In the

Supreme Court

of the

State of California

S198616

IN RE CIPRO CASES I & II

CALIFORNIA COURT OF APPEAL · FOURTH APPELLATE DISTRICT · NO. D056361
SUPERIOR COURT OF SAN DIEGO · HON. RICHARD E.L. STRAUSS
NOS. JCCP 4154 AND JCCP 4220
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ISSUES PRESENTED

1. Does the Cartwright Act forbid *per se* a pharmaceutical patent holder from dividing hundreds of millions of dollars of monopoly profits with competitors in exchange for their agreement not to challenge the monopoly? Or should courts ignore the economics of pay-for-delay settlements and virtually immunize them from review, as provided for in *In re Tamoxifen Citrate Antitrust Litigation* (2d Cir. 2006) 466 F.3d 187?

2. Regardless of the proper standard, may the People of California regulate pay-for-delay settlements via the Cartwright Act and enforce that law in their own courts? Or does *Tamoxifen* preempt the Cartwright Act and prevent California courts from enforcing it?

INTRODUCTION

This appeal presents the important question of whether or not the Cartwright Act, the UCL and California common law will protect California consumers and third-party payors from so-called "pay-for-delay" or "reverse payment" settlements of pharmaceutical patent litigation. Pay-for-delay settlements occur in the context of litigation between two pharmaceutical companies, one of which sells a patented brand-name drug, and another that originally sought to have the patent declared invalid or unenforceable so that it can sell a generic version of that drug.

The economic rationale for pay-for-delay settlements arises from the effect of generic competition on brand-name prescription drugs. Generic competition not only causes the brand-name drug to lose market share; most significantly, it drives the prices of both the brand-name and generic versions of the drug to levels far below those enjoyed under the patent. Patients receive the same amount of the drug but pay far less for it. This is the simple and natural effect of competitive entry into a market previously controlled by a monopoly.

It is this necessary and salutary effect of competition that pay-for-delay settlements eliminate. Ordinarily, patent litigation settles (if it settles) either with a payment of money from the infringer to the patent holder, or the granting of a license by the patent holder to the infringer, or some combination of the two. In a pay-for-delay settlement, however, a brand-name drug maker pays its generic competitor part of its monopoly profits from the drug to abandon the case and stay out of the market entirely, thereby preserving the monopoly. This is good for the brand-name maker, which keeps its monopoly; it is good for the generic "competitor," which shares in the monopoly and makes more money than it would have selling a generic version of the drug; and it is terrible for the patients and insurers who are denied the benefits of competition and faced with high monopoly prices for the drug. Over the last decade, having been green-lighted by certain federal courts, these settlements have exploded in popularity. The costs to consumers have exploded as well. Pay-for-delay settlements require patients and insurers nationwide to pay an estimated $3.5 billion *every year* in inflated prescription drug costs.[1] They have been almost universally condemned by prosecutors, legislators, and leading policy makers and academics in the fields of economics and law.

The pay-for-delay settlement at issue here, ending litigation over Bayer's patent on ciprofloxacin hydrochloride ("Cipro"), is the worst of a bad lot. The term "pay-for-delay" reflects precisely what Bayer purchased with its $398.1 million settlement payment to Barr, the generic entrant. Bayer bought a protracted period in which it could sell its drugs free from competition, a period longer than it expected to achieve. In other words, Bayer's payment reflects the purchase of a right to exclude competitors

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[1] http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf, at p. 2.

beyond the period that Bayer's legal rights were expected to allow. And the fact that Bayer paid almost $400 million means that it perceived itself as buying a long period of delayed competition—it can be explained no other way. Indeed, Bayer's $398.1 million payment was about three times what Barr expected to earn from Cipro sales in a competitive market. The total profits Barr gained from the agreement were 3.3 to 4 times larger than the profits Barr could reasonably have expected to gain through competition. (6AA 1203–04.) Simply put, Bayer made Barr an offer it couldn't refuse. And, by sharing its monopoly rents, Bayer invited Barr to become a stakeholder in its Cipro monopoly.

As explained in **Part One** of the argument, pay-for-delay settlements openly restrain competition; indeed, they are outright agreements not to compete. This entire category of agreements has predictable and pernicious effects on consumers of prescription drugs. Pay-for-delay settlements have no redeeming pro-competitive virtues: they do not promote innovation and prohibiting them does not discourage settlements of patent cases, which in fact settled on pro-competitive terms before certain federal courts ruled in favor of the pharmaceutical manufacturers. Because this category of horizontal agreement nakedly restrains trade and has no redeeming value, the Cipro agreements should be held *per se* illegal, in keeping with longtime California precedent.

There can be no dispute that, if not for the patent, Respondents' anticompetitive agreements violate California law on their face. The Court of Appeal, however, wrongly refused to apply California's traditional analysis in favor of a deficient interpretation of the federal Sherman Act by the United States Court of Appeals for the Second Circuit. The Second Circuit articulated this approach in *In re Tamoxifen Citrate Antitrust Litigation* (2d Cir. 2006) 466 F.3d 187 (*Tamoxifen*). The flawed *Tamoxifen*

approach virtually immunizes pay-for-delay settlements from scrutiny under the Sherman Act because it requires patients and insurers to demonstrate either that the patent holder obtained its patent by fraud or that the suit enforcing its patent rights was baseless. The standard also ignores, as a matter of law, the most salient fact demonstrating the sham nature of the patent holder's suit: the size of the reverse payment in relation to the profits expected to be earned by the generic entrant. Both the Second Circuit and the Federal Circuit have applied the *Tamoxifen* standard to dismiss federal class action lawsuits challenging the Cipro settlement.

