that the payments impermissibly

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39 *Id*. at 1066 (*citing Valley Drug*, 344 F.3d at 1312).

40 *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206 (2d Cir. 2005) ("We do not think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation.").

41 *Id*. at 213; *see also id*. at 216 ("In the absence of any plausible allegation that the reverse payment provided benefits to Zeneca outside the scope of the tamoxifen patent, the plaintiffs have not stated a claim for relief with respect to the Settlement Agreement.").

42 *In re Ciprofloxacin Hyrdochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed Cir. 2008) ("The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent.").

43 *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012) (reverse payment to generic patent challenger "is *prima facie* evidence of an unreasonable restraint of trade" but "a patent holder may attempt to rebut plaintiff's *prima facie* case of an unreasonable restraint of trade by arguing that there is in fact no reverse payment because any money that changed hands was for something other than a delay in market entry.").

44 133 S. Ct. 2223 (2013); *see generally* Aaron S. Edlin et al., *Activating Actavis*, 28 Antitrust 16 (2013).

45 *Actavis*, 133 S. Ct. at 2227 ("reverse payment settlements such as the agreement alleged in the complaint before us can sometimes violate the antitrust laws.").

46 *Actavis*, 133 S. Ct. at 2229.

compensated a would-be competitor for delaying competition. But the district court and Eleventh Circuit disagreed because the settlement negotiated entry within the temporal scope of the patent (*i.e.,* 65 months before patent expiration).[47]

In June 2013, the Supreme Court swept the scope-of-the-patent test into the dustbin of pharmaceutical antitrust history. In a five-to-three opinion, the Supreme Court held that reverse payment settlement agreements "can sometimes violate the antitrust laws."[48] The Court rejected the by-then widely followed scope-of-the-patent test because referring "simply to what the holder of a valid patent could do does not by itself answer the antitrust question."[49] The Court noted that invalidated patents confer no rights to exclude competition and exact monopoly rents, and that a generic's Paragraph IV certification "put[s] [a] patent's validity at issue, as well as its actual preclusive scope."[50]

The Court held that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects."[51] Rejecting the "quick look" approach and a presumption of illegality, the Court held that the rule of reason is the appropriate antitrust analysis because "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."[52]

The Court noted "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness," leading to an inference that the settlement was purely to forestall potential or actual competition.[53] While settling parties may demonstrate "legitimate justifications" for a large reverse payment under the rule of reason (although the Court appeared skeptical), the Court warned that "[i]f the basic reason is a desire to maintain and share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement."[54]

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47 *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012) ("[A]bsent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.").

48 *Actavis*, 133 S. Ct. at 2227. The Court distinguished reverse payment settlements from more typical litigation settlements because "[i]n reverse payment settlements, . . . a party with no claim for damages (something that is usually true of a paragraph IV litigation defendant) walks away with money simply so it will stay away from the patentee's market." *Id.* at 2233.

49 *Id.* at 2230–31.

50 *Id.* at 2231.

51 *Id.* at 2237.

52 *Id.*

53 *Id.* at 2236–37.

54 *Id.* at 2237; ("[O]ne who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments.").

To perform the rule of reason analysis, however, and answer "the basic question—that of the presence of significant unjustified anticompetitive consequences," the Court left it to the lower courts to structure the analysis, as "the quality of proof required should vary with the circumstances."[55]

VI. *CIPRO* BRINGS *ACTAVIS* TO CALIFORNIA AND THE CARTWRIGHT ACT

Once *Actavis* established that reverse payment pharmaceutical patent settlements are subject to the rule of reason, the lower courts began to struggle with exactly how to structure that analysis.[56]

On May 7, 2015, the California Supreme Court offered its view of how a post-*Actavis* rule of reason analysis of a reverse payment should be conducted in *In re Cipro Cases I & II*.[57] In doing so, the *Cipro* Court offered its own test for identifying whether a Hatch-Waxman settlement violates antitrust law—in this case, the Cartwright Act. And although "the Cartwright Act is broader in range and deeper in reach than the Sherman Act," the guidance in *Cipro* may well impact how federal courts assess the issue under the Sherman Act.[58]

