



1-1-2014

Ending Reverse-Payment Immunity: A Proposed Framework for Antitrust Scrutiny Under California's Cartwright Act

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Ending Reverse-Payment Immunity: A Proposed Framework for Antitrust Scrutiny Under California’s Cartwright Act

Anthony Serrao*

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I. INTRODUCTION

In the late 1980s, after developing a new drug, Bayer obtained a patent and marketed the product for up to \$5.30/pill under the brand name¹ Ciprofloxacin (Cipro).² Perceiving the patent to be invalid, competing producers developed a generic³ bio-equivalent of the drug to market for as little as \$1.10/pill.⁴ Our society thrives on competition, and the generic challenge to Bayer will be widely viewed as positive for consumers.⁵ Many would be surprised to learn, therefore, that the generic producer (Barr)⁶ abandoned its effort to market the drug in exchange for annual payments from Bayer amounting to nearly \$400 million.⁷ Indeed, Bayer retained its monopoly, sidestepping a potentially serious challenge to its patent,⁸ and Barr received hefty annual payments greater than the amount it stood to make by selling its drug.⁹ The challenge left consumers paying a

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1. Brand name drugs are usually innovative pharmaceuticals containing newly developed, patented substances. ABA SECTION OF ANTITRUST LAW, PHARMACEUTICAL INDUSTRY ANTITRUST HANDBOOK 2 (2009) [hereinafter INDUSTRY ANTITRUST HANDBOOK].

2. Letter Brief of California Attorney General as Amicus Curiae Supporting Petitioners at 3, *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165 (Ct. App. 2011) (No. S198616) [hereinafter Letter Brief of Attorney General].

3. *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165, 170–171 (Ct. App. 2011). Generic drugs are those that contain the same active ingredient as brand name drugs. INDUSTRY ANTITRUST HANDBOOK, *supra* note 1, at 5–6. In order to qualify as a generic, a drug must be the “bio-equivalent” of a brand name drug. See 21 C.F.R. § 320.1(e) (2009) (defining bio-equivalent as “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.”).

4. Letter Brief of Attorney General, *supra* note 2, at 3; see also FEDERAL TRADE COMMISSION, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010), available at <http://www.ftc.gov/opa/reporter/competition/payfordelay.shtml> [hereinafter FTC REVERSE-PAYMENT STUDY] (on file with the *McGeorge Law Review*) (indicating that the cost of generics are commonly lower, on average 85% less than the price of brand name equivalents).

5. See FTC REVERSE-PAYMENT STUDY, *supra* note 4, at 1 (indicating that consumers suffer when forced to pay for brand name drugs when generics may cost as little as 10% as much) . Challenges by generic producers often succeed, with brand patents being held invalid in 73% of Hatch-Waxman litigation from 1992 through June 2002. *Id.* at 3.

6. Two other drug producers later joined Barr in challenging Bayer’s patent, agreeing to share the cost of litigation in exchange for an agreement to jointly produce the generic, while sharing the profits. *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d at 171.

7. See *id.* at 171 (“By December 2003 when Bayer ceased making payments, its payments to Barr totaled approximately \$398 million . . .”).

8. Brief of Appellants at 1, *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165 (Ct. App. 2011) (No. D056361) [hereinafter Brief of Appellants].

9. The court found that the amount of money received from Bayer “was more than double the \$148 million to \$177 million Barr predicted it would earn selling generic ciprofloxacin in a competitive market . . .” *Id.* at 1–2.

premium on the drug, purchasing Bayer-manufactured Cipro at four times the cost of a generic alternative.¹⁰

Competition from manufacturers of generic drugs is a critical tool in controlling the cost of medications, which have skyrocketed in recent years.¹¹ In fact, consumers nearly always save money when purchasing generic medications.¹² The savings are especially prominent for the underprivileged and those without health insurance.¹³ Recognizing this savings potential, Congress streamlined the procedures for generic market entry in 1984 with the Drug Price Competition and Patent Term Restoration Act. Known as the Hatch-Waxman Act, this legislation incentivizes the makers of generic drugs to challenge potentially invalid patents held by brand name drug manufacturers.¹⁴ Agreements between brand name and generic drug makers stymie the development of a competitive market and work against the legislative framework that regulates that market.¹⁵ Such agreements also present a serious threat to drug innovation.¹⁶ As former FTC Commissioner Jon Leibowitz testified, “the incentive to pay a generic to abandon its patent challenge is greatest for the weakest patents.”¹⁷ That

10. Letter Brief of Attorney General, *supra* note 2, at 3. In fact, shortly after securing the reverse-payment agreements at issue, Bayer increased the cost of Cipro by 16%. Brief of Appellants, *supra* note 8, at 2.

11. See INDUSTRY ANTITRUST HANDBOOK, *supra* note 1, at 1 (noting that prescription drug spending has grown at double the rate of total health spending); Letter Brief of Attorney General, *supra* note 2, at 2 (detailing the increase of pharmaceutical costs in California); see also Press Release, Federal Trade Commission, FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market (Jan. 17, 2013), <http://www.ftc.gov/opa/2013/01/mmprpt.shtm> (on file with the *McGeorge Law Review*) (“Generic drugs are the key to making medicines affordable for millions of American consumers, and help hold down costs for taxpayer-funded health programs such as Medicare and Medicaid.”).

12. On average, the price of a generic medication is 85% less than the cost of its brand name equivalent, and the savings are such that generic medications typically achieve a 90% share of the market within a year of their entry. FTC REVERSE-PAYMENT STUDY, *supra* note 4, at 8.

13. See JON LEIBOWITZ, CHAIRMAN, FED. TRADE COMM’N, “PAY-FOR-DELAY” SETTLEMENTS IN THE PHARMACEUTICAL INDUSTRY: HOW CONGRESS CAN STOP ANTICOMPETITIVE CONDUCT, PROTECT CONSUMERS’ WALLETS, AND HELP PAY FOR HEALTH CARE REFORM (THE \$35 BILLION SOLUTION) 3–4 (June 23, 2009) (hereinafter Leibowitz).

(“Those of us with the good fortune to have health insurance don’t see these cost differences directly because we only pay the difference between the brand and the generic copay—the rest of the additional cost is hidden in our health insurance premium. But if you are one of the 46 million uninsured in this country . . . it’s an entirely different story. . . . And it’s not just a matter of economics: high prescription drug prices often cause patients to cut their pills in half or skip needed medications altogether.”).

14. See 21 U.S.C. § 355(j)(5)(B)(iv) (2012) (allowing generic producers to make themselves eligible for certain market exclusivity periods by filing an ANDA IV application).

15. See Brief *Amici Curiae* of 118 Law, Economics, and Business Professors and the American Antitrust Institute in Support of Petitioners at 9, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 391001 [hereinafter Brief of Law, Economics, and Business Professors] (expressing the dismay of the framers of the legislation, Representative Henry Waxman and Senator Orrin Hatch, to reverse-payment settlements, which Senator Hatch finds “appalling”).

16. Leibowitz, *supra* note 13, at 6.

17. *Id.* Leibowitz also noted that “[t]he Supreme Court has repeatedly observed that protecting weak patents slows rather than promotes innovation.” *Id.*

these agreements contain large payouts in exchange for a delay in competition raises serious antitrust considerations.¹⁸

At the federal level, the Supreme Court recognized such implications by reversing the Circuit Court trend and subjecting reverse-payment settlements to antitrust scrutiny under the Sherman Act.¹⁹ Nevertheless, the Court's holding fails to protect consumers from anticompetitive agreements.²⁰ The more relaxed rule-of-reason analysis, which the Supreme Court adopted in *FTC v. Actavis, Inc.*, does not explicitly condemn reverse-payment settlements.²¹ This analysis threatens the government's ability to ensure properly competitive markets for drugs because it diverts government resources toward litigating against plainly anticompetitive agreements.²² This Comment argues that the more proper antitrust analysis for reverse-payment agreements is the *per se* rule, or, in the alternative, the quick-look approach.

Although persuasive, Sherman Act case law is not controlling under California's own antitrust law—the Cartwright Act.²³ Estimated to cost Californians \$4.2 billion in higher prescription drug costs over the next ten years, the prevalence of reverse-payment settlements is a matter deserving of serious public attention within the state.²⁴ Indeed, the California Attorney General believes that reverse-payment settlements should be categorized as *per se* violations of the act, an interpretation the California Supreme Court should endorse in lieu of the *Actavis* decision.²⁵ Reverse-payment settlements are facially anticompetitive agreements that result in significant costs to the consumer; declaring these agreements to be *per se* violations of the Cartwright Act would best promote consumer welfare. Should the court reject the *per se* rule, a

18. See *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165, 174 (Ct. App. 2011) (describing the plaintiffs allegation that reverse-payment settlements raise triable issues of violation of the Cartwright Act and arguing for a *per se* bar on the agreements).

19. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013). The Court's holding subjects reverse-payment settlements to greater scrutiny than the Eleventh Circuit, which stated that a settlement should be "immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Id.*

20. See *infra* Part IX, (advocating the application of the *per se* rule to reverse-payment agreements in the interest of consumer welfare).