The *Tamoxifen* standard has rightly come under an avalanche of criticism from law enforcement agencies such as the California Attorney General's Office, the United States Department of Justice and the Federal Trade Commission, as well as a broad range of public policy, consumer protection and other non-profit organizations, including the American Medical Association; AARP; the American Antitrust Institute; Consumers Union; the National Association of Chain Drug Stores; Prescription Access Litigation; Consumer Federation of America; the Public Patent Foundation; the National Legislative Association for Prescription Drug Prices; and U.S. PIRG. Practitioners and academics have assailed the standard adopted below.[2]

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[2] (See, e.g., 1 HERBERT HOVENKAMP, ET AL., IP AND ANTITRUST (2d ed. 2010) § 15.3a1(C); David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L. J. 1303 (2010); Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should be Per Se Illegal*, 41 RUT. L. J. 255 (2009); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37 (2009); ROBIN COOPER FELDMAN, THE ROLE OF SCIENCE IN LAW, at p. 167 (Oxford 2009); Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents?* 98 AM. ECON. REV. 1347 (2008); C. Scott Hemphill, *Paying for*

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The Court of Appeal erred in several respects by adopting this standard as the law of California. First, in rejecting the *per se* rule, the Court of Appeal outright ignored prior decisions of this Court and the United States Supreme Court holding that patent settlements deserve no special privilege against the antitrust laws. It likewise ignored the economics, giving no weight to the undisputed harm that Respondents' wealth transfer and agreement not to compete inflicted on patients and consumers in California. The reasoning and result below undermine the core purposes of the Cartwright Act: *requiring* competition and protecting California consumers from monopolists. (See Bus. & Prof. Code, § 16700, *et seq.*; *Marin County Bd. of Realtors, Inc. v. Palsson* (1976) 16 Cal.3d 920, 935 ["Antitrust laws are designed primarily to aid the consumer."].) Moreover, the Court of Appeal's decision vitiates California law and policy concerning health care—which occupies "a special moral status and therefore a particular public interest" in our State. (*Potvin v. Metropolitan Life Ins. Co.* (2000) 22 Cal.4th 1060, 1070, citation omitted; see also Health & Safety Code, § 130500, stats. 2006, ch. 619, § 1 (A.B. 2911) [Legislature declared "[a]ffordability is critical in providing access to prescription drugs for California residents, particularly the uninsured and those with inadequate insurance."]; Annotations to Cal. Gov. Code, § 6254 [Governor urged "meaningful ways for reducing drug costs, including increased use of generic drugs"].)

Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. REV. 1553 (2006); Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698 (2004); Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 MINN. L. REV. 1767 (2003); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003).)

Second, the Court of Appeal wrongly prioritized the rebuttable presumption of patent validity over the widespread harmful effects of this anticompetitive agreement. The rebuttable presumption of validity is a procedural shortcut, not a substantive right. It is high irony indeed to rely on this presumption with respect to a patent that Bayer had to pay nearly four hundred million dollars to protect from scrutiny and probable findings of invalidity and unenforceability. This payment in fact demonstrates "the inherent uncertainty of the incumbent's statutorily presumptive patent validity," as Petitioners' expert economist, Dr. Ray Hartman, testified. (6AA 1190.) Yet, without so much as inquiring into the actual strength of the patent, the lower court converted the rebuttable *presumption* of validity into a conclusive *finding* of validity. In acceding to a mere presumption, the court discounted the important role of litigation in testing vulnerable patents and stripping invalid and unenforceable ones from the economy. In this case, at the time of settlement, Barr was set to obtain a judgment at trial that the Cipro patent was invalid and unenforceable—as Bayer well knew.

Third, the Court of Appeal seems to have concluded that such anticompetitive reverse payments are necessary for patent cases to settle. This is demonstrably incorrect. Even without such payments, there are readily available straightforward mechanisms for brand-name drug manufacturers and generic drug manufacturers to resolve disputes over patent rights. For example, they can simply agree to a delay in generic entry that reflects the relative strength of the patent claim. If, for instance, the brand manufacturer claims that a patent gives rise to four years of exclusivity and the generic that it provides no legitimate exclusivity at all, they could settle the dispute by, say, agreeing that generic entry will occur after two years. During the period when reverse payments were considered to be illegal, drug companies stopped agreeing to them. Meanwhile, they

continued to settle patent disputes at approximately the same rate as when reverse payments appeared to be legal. Innovation also continued unabated.

The decision below not only adopted the wrong substantive standard; in a bizarre and illogical turn the Court of Appeal also held that it could not even *apply* the wrong standard to these facts because to do so would cause the Cartwright Act, the UCL and California common law to be preempted. Here, the Court of Appeal plainly confused federal preemption under the Supremacy Clause with exclusive federal jurisdiction over claims arising under the Patent Act. (See Opinion at p. 44.) As explained in **Part Two**, the Court should correct this botched finding of preemption and, in the event the *Tamoxifen* standard governs, consider whether a triable question of fact has been demonstrated under that standard.