The genesis of the *Cipro* decision was a Paragraph IV litigation settlement that spawned antitrust suits across the country.[59] In 1987, Bayer Corporation secured a patent on ciprofloxacin hydrochloride, the active ingredient in the antibiotic Cipro. In 1991, a generic manufacturer, Barr, filed an application with the FDA to market a generic version of Cipro. Barr certified under Paragraph IV that Bayer's patent was invalid and unenforceable. Bayer filed its patent infringement suit, and Barr counterclaimed for a declaratory judgment that Bayer's patent was invalid. After five years of litigation, the branded and generic manufacturers settled in 1997.[60]

Under the settlement, Barr agreed not to market its own generic version of Cipro until after the patent expired in 2003.[61] Barr was to receive branded Cipro product for licensed resale beginning six months before patent expiration, thereby mirroring the 180-day duopoly the Hatch-Waxman Act would have provided Barr if it had demonstrated invalidity or noninfringement of Bayer's patent.[62] Between 1997 and 2003, Barr received nearly $400 million from Bayer, for which profits from Cipro sales exceeded $1 billion during that time.[63]

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55 *Id.* at 2238.

56 To date, one pay-for-delay case (*In re Nexium*) has been tried to a jury. *In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-02409-WGY (D. Mass. Dec. 2014), Dkt. 1383 (defense verdict).

57 61 Cal. 4th 116 (2015).

58 *Cianci v. Super. Ct.*, 40 Cal. 3d 903, 920 (1985).

59 *See, e.g., Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 100 (2d Cir. 2010); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003).

60 *Cipro*, 61 Cal. 4th at 132.

61 *Id.*

62 *Id.*

63 *Id.* at 132–33.

In California, indirect purchasers of Cipro brought nine coordinated class action suits against Bayer and Barr alleging violations of the Cartwright Act, unfair competition law, and the common law prohibition on monopolies. In short, the complaint alleged that Bayer and Barr's settlement of their patent litigation allowed them to preserve and split Bayer's monopoly profits at the expense of consumers.[64]

Following class certification, which was upheld on appeal, the parties stayed the action pending resolution of related federal cases. Based on the scope-of-the-patent test, the Federal Circuit and the Second Circuit both rejected the antitrust claims against Bayer and Barr.[65] Finding those rulings under the Sherman Act dispositive and applying the scope-of-the-patent test, the California trial court granted summary judgment in favor of Bayer and Barr, holding that the settlement agreement did not violate the Cartwright Act.[66] The Court of Appeal upheld summary judgment also based on the scope-of-the-patent test. After the California Supreme Court granted review in 2012, Bayer settled and was dismissed while Barr remained.[67] While the state high court appeal was pending, the United States Supreme Court issued its *Actavis* opinion.

The *Cipro* Court held that "pay-for-delay" Paragraph IV patent settlements are subject to antitrust scrutiny under the Cartwright Act, rejecting the scope-of-the-patent test because it "accords excess weight to the policies motivating patent law, [and] gives insufficient consideration to the concerns animating antitrust law."[68] The Court stated that "[p]arties illegally restrain trade when they privately agree to substitute consensual monopoly in place of potential competition that would have followed a finding of invalidity or noninfringement."[69] Relying on *Actavis,* the Court held that state antitrust law is violated by a reverse payment settlement designed "to maintain *supra*competitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market."[70]

VII. THE FOUR PART RULE OF REASON TEST UNDER *CIPRO*

Having established that the Cartwright Act may prohibit reverse payment settlements, the Court purported to set out a structured rule of reason test for courts to identify whether a violation has occurred. To make a prima facie case of illegality, a third-party plaintiff must show four elements regarding a reverse payment patent settlement:

1. The settlement includes a limit on the settling generic challenger's entry into the market;
2. The settlement includes cash or equivalent financial consideration flowing from the brand to the generic challenger;

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64 *Id.* at 133.

65 Ark. Carpenters, 604 F.3d at 106; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d at 1336.

66 *Cipro*, 61 Cal. 4th at 133.

67 *Id.*

68 *Id.* at 139.

69 *Id.* at 130.

70 *Id.* at 148 (quoting *Actavis*, 133 S. Ct. at 2236).