21. *Actavis*, 133 S. Ct. at 2237. The Court argued that "the FTC must prove its case" to the district courts in challenging reverse-payment settlements. *Id.*

22. See Leibowitz, *supra* note 13, at 5 (indicating that the FTC continues to initiate litigation against producers who enter into reverse-payment agreements, but that such litigation is "time consuming and expensive").

23. See Coordination Proceeding *Cipro Cases I & II*, No. JCCP4154, 2009 WL 2700124, (Cal. Super. Ct. Aug. 21, 2009) ("[T]he Court recognizes that the federal decisional law is not binding on this Court . . ."); see Part IV.A. for a discussion of the relevance of federal Sherman Act interpretation.

24. Letter Brief of Appellants, *supra* note 2, at 3.

25. *Id.*; see also Brief of Appellants, *supra* note 8, at 43 ("[T]he California Attorney General has consistently denounced them as unlawful.").

truncated rule of reason (quick-look) approach would better serve the interests of reverse-payment litigation than a traditional rule-of-reason approach.²⁶

Part II of this article discusses the Hatch-Waxman Act: the legal framework under which reverse-payment settlements arise. Part III then describes the efforts to litigate against reverse-payment deals. Part IV details the competing standards of review that courts may apply in antitrust challenges. Part V analyzes the Supreme Court's interpretation of reverse-payment agreements under the Sherman Act in *FTC v. Actavis, Inc.* Part VI discusses the reasoning of California lower courts in Cartwright Act challenges. Then, Part VII discusses the role of patents in antitrust litigation. Part VIII argues that recent interpretation of reverse-payment settlements under federal law should change present Cartwright Act interpretation. Part IX asserts that application of the *per se* rule is most appropriate for Cartwright Act scrutiny. However, should the California Supreme Court decline to adopt the *per se* rule, Part X suggests that it should employ a quick-look analysis.

II. THE HATCH-WAXMAN ACT

Since 1938, every drug seeking market entry in the United States must gain FDA approval certifying its safety and effectiveness by filing a New Drug Application (NDA).²⁷ The approval process mandates extensive testing to determine the safety of drugs containing newly-created active ingredients.²⁸ The Hatch-Waxman Act eases the burden of market entry for generic medications, allowing drug producers using an active ingredient identical to a drug already on the market to file an Abbreviated New Drug Application (ANDA).²⁹ The ANDA relies on the application and testing encompassed in the initial NDA.³⁰ By allowing generic producers to rely on the brand name drug's application, the

26. For a review of the truncated rule-of-reason approach, *see infra* Part IV.C. Among the most critical aspects of the approach is that it shifts the burden to the defendants to prove pro-competitive effects, rather than requiring plaintiffs to prove anti-competitive effects. Geoffrey D. Oliver, *Of Tenors, Real Estate Brokers And Golf Clubs: A Quick Look at Truncated Rule of Reason Analysis*, ANTITRUST MAGAZINE, Spring 2010, at 40.

27. *New Drug Application (NDA)*, U.S. FOOD AND DRUG ADMINISTRATION (last updated Feb. 21, 2013), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/> (on file with the *McGeorge Law Review*).

28. *Id.* Labeling and manufacturing processes of drugs are also reviewed in the initial NDA. *Id.*

29. 21 U.S.C. § 355(j)(2) (2012). Prior to the Hatch-Waxman Act, producers of generic medications were required to undertake their own extensive testing, even though the drug was presumably identical to one already approved by the FDA. *See* Brief of Law, Economics, and Business Professors, *supra* note 15, at 7 (“The first tool the legislature created to accelerate generic entry was the Abbreviated New Drug Application (“ANDA”) process that allowed generic firms to rely on the brand drug’s safety and effectiveness studies and avoid the expensive and lengthy new-drug-application process.”).

30. 21 U.S.C. § 355(j)(2)(A)(i) (dictating that an ANDA shall contain “information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a [listed] drug . . .”).

Hatch-Waxman Act directly incentivizes producers of generic medications to seek market entry by easing the cost of doing so.³¹

In addition to encouraging generic market entry, the Hatch-Waxman Act specifically encourages generics to challenge potentially invalid patents held by brand name drug manufacturers.³² While four certification options are available to a generic manufacturer filing an ANDA,³³ only one of these—challenging the validity of an existing patent—rewards successful generic applicants with a 180-day sales exclusivity grant.³⁴ The Hatch-Waxman Act also limits potential generic liability in patent-infringement litigation to the cost of that litigation by providing an affirmative defense,³⁵ freeing generic producers from the need to be overly cautious in challenging patents.³⁶

Reverse-payment settlements challenge the framework laid down by the Hatch-Waxman Act.³⁷ They are a phenomenon unique to the pharmaceutical industry, arising between producers of generic and brand name medications.³⁸ These settlements arise under a law specifically enacted to counter a pervasive, industry-wide lack of competition from generic medications.³⁹ They are clearly an unforeseen effect of that law.⁴⁰ At the time of the Hatch-Waxman Act's passage, 150 brand name medications had expired patents and yet none faced competition from generic brands.⁴¹ Agreements between producers that restrict generic market entry therefore directly contravene the intent of the Hatch-Waxman Act.⁴²

31. See H.R. REP. NO. 98-857, pt. 1, at 14 (1984) (“The purpose of . . . the bill is to make available more low cost generic drugs . . .”).

32. See, e.g., 21 U.S.C. § 355(j)(5)(B)(iv) (granting the first filing drug a 180-day period of exclusivity upon successful challenge of patent); 35 U.S.C. § 271(e)(1) (establishing an “experimental use defense” to immunize generic producers from patent infringement suits that result from Hatch-Waxman challenges).

33. See 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV) (allowing the producer of a generic medication to certify that (1) no patent exists, (2) the patent has expired, (3) the patent will soon expire, or (4) the patent is invalid).

34. See *id.* at § 355(j)(5)(B)(iv) (conditioning the grant of a 180-day exclusivity period to certifications made pursuant to § 355(j)(2)(A)(vii)(IV)).

35. See H.R. REP. NO. 98-857 at 15.

36. See *id.* at 45. The defense protects producers from patent infringement liability for experimentation “reasonably related to the development and submission of information under a federal law . . .” *Id.* The move came in response to an unfavorable holding by the Court of Appeals for the Federal Circuit. *Id.*

37. See Brief of Law, Economics, and Business Professors, *supra* note 15, at 9 (“Representative Waxman explained that such agreements ‘turn[] the . . . legislation on [its] head.’”).

38. See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013) (explaining that “[a]pparently most if not all reverse-payment settlement agreements arise in the context of pharmaceutical drug regulation . . .”).

39. See H.R. REP. NO. 98-857 at 16–17 (indicating that “there are approximately 150 drugs approved after 1962 that are off patent and for which there is no generic equivalent” while describing the need for legislation).

40. See Brief of Law, Economics, and Business Professors, *supra* note 15, at 9 (expressing the dismay of the framers of the legislation, Representative Henry Waxman and Senator Orrin Hatch, to reverse-payment settlements, which Senator Hatch finds “appalling”).

41. *Id.* at 6.

42. The Hatch-Waxman Act clearly endeavored to expand the availability of generic medications, not permit their restriction. See H.R. REP. NO. 98-857 at 14) (“The purpose of . . . the bill is to make available more

III. THE LEGAL CHALLENGES TO REVERSE-PAYMENT AGREEMENTS

Reverse-payment settlements do more than contravene the intent of the Hatch-Waxman Act—they directly undermine its effectiveness.⁴³ The 180-day exclusivity period is available only to the generic manufacturer who files first,⁴⁴ so producers of brand name drugs may “bottleneck” further generic entry by entering into a reverse-payment agreement with the first filer.⁴⁵ Brand name producers can effectively disincentivize future challenges to their patents by settling with a single generic producer.⁴⁶ Although the Hatch-Waxman Act aims to “make available more low cost generic drugs,”⁴⁷ reverse-payment settlements threaten its framework and undermine pharmaceutical competition.⁴⁸

Recognizing the implications of reverse-payment agreements, the Federal Trade Commission (FTC) began a substantial effort to pursue antitrust claims against parties to these agreements in the early 2000s.⁴⁹ Recognition of the growing use of reverse-payment agreements also led to provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that required parties to notify the FTC of settlements under the Hatch-Waxman Act.⁵⁰ Despite the reporting requirements, however, manufacturers continue to enter into reverse-payment agreements: in fiscal year 2012 the total number of agreements increased to a record 40,⁵¹ costing consumers an estimated \$3.5 billion annually.⁵²

Going forward, the FTC will continue to pursue antitrust claims against parties to reverse-payment agreements.⁵³ As Chairwoman Edith Ramirez

low cost generic drugs . . .”).

43. FTC REVERSE-PAYMENT STUDY, *supra* note 4, at 2 (“Pay-for-delay agreements have significantly postponed substantial consumer savings from lower generic drug prices.”).

44. 21 U.S.C. § 355(j)(5)(B)(iv). First-filing producers of generic medications must either have marketed their product for 180 days or forfeit the right before subsequent-filing generic producers may market their product. *Id.* at § 355(j)(5)(D).

45. FTC REVERSE-PAYMENT STUDY, *supra* note 4, at 5 (“This cork-in-the-bottle effect occurs because every subsequent generic entrant has to wait until the first generic has been marketed for 180 days.”).