As discussed in **Part Three**, such triable issues exist. Instead of considering the evidence submitted by Petitioners that Bayer's defense of Cipro was, in fact, a sham, both lower courts ruled that Bayer's success in later cases foreclosed consideration of this question as a matter of law. To the contrary, the federal authority relied on by both lower courts holds that the legality of the agreement must be evaluated as of the time it was struck, not based on *post-hoc* justifications. Moreover, Bayer's subsequent defenses of Cipro involved yet another (smaller) reverse-payment settlement and did not include many of the attacks against Cipro mounted in the original Barr litigation. These later suits were hasty and incomplete owing to the fact that by the time any of these challengers could get to trial, the patent had nearly expired. The lower courts compounded these errors with a blanket overruling of Petitioners' evidentiary objections.

The decision below should be reversed and remanded with an instruction that the case should be set for trial under the traditional *per se* analysis applicable to business agreements not to compete.

FACTUAL BACKGROUND

Petitioners, a certified class of California consumers and third-party payors, submitted the below facts in opposition to Respondents' motions for summary judgment. Respondents did not dispute the evidence Petitioners submitted, save to contend that the law makes it immaterial.[3]

1. The Patent Litigation Over Cipro.

Cipro is the brand-name form of the blockbuster anti-infection drug ciprofloxacin hydrochloride. On June 2, 1987, the United States Patent and Trademark Office (PTO) granted Bayer a United States Patent for Cipro. (10AA 2340–51.)

On October 22, 1991, Barr filed an application with the United States Food and Drug Administration to market and sell a generic, bioequivalent version of Cipro. (8AA 1683–1793.) On December 6, 1991, Barr's attorneys notified Bayer of its application and its accompanying certification that Bayer's Cipro patent—also known as the '444 patent—was invalid and unenforceable. (2AA 334–44.) On January 16, 1992, pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355, Bayer filed a patent infringement action against Barr in the United States District Court for the Southern District of New York.[4] (2AA 346–50.)

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[3] (11AA 2511 ("The only point of significance for the pending motion is that none of the additional facts alleged by plaintiffs are material to the legal issues before the Court.").) Respondents are Bayer AG and Bayer Corporation (collectively "Bayer") and the "Generic Defendants," or "Generics": Barr Laboratories, Inc. ("Barr"), Hoechst Marion Roussel, Inc. ("HMR"), The Rugby Group, Inc. ("Rugby"), and Watson Pharmaceuticals, Inc. ("Watson").

[4] The Hatch-Waxman Act established an expedited process for the approval of generic prescription drugs designed to "get generic drugs into the hands of patients at reasonable prices—fast." (*In re Barr Labs., Inc.* (D.C. Cir. 1991) 930 F.2d 72, 76; accord, *Mylan Pharms., Inc. v. Shalala* (D.D.C.

Footnote continues on next page.

Barr counterclaimed for a judgment that Bayer's patent be declared both "invalid" and "unenforceable." (2AA 352–58, 360–70.) The counterclaim for unenforceability rested on Bayer's alleged inequitable conduct in failing to inform the PTO of two prior art German patent applications: '070 and '850.[5] (8AA 1804–08, 1852–54; see *General Elec. Co. v. Jewel Incandescent Lamp Co.* (1945) 326 U.S. 242, 248 [patent is invalid if "prior art discloses the method of making an article having the characteristics of the patented product, though all the advantageous properties of the product had not been fully appreciated."]; *Digital Control Inc. v. Charles Mach. Works* (Fed.Cir. 2006) 437 F.3d 1309, 1313 [patent may be "rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information"].)

The German patent applications had identified the same co-inventors of the '444 patent and described compounds that were indistinguishable from those Bayer claimed in the '444 patent. (*Ibid.*) Barr therefore alleged that the German applications contained prior art rendering the '444 claims unpatentable, and that Bayer's deliberate decision not to disclose the applications rendered the '444 patent unenforceable, and incapable of being infringed. (2AA 354–56, 364–68.)

2000) 81 F.Supp.2d 30, 32 [central purpose of Hatch-Waxman is "to 'make available more low cost generic drugs[.]' [Citation.]"].)

[5] Barr's invalidity counterclaims rested on the prior art as well as allegations that the '444 patent did not satisfy 35 U.S.C. § 112, by virtue of its failure to describe the scientific process for making ciprofloxacin or one of its antecedent compounds—the patent instead described a separate process (the Roger-Bellon Method) that did not actually produce ciprofloxacin. (3AA 364–68, 8AA 1808–13, 1854–55.)

2. Respondents' Incentives to Settle.

A finding of inequitable conduct by the trial court supervising the patent case would have been disastrous to Bayer. In the summer of 1996, the court denied Bayer's partial motion for summary judgment. (3AA 557–61.) Bayer quickly sought litigation peace. It convened a "working group" of executives to consider the likelihood that Bayer would lose its Cipro monopoly and how such a setback would affect the company. (3AA 569–70, 4AA 670–71.) Bayer estimated that generic drug makers would capture approximately 90 percent of the ciprofloxacin market within one year of entry.[6] Christopher Seaton, Bayer's then-vice president of planning and business administration, highlighted Bayer's incentive to buy off generic competitors:

> The first point to make is that nothing will be able to offset the loss of margin that would occur if Cipro were to go generic quickly. . . . [T]here is no credible cost reduction strategy that would overcome such a massive hemorrhage.