3. The consideration exceeds the value of goods and services other than any delay in market entry provided by the generic challenger to the brand, and;

4. The consideration exceeds the brand's expected remaining litigation costs absent settlement.[71]

The first element is requisite to show some restraint of trade, without which there can be no antitrust violation. The second element is intuitive; there is no reverse payment settlement without some kind of "payment." The Court noted that cash payments have given way in practice to other forms of consideration, and thereby clarified for the Cartwright Act what is being debated in the federal courts under *Actavis*[72]—that non-cash consideration in the form of side deals is a payment that will trigger antitrust scrutiny.[73] The third and fourth elements incorporate safe harbors identified in *Actavis* that would justify a payment without implicating an illegal purpose to avoid the risk of competition; *e.g.,* a payment for valuable services or a settlement to avoid anticipated litigation costs is not anticompetitive.[74]

Although a Cartwright Act plaintiff bears the burden of proof as to these four elements, the "burden of producing evidence . . . is a slightly different matter."[75] Because manufacturer defendants have "superior knowledge" about their own litigation costs and the value of any collateral products or services provided to them as part of an agreement, they will bear the burden of production as to the third and fourth elements. "[O]nce a plaintiff has shown an agreement involving a reverse payment and delay, the defendants have the burden of coming forward with evidence of litigation costs and the value of collateral products and services."[76] If the defendants do not produce the requisite evidence, however, the plaintiff will be deemed to have satisfied the showing required for the latter two elements, resulting in a showing on all four elements.[77] If defendants do produce the requisite evidence, the plaintiff must persuade the trier of fact that the reverse payment exceeds the value of services provided and litigation costs saved.[78] The larger the gap between the payment and the value of justifiable consideration, the stronger the inference a jury will be permitted to draw about the anticompetitive effect of the settlement.[79] Satisfying the four elements establishes both a prima facie case that the settlement is anticompetitive and a presumption that a branded manufacturer has market power.[80]

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71 *Id.* at 151.

72 *King Drug Co. of Florence, Inc. v. SmithKlineBeecham Corp.*, No. 14-1243, 2015 WL 3967112 (3d Cir. June 26, 2015) (Hatch-Waxman settlement can still violate Sherman Act where it did not involve cash payment but included agreement by brand manufacturer not to sell authorized generic drug during generic's 180-day market exclusivity period); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013) (declining to "limit [the] principles [in *Actavis*] to monetary-based arrangements alone.").

73 *Cipro*, 61 Cal. 4th at 152; *see also Getz Bros. & Co. v. Fed. Salt Co.*, 147 Cal. 115, 118 (1905) (payment for agreement not to compete included with purchase of bulk salt is still illegal).

74 *Cipro*, 61 Cal. 4th at 152-53.

75 *Id.* at 153.

76 *Id.*

77 *Id.*

78 *Id.* at 154.

79 *Id.*

80 *Id.* at 157.

If a plaintiff has made a prima facie showing by satisfying the four elements, then the burden shifts to the defendants to offer "legitimate justifications and come forward with evidence that the challenged settlement is in fact procompetitive."[81] Like the United States Supreme Court, the California Supreme Court appears skeptical that large reverse payments can be justified as procompetitive, but will not foreclose defendants from attempting to meet their burden.[82]

Assuming defendants can offer procompetitive justifications of a reverse payment, a plaintiff may show that those justifications are "unsupportable" to meet its ultimate burden under the rule of reason that defendants have paid for delay in violation of the Cartwright Act.[83]

Though plaintiffs nominally have the ultimate burden throughout the litigation, the true burdens lie with the defendants. Under the *Cipro* test, antitrust plaintiffs can prove their case with very little discovery. The only discovery plaintiffs would have to provide is the subject settlement agreement and the patent issuance and expiration, all of which are public information (through the Federal Trade Commission and the U.S. Patent and Trademark Office).[84] In short, it may be challenging to show the procompetitive effects of an agreement under which a sizable amount of value has been transferred to a would-be competitor—particularly at the motion to dismiss stage.

VIII. "AVERAGE EXPECTED DURATION": THE NEW MODIFIED SCOPE-OF-THE-PATENT TEST?

Despite the "structured rule of reason" analysis formally adopted in California,[85] the ruling leaves trial courts and litigants with a challenging, if not impossible, task: divining the "average expected duration" of a federal patent being challenged in the Paragraph IV federal patent litigation. The *Cipro* Court explained:

> [T]he relevant benchmark in evaluating reverse payment patent settlements should be no different from the benchmark in evaluating any other challenged agreement: what would the state of competition have been without the agreement? In the case of a reverse payment settlement, the relevant comparison

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81 *Id.*

82 *Id.* at 158.