46. *Id.*

47. H.R. REP. NO. 98-857, pt. 1, at 14 (1984).

48. *See* Leibowitz, *supra* note 13, at 1 (describing the Hatch-Waxman Act as being “distorted” by pharmaceutical companies entering into reverse-payment agreements).

49. *See id.* at 4 (“That is why the Commission has made stopping these deals a top priority. Initially, under the leadership of both Democrat Bob Pitofsky and Republican Tim Muris, when the Commission found drug companies engaging in pay-for-delay settlements, we stopped them cold.”).

50. BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003 2 (2012).

51. FTC REVERSE-PAYMENT STUDY, *supra* note 4, at 3.

52. *Id.* at 2; BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003 2 (2012). (see suggestion for splitting this cite in comment bubble above).

53. *See Prepared Statement of the Federal Trade Commission, Before the United States Senate Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights on Pay-for-Delay Deals: Limiting Competition and Costing Consumers*, 113th Cong. 12 (2013) [hereinafter *FTC*

remarked, “[a] single anticompetitive agreement can easily increase prescription drug costs by many millions of dollars”⁵⁴ This detrimental impact on consumers—who pay up to 90% higher costs for drugs—results in bipartisan support from commission members to bring antitrust claims.⁵⁵

IV. STANDARDS OF ANTITRUST REVIEW

Antitrust standards of review determine the level of inquiry a court will undertake in evaluating an agreement.⁵⁶ While understanding the difference between the rule of reason and the *per se* rule is not difficult, determining their proper application is often an uncertain endeavor.⁵⁷

A. *The Rule of Reason*

The broad language of the Sherman Act is readily apparent: it categorically voids all restraints of trade.⁵⁸ Thus the rule of reason is a significant development in Supreme Court interpretation because it looks past the exact language of the text itself.⁵⁹ The Court first announced the rule in *Standard Oil Co. of New Jersey v. United States*, stating that the Sherman Act’s restraint-of-trade language draws on the common law—prohibiting only *unreasonable* restraints of trade.⁶⁰ Justice Brandeis offered necessary clarification to the *Standard Oil* rule in *Board of Trade of Chicago v. United States*, noting:

The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. . . . [T]he court must ordinarily consider the facts peculiar to the business to which the

Statement] (statement of Edith Ramirez, Chairwoman, Fed. Trade Comm’n) (“[T]he Commission will continue to aggressively prosecute these anticompetitive settlements.”).

54. *Id.*

55. *Id.* at 2 (“Since this issue first arose in 1998, every single member of the Commission, past and present—whether Democrat, Republican, or Independent—has supported the Commission’s challenges to these agreements.”)

56. See HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE 255 (3d ed. 2005) (“The difference between a “*per se*” and a “rule of reason” standard lies in how much we need to know before we can make [a] decision.”); see also *id.* at 257 (depending upon the standard of review, the court may “inquir[e] into the market structure or the market power of those engaged in the practice” or limit “certain justifications or defenses”).

57. See *id.* at 257 “[T]he most difficult aspect of the jurisprudence of the *per se* rule is determining when it should be followed.”

58. 15 U.S.C. § 1 (2012).

59. Originally following the passage of the Sherman Act in 1890, the Court consistently considered the extent of Section 1, which posits that “[e]very contract . . . in restraint of trade or commerce . . . is declared to be illegal.” *Id.* After declining to amend the extent of the Act several times, the Court held that only *unreasonable* restraints of trade are illegal. *Standard Oil Co. of N. J. v. United States*, 221 U.S. 1, 62 (1911).

60. *Id.*

restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts.⁶¹

The rule of reason therefore inquires into the context and circumstances surrounding an agreement and considers potential pro-competitive justifications that a party might offer.⁶² The nature, depth, and detail of that inquiry varies depending on the subject of the court's scrutiny.⁶³ Generally speaking, only those facts that are relevant—those tending to show or counter the presence of anticompetitive conduct—will be considered in a rule of reason case.⁶⁴ One cannot quickly dismiss an agreement when conducting a rule-of-reason analysis without examining the relevant market conditions and pro-competitive justifications offered.⁶⁵

B. *The Per Se Rule*

The development of the rule of reason reflects the evolution of the Court's Sherman Act interpretation: this reasoning avoids a literal reading that might restrict *every* restraint of trade.⁶⁶ However, the Court has also recognized that a reasonableness standard is not always appropriate when evaluating conduct that will consistently violate antitrust laws.⁶⁷ In *United States v. Trenton Potteries Co.*, the Court rejected an effort to assess the reasonableness of a naked price-fixing agreement, noting their long history of condemnation of such agreements.⁶⁸ The Court remarked:

The aim and result of every price-fixing agreement, if effective, is the elimination of one form of competition. . . . Agreements which create such potential power may well be held to be in themselves unreasonable

61. *Bd. of Trade of Chi. v. United States*, 246 U.S. 231, 238 (1918).

62. The amount of inquiry will vary with the circumstances, and only relevant facts and information are necessary. "What is required . . . is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint." *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 781 (1999).

63. HOVENKAMP, *supra* note 56, at 255; *see also* *Broad. Music, Inc. v. Columbia Broad.*, 441 U.S. 1, 6 (1979) ("[E]asy labels do not always supply ready answers."); *Cal. Dental Ass'n*, 526 U.S. at 779 ("The truth is that our categories of analysis of anticompetitive effect are less fixed than terms like 'per se,' 'quick look,' and 'rule of reason' tend to make them appear.").

64. HOVENKAMP, *supra* note 56, at 256.

65. *See Cal. Dental Ass'n*, 526 U.S. at 780 ("[T]he quality of proof required should vary with the circumstances.").

66. *United States v. Trenton Potteries, Inc.*, 273 U.S. 392, 395 (1927).

67. *Id.* at 397.

68. *Id.*

or unlawful restraints, without the necessity of minute inquiry whether a particular price is reasonable or unreasonable as fixed⁶⁹

The *per se* rule grants less judicial deference than its conceptual counterpart.⁷⁰ The application of the *per se* rule suggests that little information about an agreement is necessary for a court to invalidate it; the rule presupposes with certainty that anticompetitive harm will result.⁷¹ In *United States v. Socony-Vacuum Oil Co.*, the Court asserted:

Any combination which tampers with price structures is engaged in an unlawful activity. Even though members of the price-fixing group were in no position to control the market, to the extent that they raised, lowered, or stabilized prices they would be directly interfering with the free play of market forces.⁷²

Distinguishing the effect of the *per se* rule from the rule of reason is not a challenging task; however, identifying the proper application is quite difficult.⁷³ In *NCAA v. Board of Regents of University of Oklahoma*, the Court stated that the threshold question was whether “the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output.”⁷⁴ Once a particular type of agreement has been condemned as anticompetitive and subjected to the *per se* rule, future courts may invalidate similar agreements with little regard for the circumstances in which they are created.⁷⁵

C. The Quick-Look Approach

The traditional approaches to antitrust scrutiny stand in stark contrast to each other: one contemplates inquiry into the circumstances of an agreement while the other invalidates with little consideration.⁷⁶ Beginning in the late 20th century,

69. *Id.*

70. See *NCAA v. Bd. of Regents of Univ. of Okla.* 468 U.S. 85, 103–104 (1984) (“*Per se* rules are invoked when surrounding circumstances make the likelihood of anticompetitive conduct so great as to render unjustified further examination of the challenged conduct.”).

71. *Id.*

72. 310 U.S. 150, 221 (1940).

73. See HOVENKAMP, *supra* note 56, at 257 (“[T]he most difficult aspect of the jurisprudence of the *per se* rule is determining when it should be followed.”).

74. 468 U.S. 85, 100 (1984) (citing *Broad. Music, Inc. v. Columbia Broad.*, 441 U.S. 1, 19–20 (1979)).

75. See *United States v. Topco Assocs.*, 405 U.S. 596, 607–608 (1972) (“It is only after considerable experience with certain business relationships that courts classify them as *per se* violations of the Sherman Act.”).

76. Oliver, *supra* note 26, at 40 (“This dichotomy remained generally accepted throughout most of the 20th century. It proved to be a pragmatic approach that permitted courts to balance the desire to condemn quickly and efficiently those practices without redeeming value against the benefit of more careful consideration of practices . . . less well understood.”).

the Supreme Court fostered consideration of an additional standard of review for antitrust cases: the abbreviated rule-of-reason (quick-look) approach.⁷⁷ The quick-look approach is designed to ease the burden of employing a full rule-of-reason analysis for agreements that are commonly, though not always, anticompetitive.⁷⁸

The quick-look approach shifts the burden of proving that an agreement is anticompetitive away from the plaintiffs.⁷⁹ Instead, the court requires the defendant to affirmatively demonstrate the pro-competitive nature of an agreement.⁸⁰ This burden shift is appropriate for agreements deemed “inherently suspect,” but not so anticompetitive as to deserve *per se* invalidation.⁸¹ The Court suggests that the quick-look approach is properly applied when “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.”⁸²

While the quick-look approach has gained favor with the FTC in its own administrative decisions,⁸³ the Court has applied it relatively infrequently.⁸⁴ The Court employed the quick-look approach in a number of decisions in the late 20th century, which eroded the traditional distinction between the rule of reason and the *per se* rule.⁸⁵ Since then, however, lower courts have been skeptical of the quick-look approach.⁸⁶ More recently, the Court declined the FTC’s suggestion to adopt the quick-look approach in the *Actavis* decision.⁸⁷

77. *Id.*

78. *Id.* at 42 (“The purpose, said the Court, is ‘to see whether the experience of the market has been so clear . . . that a confident conclusion about the principal tendency of a restriction will follow’ from a quick look.”) (quoting *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 781 (1999)).