(6AA 1280, 1283.) Seaton sent this memorandum to David Ebsworth, then-president of the pharmaceutical division at Bayer's U.S. subsidiary. (6AA 1289.) Ebsworth agreed with Seaton's analysis. He testified that the introduction of generic ciprofloxacin in 1997 would have placed the

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[6] Jennifer Stahl, Bayer's director of the Cipro brand, wrote in an internal e-mail that generic market penetration would be "fast and furious." (6AA 1266.) Leslie Noble, Bayer's director of strategic contracting, operations, and trade relations, testified that Bayer anticipated the erosion of Cipro sales after Barr's entry would be "very quick and very steep." (6AA 1261.) More specifically, Carol D'Eugenio, Bayer's deputy director of marketing research, admitted that "within 12 months post generic entrance . . . the generic form has eroded 90 percent of the total compound; they captured 90 percent share." (6AA 1255.) This accords with the testimony of a Bayer consultant that other brand-name antibiotics lost over 90 percent in sales within six months of generic market entry. (6AA 1271–72, 1274–77.)

viability of Bayer's U.S. pharmaceutical business in jeopardy; Cipro was Bayer's most profitable product by far.[7] (6AA 1292–95.)

Bayer's Board of Directors was made painfully aware that losing the *Bayer v. Barr* trial would result in the "destruction" of its Cipro patent and monopoly profits. (4AA 691.) The company estimated it would lose $3.336 billion in sales: "Whilst a settlement may have a significant negative impact for our image, a loss would be much worse." (7AA 1440; 7AA 1434.)

At the first settlement meeting in August 1996, HMR's general counsel informed Bayer's representative that Barr would prevail in invalidating the Cipro patent.[8] (3AA 579–600.) HMR proposed that Bayer license Cipro to Barr and HMR/Rugby to settle the litigation. (3AA 599.) During subsequent meetings in the autumn of 1996, Barr reiterated this proposal to settle based on an early entry license. (3AA 607–08, 625.) Bayer refused, instead offering Barr a cash payment of approximately $50 million. (3AA 602–04, 612–13.) Negotiations continued through December 1996, by which point Bayer had convinced Barr and HMR to accept large cash payments as the main consideration. (3AA 614–15.) With the trial date fast approaching, Bayer paid Barr $3 million solely for an agreement to delay the trial. (3AA 637, 641–42.)

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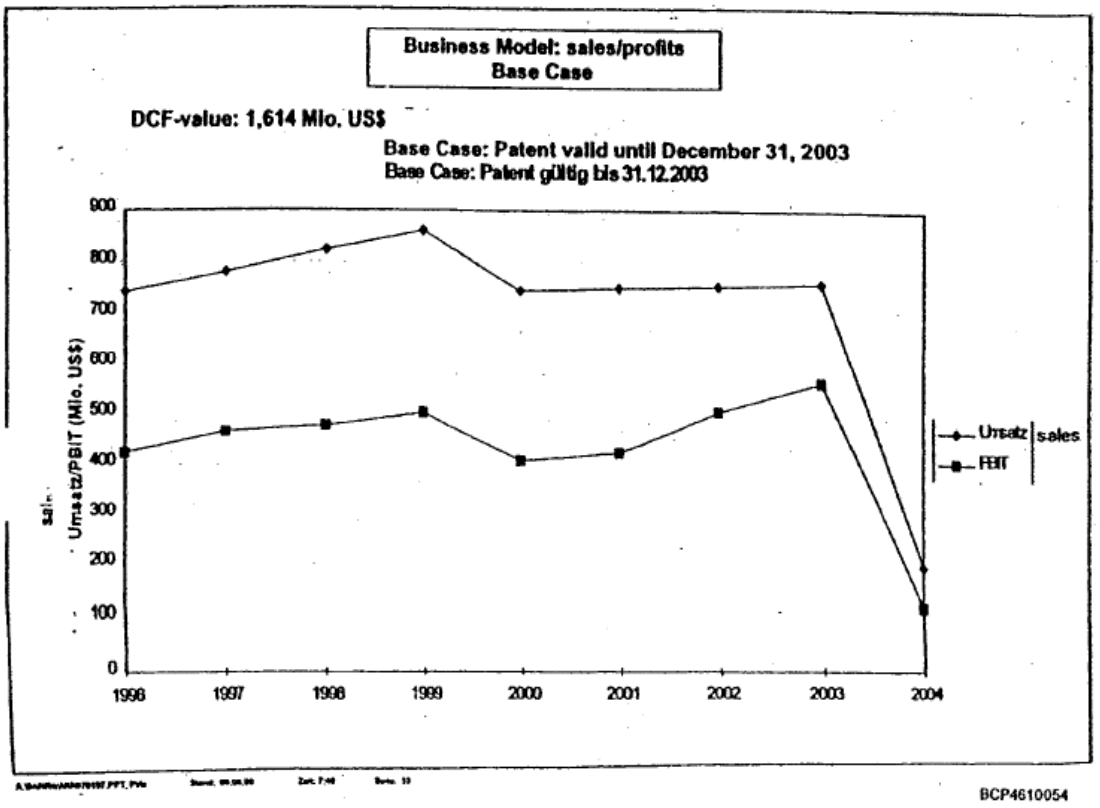
[7] Of all Bayer's products, Cipro brought in the most revenue worldwide. (6AA 1305–07.) HMR's settlement strategy proceeded from that reality: "Focus on the size of the pie is key -- focus on the share of a smaller pie is a mistake." (3AA 596.)