83 *Id.* at 159; *see Id.* at 160 ("We summarize the structure of the rule of reason applicable to reverse payment patent settlements. To make out a prima facie case that a challenged agreement is an unlawful restraint of trade, a plaintiff must show the agreement contains both a limit on the generic challenger's entry into the market and compensation from the patentee to the challenger. The defendants bear the burden of coming forward with evidence of litigation costs or valuable collateral products or services that might explain the compensation; if the defendants do so, the plaintiff has the burden of demonstrating the compensation exceeds the reasonable value of these. If a prima facie case has been made out, the defendants may come forward with additional justifications to demonstrate the settlement agreement nevertheless is procompetitive. A plaintiff who can dispel these justifications has carried the burden of demonstrating the settlement agreement is an unreasonable restraint of trade under the Cartwright Act.").

84 Medicare Prescription Drug Improvement & Modernization Act of 2003, Pub. L. No. 108-173, §§ 1111-1118, 117 Stat. 2066, 2461-64 (codified as amended at 21 U.S.C. § 355(j)) (requiring branded and generic manufacturers to file patent litigation settlements with the FTC and DOJ).

85 On July 8, 2015, the California Supreme Court denied rehearing of its *Cipro* decision.

> is with the average level of competition that would have obtained absent settlement, *i.e.,* if the parties had litigated validity/invalidity and infringement/noninfringement to a judicial determination.[86]

The Court noted that "*Actavis* makes clear that for antitrust purposes patents are no longer to be treated as presumptively ironclad. This means the period of exclusion attributable to a patent is not its full life, but its expected life had enforcement been sought. This expected life represents the baseline against which the competitive effects of any agreement must be measured."[87] In other words, "[t]he measure of the statutory grant, and the limit on the monopoly that may be preserved by agreement, is the average expected duration that would have resulted from judicial testing."[88]

According to the Court, the objective of a rule of reason test, therefore, is to determine whether a settlement agreement "eliminates competition beyond the point at which competition would have been expected in the absence of an agreement."[89] Indeed, in a *Cipro* analysis, "what matters is whether a settlement postpones market entry beyond the average point that would have been expected at the time in the absence of agreement."[90]

In short, the *Cipro* Court went to great and repeated lengths to explain that the key test of legality is to determine what the "average expected duration" of a particular patent was at the time of settlement of a litigation challenging its validity, and compare that duration to the entry date agreed to in the settlement agreement. According to the Court's logic, if a patent litigation settlement results in a generic manufacturer entering the market later than the "expected duration" that would have resulted from continued litigation, then a settlement may be found anticompetitive. If the settlement results in generic entry earlier than or precisely at the expected duration of the patent being challenged, then there is no anticompetitive effect. From this holding, it appears clear that determining the "average expected duration" of a patent monopoly, assuming a litigation challenge, would be the pivotal challenge for any state court judge or jury considering a reverse payment case under the Cartwright Act.

This new standard begs the question: how exactly does a state court judge or jury determine what the average expected duration of a federal patent would be? Calculating the remaining life of the patent at the time of settlement is an easily determinable fact. But the *Cipro* analysis at its core would require a state court jury to determine the odds that a federal patent would have withstood an attack on its validity.[91] The rationale in this new Cartwright Act standard is that a challenged pharmaceutical patent had a "chance of

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86 *Cipro*, 61 Cal. 4th. at 149; *see id.* at 158 ("[T]he relevant baseline is the average period of competition that would have obtained in the absence of settlement.").

87 *Id.* at 149.

88 *Id.* at 150.

89 *Id.*

90 *Id.* at 158–59; *see also id.* at 150 ("Purchasing freedom from the possibility of competition, whether done by a patentee or anyone else, is illegal. An agreement to exchange consideration for elimination of any portion of the period of competition that would have been expected had a patent been litigated is a violation of the Cartwright Act.").

91 *Id.* at 149 (offering an example that a patent with a 50% "chance of being upheld" in litigation means that "on average, consumers would be subject to a monopoly for half the remaining life of the patent" so a settlement setting generic entry at that halfway mark would not be anticompetitive).

being upheld" in litigation that is somewhere less than one hundred percent (otherwise the litigants would not have settled). The *Cipro* decision makes this fact-finding determination about the strength of a federal patent subject to federal patent litigation the lynchpin to any state court analysis under the Cartwright Act.