79. *Id.* at 40 (“[A] truncated analysis permits the plaintiff to satisfy its initial burden of production without presenting evidence that the defendant’s challenged conduct caused or is likely to cause actual harm to competition.”).

80. *Id.* (“The burden of production . . . shifts to the defendant to rebut the plaintiff’s showing. It may do so by demonstrating that the restraint has a plausible procompetitive justification. If the defendant does so, a full rule of reason analysis must be undertaken”).

81. *See e.g.* *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 100–101 (1984). The Court dealt with suspect broadcasting restrictions. *Id.* at 91–94. It refused to apply the *per se* rule, but nevertheless limited the inquiry by hearing some pro-competitive justifications for the restrictions proffered by the NCAA. *Id.* at 100. However, it ultimately rejected those justifications and remanded the case without the need for further analysis. *Id.* at 120.

82. *See* *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 770 (1999).

83. *See, e.g.*, *Realcomp II, Ltd.*, FTC Docket No. 9320, Op. of the Comm’n (Oct. 30, 2009), available at <http://www.ftc.gov/os/adjpro/d9320/091102realcompopinon.pdf>. (analyzing the matter under all three standards of review and extensively exploring the Court’s quick-look jurisprudence, including the *Cal. Dental Ass’n* decision)

84. *See, e.g.*, *Cal. Dental Ass’n*, 526 U.S. at 771 (“The case before us, however, fails to present a situation in which the likelihood of anticompetitive effects is comparably obvious.”).

85. Oliver, *supra* note 26, at 40–41.

86. *Id.* at 41.

(“Abbreviated rule of reason analysis has received a mixed reception in lower courts. Generally, U.S. courts of appeal have acknowledged that a quick look analysis permits condemnation of certain

V. REVERSE-PAYMENT SETTLEMENTS UNDER THE SHERMAN ACT: *FTC v. ACTAVIS, INC.*

Prompted by years of uncertainty and varying Circuit Court interpretations, the Supreme Court finally addressed reverse-payment settlements in 2013.⁸⁸ In *FTC v. Actavis, Inc.*,⁸⁹ the Court held that parties could challenge reverse-payment settlements under the Sherman Act using a rule-of-reason analysis.⁹⁰

The Court rejected the Eleventh Circuit's position that reverse-payment settlements are valid so long as they do not fall outside of a patent's exclusionary scope.⁹¹ Under the circuit court's reasoning, the payment at issue was valid because it did not restrict competition any more than a patent could.⁹² In rejecting this "exclusionary potential" test, the Supreme Court clearly endorsed the application of antitrust principles to reverse-payment settlements.⁹³ Merely applying patent law principles to the settlements would not address the potential for consumer detriment that implicates antitrust concerns.⁹⁴ The Court recognized the deficiency of the exclusionary potential test when it remarked that "there is reason for concern that settlements taking this form tend to have significant adverse effects on competition."⁹⁵

In holding that antitrust analysis is an appropriate framework for review of reverse-payment settlements, the Court noted that such review should proceed under the rule-of-reason analysis.⁹⁶ The Court suggested that the payments might sometimes be justified as traditional settlement considerations.⁹⁷ Such

practices without extensive evidence of actual anticompetitive effects but sometimes have been reluctant to apply an abbreviated analysis to the specific cases before them.").

87. See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013) ("The FTC urges us to hold that reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a 'quick look' approach, rather than applying a 'rule of reason.' . . . We decline to do so.").

88. *Id.* at 2227.

89. The facts of the case mirror that of typical of reverse-payment agreements. Solvay Pharmaceuticals filed an NDA for Androgel in 1999. *Id.* at 2229. Shortly after obtaining a patent in 2003, Actavis, Inc. (formerly Watson Pharmaceuticals) filed an ANDA challenging the validity of Solvay's patent. *Id.* That ANDA was followed by applications from three more generic producers. *Id.* During the ensuing Hatch-Waxman litigation, Solvay settled with the producers by providing lump-sum and annual payments in exchange for withdrawal of their generic alternatives to Androgel. *Id.*

90. *Id.* at 2237. The FTC had urged the Court to adopt a quick-look approach to the agreements. *Id.*

91. *Id.*

92. *Id.* at 2230 ("Solvay's patent, if valid and infringed, might have permitted it to charge drug prices sufficient to recoup the reverse settlement payments it agreed to make to its potential generic competitors.").

93. *Id.* at 2232 ("For another thing, this Court's precedents make clear that patent-related settlement agreements can sometimes violate the antitrust laws.").

94. See *Id.* at 2231 ("[P]atent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent.") (emphasis added).

95. *Id.*

96. *Id.* at 2237.

97. "The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement." *Id.* at 2236. In addition to avoided litigation costs, the Court

considerations, like avoided litigation costs, arguably would not serve the purpose of buying off generic market entry and thereby not implicate antitrust concerns.⁹⁸ The FTC had urged the court to adopt a more stringent approach to reverse-payment settlements, shifting the burden to the defendants to justify payments.⁹⁹ The Court rejected that theory, reasoning that the settlements might serve valid purposes.¹⁰⁰

VI. REVERSE-PAYMENT SETTLEMENTS IN CALIFORNIA: CARTWRIGHT ACT CHALLENGES

Like many states, California has its own antitrust statute that supplements the federal Sherman Act.¹⁰¹ This section discusses that statute—the Cartwright Act—including the relevance of federal Sherman Act decisions. It also discusses the primary reverse-payment challenge arising under the Cartwright Act.

A. *The Cartwright Act Distinguished*

The U.S. Supreme Court’s decision in *FTC v. Actavis, Inc.*, alongside underlying circuit court opinions, interpreted the legality of reverse-payment settlements under the Sherman Act.¹⁰² In California, the Cartwright Act has been the primary state antitrust statute for a century.¹⁰³ Passed in 1907, the Cartwright Act resembles other state antitrust statutes under consideration at the time.¹⁰⁴ While the exact legislative history and intent of the Act is debated, the breadth of

suggests the payments might “reflect fair value for services” rendered. *Id.*

98. *Id.* at 2237.

99. *Id.*; see HOVENKAMP, *supra* note 56, at 265–266 (“The [quick-look] inquiry is usually best reserved for circumstances where the restraint is sufficiently threatening to place it presumptively in the per se class, but lack of judicial experience requires at least some consideration of proffered defenses or justifications.”).

100. *Actavis*, 133 S. Ct. at 2236–27. The Court did not give much consideration to other potential justifications for the agreements. However, Justice Breyer acknowledged “[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.” *Id.* at 2236.

101. CAL. BUS. & PROF. CODE § 16720 (West 2008).

102. *Actavis*, 133 S. Ct. at 2227.

103. Don T. Hibner, Jr. & Heather M. Cooper, *The Cartwright Act at 100 – A History of Complementary Antitrust Enforcement—A Celebration*, 17 J. OF ANTITRUST AND UNFAIR COMPETITION L. SEC. OF ST. B. OF CAL. 81, 81 (2008).

104. *See id.* at 90–92 (describing a number of similar state antitrust statutes). The exact history of the Cartwright Act is unclear, with other earlier state statutes potentially serving as models for the Act. *Id.* at 93. For example, the state of Ohio enacted the Valentine Act in 1898. 13 OHIO REV. CODE ANN. § 1331 (LexisNexis 2006). The Valentine Act prohibits a trust that exists for any unlawful purpose. *Id.* at § 1331.01(B). Among these restricted purposes is “[t]o create or carry out restrictions in trade or commerce.” *Id.* at § 1331.01(B)(1). This language is identical to the Cartwright Act, which reads “[t]o create or carry out restrictions in trade or commerce.” BUS. & PROF. CODE § 16720(a). Other states with similar laws include Texas and Michigan. *See Hibner & Cooper, supra* note 103, at 93.

its application is indisputable.¹⁰⁵ The Act prohibits any “combination of capital, skill or acts by two or more persons” to further an improper purpose.¹⁰⁶

Federal decisional law interpreting the Sherman Act does not bind the Cartwright Act because the latter is a separate and distinct state statute.¹⁰⁷ Given their similarities, it is not surprising that courts in California treat the jurisprudence behind the Sherman Act as persuasive authority.¹⁰⁸ Yet the two remain invariably distinct, with the California Supreme Court going so far as to broaden antitrust regulation in California beyond the purview of the Sherman Act.¹⁰⁹

B. Reverse-Payment Challenges Under the Cartwright Act

The primary Cartwright Act challenge to reverse-payment settlements developed following an agreement between brand name producer Bayer and generic producer Barr concerning the drug Cipro.¹¹⁰ Within months of Bayer’s patent filing for Cipro, Barr filed an ANDA that challenged the patent as invalid.¹¹¹ Following the procedures required by the Hatch-Waxman Act, Bayer filed suit to resolve the validity of the patent.¹¹² Barr’s case against Bayer appeared likely to succeed due to evidence of bad faith in the patent filing process.¹¹³ Indeed, two other generic producers predicted Barr’s imminent victory and joined the suit, agreeing to share litigation costs.¹¹⁴ Nevertheless, in exchange for annual payments totaling \$398.1 million, the generic producers dropped the challenge to Bayer’s patent and abandoned their efforts to manufacture a generic

105. See *Cianci v. Superior Court*, 40 Cal. 3d 903, 919 (1985) (“[N]o direct sources for the legislative history of the Cartwright Act exist . . .”); *id.* at 920–921 (“First, as shown by the plain meaning of the statutory language, the evident implication of such language, and the manifest purpose of the Act, the Legislature intended to strike as broadly as it could in the Cartwright Act.”).