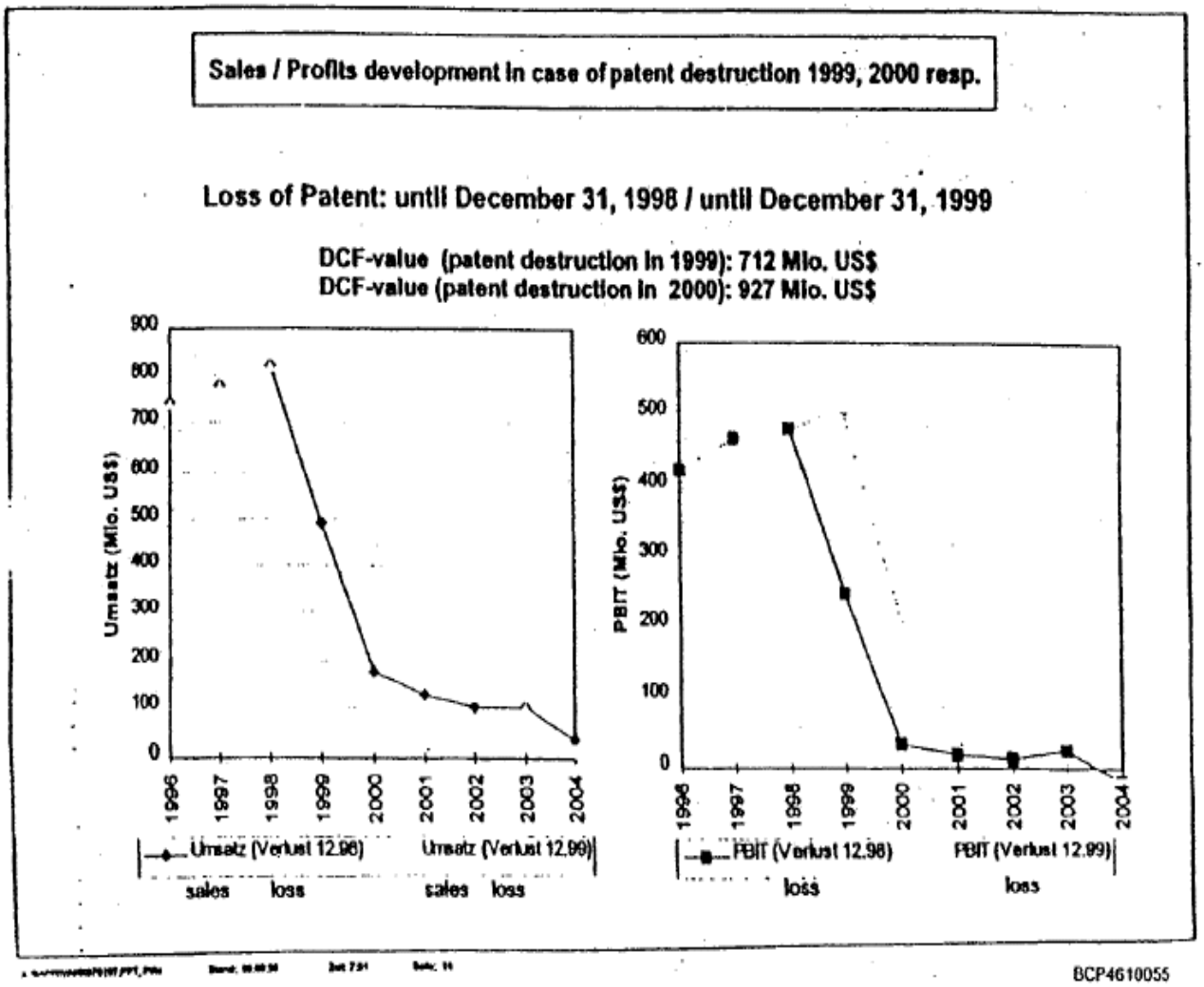
[8] Barr, Rugby, and Rugby's subsidiary HMR had previously entered into an agreement to jointly manufacture, sell, and distribute generic ciprofloxacin. (3AA 385–496.) HMR and Rugby had agreed to help fund Barr's litigation against Bayer. In exchange, Barr had agreed to provide Rugby and HMR with half of its generic ciprofloxacin profits, or half of any settlement payment from Bayer.

Two charts shown to the Board on January 7, 1997, the day before the settlement, portray its economic rationale in black and white. The first chart showed Bayer's projected revenues from Cipro through December 31, 2003, at which point Bayer's Cipro patent would expire and its Cipro revenues would fall sharply. Upon expiration, generic manufacturers would compete to sell ciprofloxacin, driving down the price.



(4AA 690.)

The next chart projected Bayer's revenues from Cipro after it lost its lawsuit to Barr and generics began to compete in 1999 or 2000. The graph on the left assumed Bayer maintained its monopoly through 1998, with "patent destruction" in 1999; the graph on the right assumed Bayer maintained its monopoly through 1999 with destruction in 2000. Each graph shows a steep, rapid drop in Bayer's revenue stream:



(4AA 691.) It was therefore in Bayer's interest to pay $398.1 million to obtain the Generic Defendants' agreement to stay out of the Cipro market.

It was also in Barr's interest to accept the offer. Barr predicted it would earn only $148 million to $177 million selling generic ciprofloxacin in a competitive market through 2003. (6AA 1203, citing Barr documents at 10AA 2353–75, 2377–2401.) The total profits Barr gained from the anticompetitive agreement were 3.3 to 4 times larger than the profits Barr could reasonably have expected to gain through competition. (6AA 1204.)