To do their jobs, California state court judges and juries would need to assess the strength of a federal patent (pharmaceutical or otherwise) and make factual findings regarding average expected duration at a singular point in time. Establishing average expected duration will surely become a heated topic of dueling expert testimony. Indeed, expert economists are already proposing economic models for how to determine the average expected duration of a patent and how to properly evaluate reverse payment settlements. Judges and juries may be asked to rule based on economic models like this one: $Pr(Loss) \geq (S - C_B) / (B^{no\ entry} - B^{entry})$.[92]

Trial lawyers will be forced to litigate, or re-litigate, patent validity issues from the underlying federal Paragraph IV litigation in the subsequent state antitrust trial. Thus, the new *Cipro* standard has the potential to create a patent trial within an antitrust trial. While this already occurs in certain types of federal patent/antitrust cases,[93] for a state court jury it may well be a bridge too far.

In *Actavis,* Justice Breyer stated that "it is *normally* not necessary to litigate patent validity" to determine if a settlement violates antitrust law because "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."[94] The *Cipro* Court also adopted this imprecise proxy for patent strength: "stronger patent, smaller settlement; weaker patent, bigger settlement."[95] The Court stated that "it is entirely possible to resolve an antitrust challenge to a reverse payment patent settlement without adjudicating the patent's validity."[96]

While acknowledging Justice Breyer's opinion (and in fact relying on the non-necessity of litigating the patent in order to assert jurisdiction at the state level), litigating patent validity appears to be a virtual requirement of the *Cipro* Court's new "average expected duration" standard. The *Cipro* Court's rejection of the ironclad scope-of-the-patent test appears to have been followed by the creation of a probabilistic modified scope-of-the-patent test (*i.e.,* what is the scope of the patent assuming a litigation challenge?).

Because the expected duration test explicitly requires concrete calculations—"chance" of litigation success and remaining patent life compared to agreed-upon entry date—it is problematic to rely solely on the size of a reverse payment as a proxy for patent strength. A simplistic "big is bad" rule is not a practical means of assessing antitrust risk to guide conduct; it is an ambiguous quagmire that conflicts with a core principle of antitrust. The United States Supreme Court has "repeatedly emphasized the importance of clear rules in antitrust law."[97] As Justice Breyer has explained:

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92 Joshua Gans & Lisa Cameron, *An Empirical Approach To Reverse Payment Settlements*, Law360 (July 6, 2015), http://www.law360.com/articles/674387/an-empirical-approach-to-reverse-payment-settlements.

93 *See, e.g., Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

94 133 S. Ct. at 2236–37 (emphasis added).

95 61 Cal. 4th. at 135, 159.

96 *Id.* at 162, n.21.

97 *Pac. Bell Tel. Co. v. Linkline Commc'ns., Inc.*, 555 U.S. 438, 452 (2009).

> [A]ntitrust rules . . . must be clear enough for lawyers to explain them to clients. They must be administratively workable and therefore cannot always take account of every complex economic circumstance or qualification. . . . They must be designed with the knowledge that that firms ultimately act, not in precise conformity with the literal language of complex rules, but in reaction to what they see as the likely outcome of court proceedings.[98]

The new *Cipro* standard for Cartwright Act liability offers very little in terms of ultimate clarity on what a California state court judge or jury in a reverse payment litigation is likely to do.

IX. REVERSE PAYMENT LITIGATION WILL HEAT UP IN CALIFORNIA

Despite its internal tension and seeming lack of clarity, the *Cipro* decision has already been heralded by one federal court as "one of the most thorough and thoughtful discussions of *Actavis* yet issued by any court."[99] To be sure, the new standard for a *prima facie* case places a small burden on plaintiffs and a significant burden on defendants. Purchasers and indirect purchasers of pharmaceutical drugs involved in settlements of Paragraph IV patent litigation will no doubt urge reliance on *Cipro* in both federal and state litigation. *Cipro* is likely to make California state court a favored jurisdiction for future antitrust litigation in the pay-for-delay arena. To paraphrase Chief Justice Roberts' dissent in *Actavis:* Good luck to the California Superior Courts.[100]

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98 *Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990).

99 *In re Aggrenox Antitrust Litig.*, No. 3:14-MD-2516 SRU, 2015 WL 4459607 *9 (D. Conn. July 21, 2015) (adopting *Cipro* approach that the period of exclusion attributable to patent is its expected life rather than full statutory grant).

100 *See Actavis*, 133 S. Ct. at 2245 (Roberts, C.J., dissenting).