106. BUS. & PROF. CODE § 16720.

107. See *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165, 175 (Ct. App. 2011) (“Since the Cartwright Act and the federal Sherman Act share similar language and objectives, California courts often look to federal precedents under the Sherman Act for guidance.”).

108. *Id.*

109. See *e.g.* *Union Carbide Corp. v. Superior Court of San Francisco*, 36 Cal. 3d 15, 19–20 (1984) (ruling that indirect purchasers may bring alleged antitrust violations, in contrast to Sherman Act’s restriction of such claims under the *Illinois Brick* doctrine).

110. See *In re Cipro Cases I & II*, No. S198616 (Cal. Feb. 15, 2012) (granting petition for review of Cartwright Act challenge to reverse-payment agreement).

111. Brief of Appellants, *supra* note 8, at 8–9.

112. *Id.* at 9.

113. *Id.* at 11 (“Barr’s evidence of inequitable conduct was persuasive.”). Barr introduced evidence that Bayer’s German patent admitted the company knew the patent constituted prior art when filed in Germany. *Id.* Bayer mounted an insanity claim against the 72 year old agent in an attempt to discredit his claim. *Id.* at 11–12. In challenges before the U.S. Trademark and Patent Office, Bayer made related arguments, discrediting the agents testimony by noting that had retired 10 years before being deposed, and “had a cerebral hemorrhage after he retired which affected his memory and overall health.” *Id.* at 12.

114. *Id.* at 13.

alternative.¹¹⁵ Challenges to the agreement brought under the Cartwright Act focused on the injury to California consumers resulting from unavailable lower-cost generics.¹¹⁶

1. Superior Court Interpretation

The trial court reasoned that no Cartwright Act violation had occurred because the Cipro agreements did not restrict competition beyond the ordinary scope of the patent.¹¹⁷ In doing so, the trial court adopted the same reasoning employed by the Second Circuit to nearly immunize reverse-payment agreements.¹¹⁸ The court's ruling did not extensively analyze the plaintiffs' claims under the rule of reason or the *per se* rule, holding that the plaintiffs' claim failed as a matter of law because of the exclusionary nature of the Cipro patent.¹¹⁹

2. Court of Appeal Interpretation

On appeal, plaintiffs claimed the trial court erred by failing to rule that the Cipro agreements constituted a *per se* violation of the Cartwright Act.¹²⁰ The appellate court was unconvinced and affirmed the decision of the superior court.¹²¹ As in many of the circuit court cases that preceded the *Actavis* decision,¹²² the court perceived a fundamental conflict between patent and antitrust law as applied to reverse-payment agreements.¹²³ The court remarked: “[c]onsidering the important public policies underlying patent law . . . and favoring the settlement of patent litigation . . . and the fact that the Cipro agreements did not restrain competition outside the exclusionary zone of the . . .

115. *Id.* at 17–18. The payments included “an initial payment of \$49.1 million and quarterly cash payments until December 2003.” *Id.* at 18.

116. Brief of Appellants, *supra* note 8, at 2 (The plaintiffs in the Cipro action were a “certified class of ‘hundreds of thousands’ of California consumers and third-party payor insurers . . .”). The right of third-party indirect purchasers to join in an antitrust suit is unique to the Cartwright Act and unavailable for Sherman Act challenges under the *Illinois Brick* doctrine. *See infra*, note 175–179 and accompanying text.

117. Coordination Proceeding Cipro Cases I & II, No. JCCP4154, 2009 WL 2700124 (Cal. Super. Ct. Aug. 21, 2009).

118. *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 216 (2nd Cir. 2006) (declining to undertake antitrust scrutiny of reverse-payment agreements unless the restrictions involved exceed the exclusionary scope of the patent).

119. *See In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165, 184 (Ct. App. 2011) (“[B]ecause a patent is presumed to be valid and gives the patent holder the right to exclude others from marketing the patented invention, a settlement of patent infringement litigation ‘is not unlawful if it serves to protect that to which the patent holder is legally entitled . . .’”).

120. *Id.* at 169.

121. *Id.* at 184. The court endorsed the reasoning of the federal courts as well. *Id.*

122. *E.g.* *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1306 (11th Cir. 2012); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323, 1335 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 203 (2nd Cir. 2006).

123. *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165, 184 (Ct. App. 2011).

patent, we cannot view the Cipro agreements as lacking any redeeming virtue.”¹²⁴ While its opinion lacks a detailed analysis of the Cartwright Act, the court held that reverse-payment agreements that do not exclude competition beyond the scope of the patent violate neither the *per se* rule nor the rule of reason.¹²⁵

3. California Supreme Court Certiorari

The California Supreme Court granted certiorari following the court of appeal’s rejection of the Cartwright Act claim.¹²⁶ However, the plaintiffs reached a settlement agreement with some of the defendants before arguments took place.¹²⁷ The court approved the settlement and requested supplemental briefing to consider the impact of the *Actavis* decision before the continuation of litigation against remaining defendants.¹²⁸

That the California Supreme Court granted certiorari demonstrates the important legal issues raised under the Cartwright Act by reverse-payment settlements. The absence of generic alternatives eliminates the potential for consumer savings, and the cost to Californians in particular represents a substantial portion of any harm rendered.¹²⁹

VII. THE PATENT PROBLEM: POLICY CONCERNS OF IMMUNIZING PATENTS FROM ANTITRUST SCRUTINY

Litigation plays an important role in determining the validity of patents.¹³⁰ Obtaining a patent is a relatively low-threshold achievement, usually involving some hours of review with limited resources by the Patent Office, which then makes a determination of novelty.¹³¹ The Court has itself referred to patents as “a legal conclusion reached by the Patent Office. . . . predicated on factors as to which reasonable men can differ widely.”¹³² In *Lear, Inc. v. Adkins*, the Court recognized these difficulties by requiring parties to defend the Patent Office’s judgment in court.¹³³ Today, the Patent Office reviews exponentially more

124. *Id.*

125. *Id.*

126. See *Cipro*, JOSEPH SAVERI LAW FIRM, <http://saverilawfirm.com/our-cases/cipro-case/> (last visited March 20, 2014) (on file with the *McGeorge Law Review*).

127. *Id.*

128. *Id.*

129. See Letter Brief of Attorney General, *supra* note 2, at 2 (noting that “California citizens paid \$21.7 billion for [prescription] drugs in 2010”). The cost of reverse-payment agreements to Californians is estimated at \$4.2 billion over 10 years. *Id.* at 3.

130. See Brief of Law, Economics, and Business Professors, *supra* note 15, at 15.

131. *Id.* (“Such a judgment comes after limited scrutiny with examiners having, on average, less than 20 hours to read an application, search for prior art, evaluate patentability, and reach and write up conclusions.”).

132. *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969).

133. *Id.*

applications—about 500,000 a year total—than it did fifty years ago when *Lear* was decided.¹³⁴ The Supreme Court’s reasoning, therefore, is of greater importance today than ever before.

Due to the patent evaluation process, invalid patents are certain to exist. In fact, studies have consistently shown that more than 40% of patents granted are actually invalid.¹³⁵ The adversarial role of litigation in determining the validity of a patent is therefore of heightened importance; courts have greater resources at their disposal to make an informed decision about patent validity, including briefs, testimony, and any other relevant materials with which a party might make their case.¹³⁶ Effectively immunizing patents from antitrust scrutiny, as lower courts have done, ignores the realities of the patent approval process and undermines the ability to ensure that only novel materials and processes are protected.

In the pharmaceutical industry, the need for judicial scrutiny of patents is even greater.¹³⁷ An FTC study found that courts held 73% of brand name patents invalid following generic challenges under Hatch-Waxman between 1992 and 2002.¹³⁸ That number confirms that relying merely on the Patent Office’s judgment is not an effective determination of a patent’s validity.¹³⁹ Further, it highlights the questionable nature of some patents in the pharmaceutical industry, as producers have attempted to protect non-active ingredients, “methods of use,” and other less innovative processes.¹⁴⁰ For example, at the heart of the dispute in *Actavis* was a patent for synthetic testosterone.¹⁴¹ The active ingredient in that patented substance was first created in the early twentieth century, and had been available in various drugs for more than fifty years.¹⁴² The patent did not cover

134. Brief of Law, Economics, and Business Professors, *supra* note 15, at 17.

135. Brief of Law, Economics, and Business Professors, *supra* note 15, at 15–16; See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998) (finding in a study of 300 patent validity decisions that patents were found to be invalid in 46% of cases).