3. The Cipro Agreements.

Bayer, Barr, and the other Generic Defendants reached their settlement on January 8, 1997.[9] (3AA 616, 4AA 699–700.) Barr, HMR, Rugby, Apotex, and Bernard Sherman agreed to abandon any challenge to the validity or enforceability of Bayer's '444 patent for Cipro.[10] In exchange, Bayer agreed to make total payments of $398.1 million to Barr, including an initial payment of $49.1 million and quarterly cash payments until December 2003. (4AA 703–04, 788.) If a litigant subsequently were to obtain a judgment of invalidity or unenforceability against the '444 patent, Bayer would stop making cash payments to Barr. (4AA 768, 788–90.) Bayer and Barr authorized their counsel to file a two-page "Consent Judgment" ending their patent litigation. (4AA 704–06.) The Consent Judgment disclosed no details of the settlement, nor did the parties ever provide them to the court supervising the *Bayer v. Barr* litigation.

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[9] The Cipro agreements consist of four documents:

- Settlement Agreement and Mutual Release among Bayer AG, Bayer US and Barr Laboratories (4AA 702–33);
- Settlement Agreement and Mutual Release among Bayer AG, Bayer US, HMR and Rugby (4AA 735–48);
- Settlement Agreement and Mutual Release among Bayer AG, Bayer US, Bernard Sherman and Apotex, Inc. (4AA 750–60); and
- Supply Agreement among Bayer AG, Bayer US, Barr and HMR (4AA 762–813).

The Supply Agreement was amended on August 28, 2003, to extend the parties' arrangement until the end of 2005. (4AA 830.)

[10] HMR, Rugby, Apotex, and Mr. Sherman—non-parties to the *Bayer v. Barr* litigation—were well-established generic drug manufacturers, each of whom was capable of winning FDA approval to bring a generic version of Cipro to market at lower prices. Mr. Sherman was the majority controlling shareholder of Barr as well as the CEO and controlling shareholder of the Canadian generic drug company Apotex. As such, he was privy to the details of the *Bayer v. Barr* litigation that Bayer sought to cloak in secrecy.

Bayer paid Barr the entire amount. (4AA 847–48, 5AA 902–80.)

4. Bayer Passes the Cost of the Settlement to Purchasers.

Bayer recouped these settlement payments and much more, by passing on the cost to purchasers. Beginning in 1997, Bayer raised Cipro prices at rates that were among the highest in the pharmaceutical industry, more than doubling its pre-settlement annual rate of price increase: "Measured as the percentage price increase over the entire period divided by the number of years in the period, Bayer increased the prices for the three major [Cipro] dosages 4.56%, 4.85% and 4.33% annually in the five years prior to the settlement agreements and 10.53%, 11.66% and 74.83% respectively for the seven years after the settlement agreements." (6AA 1208.) The price of Cipro increased 16 percent from the beginning of 1997 to the end of 1998 alone. (6AA 1167.) During its monopoly period, a single Cipro pill cost consumers upwards of $5.30, whereas a generic pill would have cost only $1.10. (6AA 1093.) Between 1997 and 2003, Bayer gained revenues of $5.717 billion, and profits of approximately $4.859 billion, from sales of Cipro tablets. (6AA 1202.)

Pursuant to the Supply Agreement, Barr began re-selling Bayer-manufactured Cipro in June 2003, six months before the '444 patent was set to expire. (4AA 780.) Because the agreement required Barr to buy the Cipro from Bayer at 85 percent of its current price, Barr did not undercut Bayer's price on the Cipro that it re-sold. (4AA 779–80.) Between June 2003 and December 2003, Barr sold Bayer-manufactured Cipro at prices that equaled or exceeded the prices Bayer charged for Cipro. (5AA 999, 1037, 6AA 1207–08.)

PROCEDURAL HISTORY OF THIS CASE

Petitioners filed their consolidated amended complaint on August 5, 2002, alleging violations of the Cartwright Act, the Unfair Competition Law, and the common law doctrine prohibiting monopolistic acts. Following removal, the federal district court remanded the case to the Superior Court. (See *In re Ciprofloxacin Hydrochloride Antitrust Litig.* (E.D.N.Y. 2001) 166 F.Supp.2d 740, 746-757.)

The Superior Court overruled Respondents' demurrer as to all claims on November 26, 2002. Discovery commenced in January 2003. On November 25, 2003, the Superior Court certified a class of the "hundreds of thousands" of California consumers and third-party payors who purchased Cipro during the Class Period, which began on January 9, 1997, and ended when the effects of Respondents' illegal conduct ceased. (*In re Cipro Cases I and II* (2004) 121 Cal.App.4th 402, 408.) The Court of Appeal affirmed the class certification order on July 21, 2004. (*Ibid.*)

On August 20, 2009, the Superior Court issued a tentative ruling granting summary judgment to Respondents. On August 21, 2009, the Superior Court heard oral argument. In an order dated that same day, the court granted the motions, finding federal authority "dispositive." (Order at p. 4 (11AA 2685).) The court summarily overruled all of Petitioners' objections to the evidence submitted by Respondents. (See Order at p. 7 (11AA 2688).) Petitioners appealed. (11AA 2715.)

Following briefing and argument, the Court of Appeal affirmed, in an opinion issued on October 31, 2011. Like the Superior Court, the Court of Appeal found "the reasoning of the federal cases . . . regarding the legality of settlements of Hatch-Waxman patent litigation to be sound and applicable to plaintiffs' cause of action under the Cartwright Act." (Opinion at p. 33.) The Court of Appeal "conclude[d] that because the

Cipro agreements undisputedly did not restrain competition beyond the exclusionary scope of the '444 patent, they do not violate the Cartwright Act." (Opinion at p. 38.) Unlike the Superior Court, the court also reached the federal preemption issue raised by Bayer and held the claims preempted. (See Opinion at pp. 42–45.)