136. See *April 2014 Patents Data, at a Glance*, UNITED STATES PATENT AND TRADEMARK OFFICE www.uspto.com/dashboards/patents/main.dashxml (last visited May 20, 2014, 1:39AM) (on file with the *McGeorge Law Review*) (indicating that as of April 2014, the Patent Office had 619,204 unexamined patent applications pending review, with hundreds of thousands of applications continuing to pour in to the Patent Office, and a staff of only around 8,000 patent examiners). Legal scholarship has been critical of the Patent Office’s resources and its limited ability to handle the evolving technological developments that utilize patents. Kevin Mack, *Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands*, 21 BERKELEY TECH. L.J. 147 (2006).

137. See Brief of Law, Economics, and Business Professors, *supra* note 15, at 16 (indicating that the problem of invalid patents is worse in the pharmaceutical industry than elsewhere).

138. FTC REVERSE-PAYMENT STUDY, *supra* note 4, at 3.

139. See *id.* (indicating that the Patent Office is approving invalid pharmaceutical patents at a high rate).

140. See Brief of Law, Economics, and Business Professors, *supra* note 15, at 19. (“Those patents are less innovative (and so less likely to be valid) and easier to avoid. Asserting them accordingly bears more potential for anticompetitive mischief.”).

141. See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013) (describing the subject of the challenge, Androgel®).

142. See Brief of Law, Economics, and Business Professors, *supra* note 15, at 20 (“The active ingredient, synthetic testosterone, was artificially synthesized in 1935 and has been available in drug products since the

the ingredient, however, but instead protected “the use of a particular gel formulation containing ingredients in certain amounts.”¹⁴³

Unfortunately, the regulatory framework of the Hatch-Waxman Act allows these questionable patents to thwart potential competition.¹⁴⁴ The patenting of inactive ingredients and methods of delivery blocks generic manufacturers from producing cheaper alternatives for consumers when the patent on an active ingredient has run out.¹⁴⁵ Instead, it forces generic manufacturers to initiate a Paragraph IV legal challenge to the brand name producer’s patent.¹⁴⁶ Coupled with the “bottlenecking” of future challenges, this exploitation of the patent process stymies competition and derails congressional efforts to encourage greater competition from generic producers.¹⁴⁷

In evaluating reverse-payment agreements, lower courts should consider the policy implications of immunizing such agreements from antitrust scrutiny, especially in light of generic-friendly legislation like the Hatch-Waxman Act. As Justice Breyer opined in *Actavis*, “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.”¹⁴⁸ The *Actavis* decision rejected the circuit courts’ reasoning, which would have allowed the exploitation of potentially invalid patents to continue.¹⁴⁹ Courts in California should employ a similar shift in reasoning.

VIII. THE SUPREME COURT’S IMPACT ON REVERSE-PAYMENT LEGALITY IN CALIFORNIA

The U.S. Supreme Court’s decision in *Actavis* represents a decisive endorsement of the use of antitrust principles to resolve reverse-payment

1950s.”).

143. *Id.*

144. For a review of the Hatch-Waxman Act, designed to incentivize and facilitate the market entry of generic drugs, see *supra* Part II.

145. See Brief of Law, Economics, and Business Professors, *supra* note 15, at 19.

(“Drug companies, however, are increasingly patenting and asserting ancillary, non-active ingredients, like a formulation, dissolution profile, or method of use. . . . Asserting them accordingly bears more potential for anticompetitive mischief. For under the regulatory regime, even a weak patent or one on a minor advance like a method of delivery can prevent market entry by the generic.”).

146. For a description of the types of challenges available to generic manufacturers under the Hatch-Waxman Act, see *supra* Part II.

147. See *supra* text accompanying notes 51–56 (describing the ways that brand name drug manufacturers frustrate the goals of the Hatch-Waxman Act). Many of the incentives for generic entry under the Hatch-Waxman Act are available only to first-filer drug manufacturers. *Id.* Future challengers must wait until the resolution of the initial generic challenge against a brand name producer. *Id.*; see also FTC REVERSE-PAYMENT STUDY, *supra* note 4, at 3.

148. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2231 (2013).

149. *Id.* (“[T]his Court has indicated that patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’—and consequently antitrust law immunity—that is conferred by a patent.”).

agreement litigation under the Sherman Act.¹⁵⁰ The Court's opinion rejects the idea that the settlements are acceptable so long as they do not restrict competition beyond the scope of the patent.¹⁵¹ The reasoning rejected by the Court effectively prevents any antitrust scrutiny because the patent is viewed as a legal instrument allowing restrictions on competition.¹⁵² Indeed, the Court remarked that the Eleventh Circuit's reasoning would have "provide[d] near-automatic antitrust immunity to reverse-payment settlements."¹⁵³

In rejecting the reasoning of the Eleventh Circuit, the Court indirectly rejected the reasoning of the lower courts in California that reviewed the Cipro agreements.¹⁵⁴ The trial court and court of appeal that considered the Cipro cases specifically cited reasoning from the Second, Sixth, Eleventh, and Federal Circuit Courts that rejected antitrust challenges to reverse-payment settlements.¹⁵⁵ The trial court remarked that "[t]he federal court cases dealing generally with Hatch Waxman settlements, and specifically with this agreement, have uniformly held that settlements within the scope of the patent do not violate antitrust laws."¹⁵⁶ The court of appeal affirmed, noting that much of the federal Sherman Act interpretation was reasonable and applicable to similar challenges under the Cartwright Act.¹⁵⁷

This pronounced reliance on the Sherman Act cases by lower courts in California suggests that any change at the federal level might impact the reasoning applied in Cartwright Act challenges as well. The federal Sherman Act decisions were important to the California court holdings given the absence of Cartwright Act precedent on reverse-payment settlements.¹⁵⁸

150. *See id.* at 2237 ("In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects . . .").

151. *Id.* ("In our view, these considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.").

152. *See* FTC v. Watson Pharmaceuticals, Inc., 677 F.3d 1298, 1312 (2012) ("[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.").

153. *Actavis*, 133 S. Ct. at 2237.

154. *See In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165 (Ct. App. 2011); Coordination Proceeding Cipro Cases I & II, No. JCCP4154, 2009 WL 2700124 (Cal. Super. Ct. Aug. 21, 2009).

155. Coordination Proceeding Cipro Cases I & II, No. JCCP4154, 2009 WL 2700124 (Cal. Super. Ct. Aug. 21, 2009).

156. *Id.*

157. *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165, 184 (Ct. App. 2011) ("We find the reasoning of the federal cases discussed above regarding the legality of settlements of Hatch–Waxman patent litigation to be sound and applicable to plaintiffs' cause of action under the Cartwright Act.").

158. Coordination Proceeding Cipro Cases I & II, No. JCCP4154, 2009 WL 2700124 (Cal. Super. Ct. Aug. 21, 2009); *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165, 184 (Cal. Ct. App. 4th, 2011). Indeed, there was very little consideration of the Cartwright Act itself—either its text or legislative history or judicial interpretation. *Id.*

The U.S. Supreme Court discussed many of the California court's concerns regarding applying antitrust scrutiny to reverse-payment settlements.¹⁵⁹ The California courts, relying on the Eleventh Circuit, emphasized the favorability of settling disputes and expressed concern for the chilling effect on settlements in patent-infringement cases should the agreements be subject to antitrust scrutiny.¹⁶⁰ In contrast, the U.S. Supreme Court highlighted the potential for consumer harm should reverse-payment settlements be immunized from scrutiny,¹⁶¹ finding that concerns of a chilling effect should not prohibit an inquiry that was "likely to prove more feasible administratively than the Eleventh Circuit believed."¹⁶²

This Comment proposes that California courts should follow the approach of the U.S. Supreme Court by denouncing the exclusionary scope test adopted by lower courts and embracing antitrust scrutiny of reverse-payment agreements. On order from the California Supreme Court, reevaluation of the Cipro cases under the Cartwright Act must consider the *Actavis* decision.¹⁶³

The case for reevaluation extends beyond the change in relied-upon federal interpretation. Many Californian consumers continue to lack a sufficient remedy under the Sherman Act.¹⁶⁴ Under the *Illinois Brick* doctrine, consumers who do not purchase a product directly from the alleged antitrust violator cannot bring a Sherman Act claim.¹⁶⁵ In the context of reverse-payment agreements, an indirect purchaser might be any consumer who purchased their medication from a hospital or doctor's office—most people do not purchase their prescriptions directly from the producers.¹⁶⁶ Therefore, under the doctrine, many California consumers cannot bring Sherman Act claims against the drug producers who enter into reverse-payment agreements; they must instead rely on government enforcement.¹⁶⁷ The *Illinois Brick* Court reasoned that the administrative

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

160. *See In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165, 185 (Ct. App. 2011) ("[A] rule prohibiting [reverse-payment agreements] could harm competition by reducing the incentive to challenge patents by reducing the challenger's settlement options in a suit for infringement.").

161. *Actavis*, 133 S. Ct. at 2226 (highlighting the "potential for genuine adverse effects on competition" in rejecting the Eleventh Circuit's decision).

162. *Id.* at 2236–37 ("In a word, 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.").

163. *In re Cipro Cases I & II*, No. S198616 (Cal. Feb. 15, 2012) (granting petition for review of Cartwright Act challenge to reverse-payment agreement). "The parties are directed to submit simultaneous supplemental letter briefs discussing the relevance of *FTC v. Actavis, Inc.*" *Id.*

164. *See* Letter Brief of Attorney General, *supra* note 2, at 2 ("[B]ecause of the *Illinois Brick* doctrine, federal antitrust law provides no relief to California consumers injured by antitrust violations if they did not purchase the affected goods directly from the antitrust violators.").

165. *Id.*; *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 728 (1977).

166. *See* Letter Brief of Attorney General, *supra* note 2, at 2 ("[F]ederal antitrust law provides no relief to California consumers injured by antitrust violations if they did not purchase the affected goods directly from the antitrust violators.").

167. *Id.*

difficulties in assessing the impact of antitrust violations throughout the market chain, as well as a defendant's potential exposure to multiple liabilities, justified an outright ban on indirect purchaser claims.¹⁶⁸ Many states, including California, reject the *Illinois Brick* doctrine in interpreting their own antitrust laws.¹⁶⁹ Allowing reverse-payment challenges to proceed under the Cartwright Act is therefore a crucial tool in promoting consumer welfare.¹⁷⁰ Without a Cartwright Act remedy, California consumers will not be able to bring antitrust claims against producers who enter into reverse-payment agreements.¹⁷¹

IX. THE CASE FOR REVERSE-PAYMENT EVALUATION UNDER THE *PER SE* RULE IN CARTWRIGHT ACT CHALLENGES

The case for antitrust scrutiny of reverse-payment settlements under the Cartwright Act is compelling: the plain language of the Act and recent changes in Sherman Act interpretation suggest that the agreements should not be immunized from inquiry.¹⁷² However, courts must still determine the level of review to undertake in such cases.¹⁷³ This Comment proposes that the *per se* rule is the optimum lens with which to analyze reverse-payment agreements. In the alternative, the quick-look approach could also serve as an acceptable standard of review should the California Supreme Court decline to embrace a *per se* ban.

A. *The Agreements Violate the Plain Language of the Act*

The decisive starting point in antitrust analysis mirrors that of all legal analysis—to look first at the text itself.¹⁷⁴ The Cartwright Act is broadly constructed, mandating that “every trust is unlawful, against public policy and void.”¹⁷⁵ The Act enumerates several definitions of trusts, many of which

168. *Illinois Brick*, 431 U.S. at 741. The Court refused “to ignore the burdens that such an attempt would impose on the effective enforcement of the antitrust laws.” *Id.* The potential itself, without such a guarantee, was enough to justify the ban. *Id.* at 740. The Court feared allowing indirect purchasers “would transform treble-damages actions into massive multiparty litigations involving many levels of distribution and including large classes of ultimate consumers remote from the defendant.” *Id.*

169. Letter Brief of Attorney General, *supra* note 2, at 2; see *Union Carbide Corp. v. Superior Court of San Francisco*, 36 Cal. 3d 15, 19–20 (1984) (adopting the *Illinois Brick* dissent’s position to allow indirect purchaser claims under the Cartwright Act).

170. Letter Brief of Attorney General, *supra* note 2 at 2.

171. *Id.*

172. See *supra* Part VIII (describing the effect of the Supreme Court’s *Actavis* decision).

173. See *Coordination Proceeding Cipro Cases I & II*, No. JCCP4154, 2009 WL 2700124 (Cal. Super. Ct. Aug. 21, 2009) (“Thus, the Court turns to federal decisions concerning the Sherman Act as persuasive authority to guide its decision.”).

174. See *Cianci v. Superior Court*, 40 Cal. 3d 903, 917 (1985) (analyzing the plain language of the Cartwright Act prior to any further discussion). The court began its analysis with the text of the Cartwright Act, noting that “the statute is comprehensive in its attack on threats to competition, and thereby implies that its coverage extends to all economic combinations, regardless of the nature . . .” *Id.* at 917.

175. CAL. BUS. & PROF. CODE § 16726 (West 2008); see *Cianci*, 40 Cal.3d at 918 (“The Act is broad in

implicate reverse-payment agreements.¹⁷⁶ The California lower courts, in holding that the agreements are valid if they are within the exclusionary scope of the patent, did not undertake a textual analysis of the Act.¹⁷⁷

Among the enumerated listing of restricted trusts, the Cartwright Act prohibits those that “limit or reduce the production, or increase the price of merchandise or any commodity.”¹⁷⁸ Similarly, restricted trusts include those that “prevent competition in manufacturing, making, transportation, sale or purchase of merchandise, produce or of any commodity.”¹⁷⁹ Reverse-payment agreements will always fit within these definitions of restricted trusts.¹⁸⁰ The agreements involve payments from one manufacturer to another to limit production of a cheaper alternative.¹⁸¹ Therefore, these agreements will always limit production by restricting the generic drug from entering the market, thereby increasing costs to the consumer.¹⁸² Competition is always impacted negatively, because these cheaper drugs no longer compete with brand name alternatives.¹⁸³ These textual considerations were not considered by the Supreme Court because the Sherman Act does not offer the same language.¹⁸⁴

B. *The Extraordinarily Anticompetitive Nature of the Agreements Requires Application of the ‘Per Se’ Rule*

Beyond violating the plain language of the Cartwright Act, reverse-payment agreements are anticompetitive enough to warrant little evaluation by courts

scope: “[it] is “couched in . . . comprehensive language” and “forbids combinations of the kind described with respect to every type of business.””).

176. See BUS. & PROF. § 16720(a) (“To create or carry out restrictions in trade or commerce.”); *id.* § 16720(b) (“To limit or reduce the production, or increase the price of merchandise or of any commodity.”); *id.* § 16720(c) (“To prevent competition in manufacturing, making, transportation, sale or purchase of merchandise, produce or any commodity.”).

177. *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165, 184 (Ct. App. 2011); see Letter Brief of Attorney General, *supra* note 2, at 4 (“The court below erred by failing to engage in any part of this prescribed analysis of our state antitrust law when reviewing reverse-payment agreements.”).

178. BUS. & PROF. § 16720(b).

179. BUS. & PROF. § 16720(c).

180. See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013) (Justice Breyer delivered the Court’s opinion with the following opening statement, describing the typical reverse-payment scenario: “Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent’s term expires, and (2) Company A, the patentee, to pay B many millions of dollars.”).

181. See Brief of Appellants, *supra* note 8, at 25 (“It is hard to imagine a more blatantly illegal and pernicious arrangement than a monopolist’s payment to a competitor to stay out of its market.”).

182. See *FTC REVERSE-PAYMENT STUDY*, *supra* note 4, at 3. In describing the payments, the FTC notes that “[c]onsumers lose, however: they miss out on generic prices that can be as much as 90 percent less than brand prices.” *Id.* at 1.

183. *Id.*; See Leibowitz, *supra* note 13, at 3 (“Now, as most of you already know, when multiple generics are on the market, the price for the generic version can drop more than 90 percent below the price of the branded product, which means enormous savings for Americans.”).

184. 15 U.S.C. § 1 (2012).

under the rule of reason. As the plaintiffs in the Cipro action have remarked, “[i]t is hard to imagine a more blatantly illegal or pernicious arrangement than a monopolist’s payment to a competitor to stay out of its market.”¹⁸⁵ The impact of reverse-payment agreements on the market for a drug is immediate.¹⁸⁶ The opportunity for pro-competitive justifications and the time consumed in undertaking a rule-of-reason analysis, as well as the high cost of litigation and discovery to prove anti-competitiveness, thereby might prove detrimental to consumer welfare in contradiction to antitrust goals, making the *per se* rule more appropriate.¹⁸⁷

Reverse-payment agreements are not so different from other practices that courts consider *per se* violations of the Cartwright Act.¹⁸⁸ In fact, the Act already prohibits traditional covenants not to compete.¹⁸⁹ The presence of a patent should not dissuade courts from noting the basic invalidity of agreements like the one between Bayer and Barr in which a competitor may choose to withdraw their product in exchange for large payments.¹⁹⁰ These reverse-payment agreements are not readily distinguishable from covenants not to compete or market-division agreements.¹⁹¹ Courts considering application of the *per se* rule should rely on prior interpretation of these agreements.

C. Use of the Rule of Reason Contravenes Antitrust Goals

In addition to the Cartwright Act’s plain language, its foundational goals of consumer welfare and protection also compel application of the *per se* rule.¹⁹² The court of appeal emphasized that “public policy favoring the settlement of disputes was an important factor in its analysis.”¹⁹³ But, as the California Supreme Court has reiterated, “[c]onsumer welfare is a principal, if not the sole,

185. See Brief of Appellants, *supra* note 8, at 25.

186. See *FTC Statement*, *supra* note 53, at 5 (“Typically, the first generic sells at a 20 percent discount off the branded price, and a discount of as much as 85 percent is common in a mature generic market with multiple generic entrants.”).