This Court granted review on February 15, 2012.

STANDARD OF REVIEW

This Court reviews a grant or denial of summary judgment *de novo*. (*Aguilar v. Atlantic Richfield Co.* (2001) 25 Cal.4th 826, 860.) At summary judgment, "a reviewing court must examine the evidence de novo and *should draw reasonable inferences in favor of the nonmoving party*." (*Miller v. Department of Corrections* (2005) 36 Cal.4th 446, 470, italics in original.) Summary judgment is not warranted unless Respondents can demonstrate "that one or more elements of the cause of action in question cannot be established, or that there is a complete defense thereto." (*Aguilar, supra*, 25 Cal.4th at p. 850, citation and quotation marks omitted.)

ARGUMENT

I. The Court of Appeal Erred in Holding that the Cartwright Act and the UCL Do Not Prohibit Respondents' Market Exclusion Payment.

The Cipro agreements violate California law because they constitute a naked payoff of $398.1 million from one horizontal competitor to other horizontal competitors to suppress competition. The agreements significantly harmed California purchasers by denying them the benefits of a competitive market and requiring them to pay higher prices. The assertion of a patent cannot immunize these agreements, which fall into a category that experience has shown lacks any redeeming value: covenants not to compete in an entire market. The case should go to a jury.

A. The Cipro Agreements Violate California Law *Per Se.*

One of the chief benefits of the *per se* rule of antitrust liability is the predictability it establishes. If applied here, as Petitioners submit the rule should be, it will set everyone's expectations such that pharmaceutical companies, to avoid imposition of *per se* liability, will stop reaching pay-for-delay settlements. As in the past, should they choose to settle patent cases, they will employ other mechanisms that do not violate California law, such as early entry licenses that provide some benefit to consumers—in contrast to the pernicious cash settlement at issue here. Pay-for-delay agreements are not necessary, either to settle patent litigation or to promote innovation. The Court of Appeal's superficial analysis of the patent's presumed exclusionary effect is a distortion of antitrust and patent law, and disregards the record evidence—including the large exclusion payment—that casts serious doubt on the Cipro patent's actual ability to exclude. Consistent with longstanding precedent, pay-for-delay agreements should be illegal *per se* under California antitrust law.

1. The Cartwright Act Prohibits Payments Not to Compete, Like Those at Issue Here.

Bayer's open payment in restraint of trade secured an agreement to head off competition, violating the Cartwright Act. The Cartwright Act forbids *any* "tampering with prices; they must be determined, we have stated, by the 'interplay of the economic forces of supply and demand.' [Citation.]" (*Mailand v. Burckle* (1978) 20 Cal.3d 367, 377.) The Cartwright Act has long outlawed anticompetitive behavior in categorical terms—agreements restraining free competition are "absolutely void." (Bus. & Prof. Code, § 16722.) The Act establishes specific categories of restraints that are illegal *per se*. Particularly relevant here, it bans all agreements between businesses "to pool, combine or directly or indirectly

unite any interests that they may have connected with the sale or transportation of any such article or commodity, that its price might in any manner be affected." (*Id.*, § 16720(e)(4).)

In the application of these clear prohibitions, certain types of anticompetitive practices are "conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use. [Citation.]" (*B.W.I. Custom Kitchen v. Owens-Illinois, Inc.* (1987) 191 Cal.App.3d 1341, 1348.) California law condemns, as *per se* unlawful, conduct that has a "pernicious effect on competition and lack of any redeeming virtue[.]" (*Ibid.*, citation omitted.) Where a case involves such conduct, the jury need not weigh its anticompetitive effects against any purported justifications. (*Ibid.*)

The Cipro agreements run afoul of California's *per se* prohibition of business practices that monopolize a market. "The offense of monopoly involves the willful acquisition of the power to control prices or exclude competition from commerce in a particular geographic area with respect to a specific product." (*Lowell v. Mother's Cake & Cookie Co.* (1978) 79 Cal.App.3d 13, 23.) At common law, this Court nullified contracts providing for payments to divide up markets or to block the entry of competing firms. "Contracts which go to the total restraint of trade, as that a man will not . . . carry on his business *anywhere in the State*, are void, upon whatsoever consideration they may be made. [Citations.]" (*Wright v. Ryder* (1868) 36 Cal. 342, 359, italics in original; see, e.g., *Callahan v. Donnolly* (1872) 45 Cal. 152, 153-154; *Getz Bros. & Co. v. Federal Salt Co.* (1905) 147 Cal. 115, 118 [condemning $10,000 payment made in exchange for a covenant "to refrain from purchasing salt from any other parties than the defendant, and to refrain from importing or causing to be imported, or in any way bringing any salt to the Pacific Coast . . . other than