187. See *HOVENKAMP*, *supra* note 56, at 255 (3d ed. 2005); *Leibowitz*, *supra* note 13, at 4 (noting the FTC’s prioritization of litigating reverse-payment agreements).

188. Brief of Appellants, *supra* note 8, at 25 (drawing analogies between reverse-payment agreements and more traditional market division or consumer allocation agreements, which effectively prevent producers from competing directly in the same geographic area). “It has long been considered a *per se* violation of California and federal antitrust law for one company to pay a competitor to stay out of a market.” Letter Brief of Attorney General, *supra* note 2, at 3.

189. CAL. BUS. & PROF. CODE § 16720(c) (West 2008).

190. See Brief of Appellants, *supra* note 8, at 26 (“Under settled California law, the reverse payment from Bayer to Barr violates the Cartwright Act *per se* because it secured an agreement not to compete and allocated the market to Bayer in exchange for monopoly profits.”).

191. See Brief of Law, Economics, and Business Professors, *supra* note 15, at 13 (“Settlements by which brands pay generics not to enter the market pose dangers analogous to territorial market allocation.”).

192. *Cianci v. Superior Court*, 40 Cal. 3d 903, 918–919 (1985).

193. *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165, 177 (Ct. App. 2011).

goal of antitrust laws.”¹⁹⁴ One should question whether a policy that favors settlement of disputes lends itself to improve consumer welfare. Interpretation of the law and its application in various contexts should focus primarily on promoting consumer welfare and fair competition practices, as opposed to concerns for a producer’s patent.¹⁹⁵ A court focusing on promoting consumer welfare should dismiss these agreements as invalid with little consideration.¹⁹⁶ A single reverse-payment agreement immediately results in higher drug costs and lower competition.¹⁹⁷ Previous courts have addressed conflicting concerns in addition to consumer welfare, such as the relevance of valid patents.¹⁹⁸ Yet under antitrust analysis, consumer welfare and potential for detriment should be the focus of the litigation.¹⁹⁹ A removal of secondary considerations, like the presence of patents, should suggest to courts that application of the *per se* rule is the most practical standard of review in light of antitrust concerns.

X. AN ALTERNATIVE APPROACH: QUICK-LOOK ANALYSIS IN LIEU OF TRADITIONAL APPLICATION OF THE RULE-OF-REASON

As FTC Chairwoman Edith Ramirez has remarked, even “[a] single anticompetitive agreement can easily increase prescription drug costs by many millions of dollars.”²⁰⁰ The application of the *per se* rule to reverse-payment agreements represents the most appropriate framework for judicial inquiry.²⁰¹ Indeed, with over 70% of brand name patents held invalid following generic challenges, a sweeping judicial condemnation of reverse-payment agreements seems appropriate.²⁰²

Nevertheless, the California Supreme Court may hesitate to apply the *per se* rule in this context. Sherman Act jurisprudence is not controlling, but it remains

194. *Cianci*, 40 Cal. 3d at 918.

195. *See* *FTC v. Actavis*, 133 S. Ct. 2223, 2227 (2013) (“In our view, however, reverse payment settlements such as the agreement alleged in the complaint before us can sometimes violate the antitrust laws. We consequently hold that the Eleventh Circuit should have allowed the FTC’s lawsuit to proceed.”).

196. *See* FTC REVERSE-PAYMENT STUDY, *supra* note 4, at 8 (indicating that generic drugs often cost 85% less than brand name alternatives, resulting in significant benefit to the consumer); *Cianci*, 40 Cal.3d at 918 (observing that consumer welfare is the focus of antitrust laws).

197. *FTC Statement*, *supra* note 53, at 12.

198. *FTC v. Watson Pharmaceuticals*, 677 F.3d 1298, 1306 (11th Cir. 2012) (discussing the competing interests of precedent, “pro-exclusivity” patent law, and “pro-competitive” antitrust law); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) (considering whether the validity of a patent is relevant to an antitrust claim); *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 203 (2nd Cir. 2006) (admitting that the policy of furthering settlement of litigation may not align with policies benefitting the consumer).

199. *Cianci v. Superior Court*, 40 Cal. 3d 903, 918.

200. *See* *FTC Statement*, *supra* note 53, at 12.

201. *See* *supra* Part IX.

202. *See* FTC REVERSE-PAYMENT STUDY, *supra* note 4, at 3 (“In 2002, the FTC issued a study showing that generics prevailed in 73% of the patent litigation ultimately resolved by a court decision between 1992 and June 2002.”).

persuasive.²⁰³ The lack of Sherman Act decisions applying the *per se* rule might compel the court to be more cautious in imposing a near-sweeping ban on the agreements. Both the trial court and the court of appeal relied heavily on federal interpretation in determining the legality of agreements under the Cartwright Act.²⁰⁴ Even though Sherman Act decisional law is merely persuasive, it carries significant weight within California.

The *Actavis* decision, however, came down as plaintiffs in the Cipro action appealed to the California Supreme Court.²⁰⁵ It renders obsolete the lower court's reliance on federal interpretation.²⁰⁶ If the California Supreme Court declines to adopt the *per se* approach, then it should adopt a quick-look analysis instead. Such an application, urged by the FTC in the *Actavis* case, would be appropriate in the context of reverse-payment agreements under the Cartwright Act.²⁰⁷ As the U.S. Supreme Court remarked, quick-look analysis is appropriate where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets."²⁰⁸ Indeed, the anticompetitive impact from a bar to generic market entry is immediate and obvious.²⁰⁹ This impact conforms to the Court's view of appropriate quick-look application.²¹⁰

If applying the quick-look analysis, the California Supreme Court would place the burden of proof on the brand name defendants, requiring them to affirmatively demonstrate the pro-competitive nature of their agreements.²¹¹ This scenario is preferable to the rule of reason, which leaves to consumer plaintiffs the responsibility of mounting more complex challenges to the agreements.²¹² From a practical perspective, the defendants in any reverse-payment action will more likely possess the relevant information for a proper antitrust analysis. From a policy standpoint, courts should not place the burden of proof on injured

203. See Coordination Proceeding Cipro Cases I & II, No. JCCP4154, 2009 WL 2700124 (Cal. Super. Ct. Aug. 21, 2009) ("Thus, the Court turns to federal decisions concerning the Sherman Act as persuasive authority to guide its decision").

204. See *supra* Part VI.B.1-2.

205. See *In re* Cipro Cases I & II, No. S198616 (Cal. Feb. 15, 2012) (granting petition for review of Cartwright Act challenge to reverse-payment agreement).

206. *In re* Cipro Cases I & II, 134 Cal. Rptr. 3d 165 (Ct. App. 2011); Coordination Proceeding Cipro Cases I & II, No. JCCP4154, 2009 WL 2700124 (Cal. Super. Ct. Aug. 21, 2009).

207. *FTC v. Actavis*, 133 S. Ct. 2223, 2237 (2013).

208. *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999).

209. Brief of Appellants, *supra* note 8, at 1 ("It would be hard to design a more anticompetitive, more unlawful, or more harmful restraint of trade than paying a potential competitor to stay out of the market.").

210. *Cal. Dental Ass'n*, 526 U.S. at 770.

211. Oliver, *supra* note 26, at 40 ("The burden of production . . . shifts to the defendant to rebut the plaintiff's showing. It may do so by demonstrating that the restraint has a plausible procompetitive justification. If the defendant does so, a full rule of reason analysis must be undertaken.").

212. See HOVENKAMP, *supra* note 56, at 257 (saying that the *per se* rule requires less inquiry into questionable practices before determining legality).

consumers. Nevertheless, this application remains a secondary preference; the *per se* rule is superior from both a policy and an administrative standpoint.

XI. CONCLUSION

Even in light of Bayer and Barr's settlement with California plaintiffs, the question of the legality of reverse-payment agreements under the Cartwright Act will eventually be addressed by either the legislature or the California Supreme Court. Prior California interpretation has followed that of early federal cases in effectively immunizing reverse-payment agreements from scrutiny due to patent concerns.²¹³ As a result, producers of brand name and generic drugs may continue to collude to keep cost-effective medications off the market. While brand name producers maintain their patent monopolies, and generic manufacturers receive a hefty share of the profits, consumers are left to pay the price.²¹⁴ However, the renewal of antitrust interest in reverse-payment agreements by the U.S. Supreme Court's *Actavis* decision should signal a similar renewal in California.²¹⁵ The Cartwright Act's language and intent compels application of the *per se* rule to these highly consumer-unfavorable agreements.²¹⁶

213. Coordination Proceeding Cipro Cases I & II, No. JCCP4154, 2009 WL 2700124 (Cal. Super. Ct. Aug. 21, 2009); *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165, 184 (Ct. App. 2011).

214. Letter Brief of Attorney General, *supra* note 2, at 3 (indicating that in California, that price was at least \$4.2 billion over 10 years). As use of prescription drugs continually rises, one can infer the cost of reverse payments will rise. *See id.* at 2 (indicating that prescription drug costs continue to increase every year).

215. *FTC v. Actavis*, 133 S. Ct. 2233 (2013).

216. *See supra* Part IX.

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