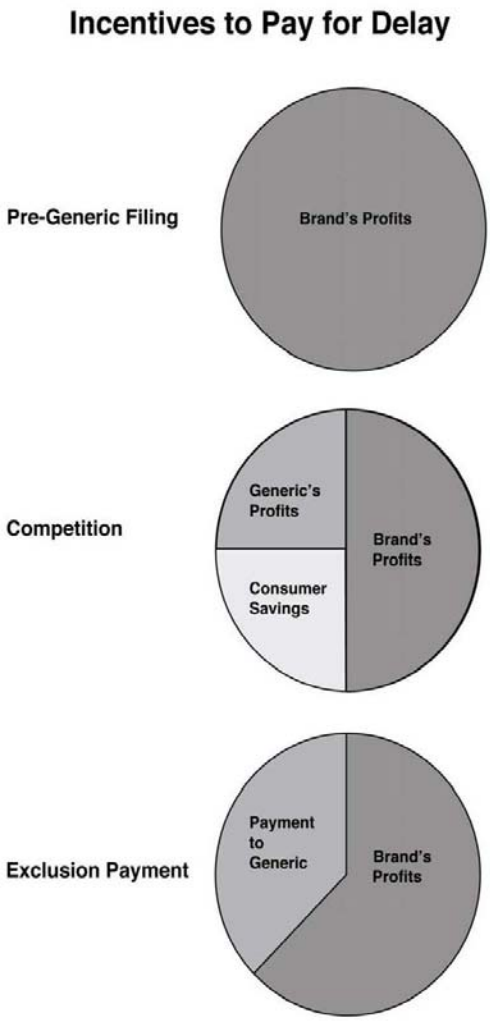
such as may be purchased by the defendant."].)

Such monopoly practices are *per se* illegal under California law. "Though not specifically listed [in the Cartwright Act], monopoly is a prohibited restraint of trade." (*Mother's Cake & Cookie, supra*, 79 Cal.App.3d at p. 23 [needs full cite]; see also *Dimidowich v. Bell & Howell* (9th Cir. 1986) 803 F.2d 1473, 1478 ["Combinations to monopolize would appear to fall within the general prohibitions of the Cartwright Act."].) Similarly, horizontal agreements to allocate markets have long been held to violate the Cartwright Act *per se*. A leading case is *Guild Wineries & Distilleries v. J. Sosnick & Son* (1980) 102 Cal.App.3d 627. There, the defendant took over the operations of one of its wholesalers and tried to persuade another wholesaler not to compete with it, triggering *per se* liability. (*Id.* at p. 633.) The deleterious economic effects of pay-for-delay settlements justify this categorical ban here.

Respondents—horizontal competitors—*do not dispute* that they entered into the Cipro agreements for the purpose of eliminating competition with a reward funded by the same monopoly profits that Bayer gained through its illegal agreement. Hence, Respondents pooled their interests to affect prices in violation of section 16720(e)(4). In fact, Bayer's payment violates the Cartwright Act *per se* in multiple ways: it constitutes a monopoly practice, it secured an agreement not to compete, and it horizontally allocated the entire Cipro market to Bayer.

The fact that Bayer and the Generics maximized *their* profit through a horizontal agreement to eliminate competition, raise prices, and divide the market does not mean their settlement is in the public interest. On the contrary, they extracted their extra profit directly from consumers, through higher Cipro prices. With its exclusion payment, Bayer bought assurance that its patent would not be invalidated, something the patent law does not

give and that the Hatch-Waxman Act intended to prohibit. Bayer used some of this extra monopoly profit, obtained by avoiding Barr's likely successful challenge, to pay Barr off.[11]



[11] As Dr. Hartman found: "The incumbent and the first entrant coordinated their behavior and settled their IP dispute to their mutual economic advantage; each of the settling parties (Bayer and Barr) was economically better off under the settlement than they were absent the settlement; and the settling parties optimized their combined economic self-interest to the disadvantage of the third group of self-interested individuals (the consumers). These are classic characteristics of an agreement in restraint of trade rather than an agreement to mitigate the litigation risk of two parties to an IP dispute." (6AA 1210; see also 10AA 2251.)

Given these clear pernicious effects, the relative novelty of pay-for-delay settlements does not justify declining to enforce the *per se* ban. No court has ever held that the *per se* rule will not be applied simply because an agreement occurred within a certain economic sector or other courts declined to apply the rule in a similar situation. This circular reasoning would make the *per se* rule a dead letter. In fact, the *per se* rule exists in order for the courts to make categorical judgments. It does not condemn specific agreements based on their particular language or details; it condemns entire classes of agreements based on their nature and economic effects. (7 Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* (3d ed. 2010) ¶ 1509a, at pp. 440–441 [noting that "sometimes the reasonableness judgment can be generalized for a class of behavior or for a class of claimed defenses."].) Economic analysis, not *stare decisis* alone, drives the inquiry. (*Id.*, ¶ 1509b, at p. 448 [explaining that the *per se* rule applies where "serious pernicious effects are likely to result from most of its concrete manifestations, and social benefits are likely to be absent or small or readily achievable in other ways."]; see also *Oakland-Alameda County Builders' Exchange v. F. P. Lathrop Constr. Co.* (1971) 4 Cal.3d 354, 361 [holding that the *per se* rule in California "does not denote an arbitrary rigid classification, but rather encompasses certain practices that normally tend to eliminate competition."].)

Thus, in 1972, no court had held simple market division to be *per se* illegal under the Sherman Act—a proposition we now take for granted. (Eleanor M. Fox & Lawrence A. Sullivan, *Cases and Materials on Antitrust* (1989), at p. 344 ["Before 1972, although commentators often asserted that agreements by competitors to divide markets were, without more, *per se* unlawful, there was as yet no case explicitly so holding."].) That did not

stop the United States Supreme Court from finding such a division to be *per se* unlawful in *United States v. Topco Associates, Inc.* (1972) 405 U.S. 596, even in the context of a then-novel joint venture between supermarkets to create a generic brand. Similarly, novelty and the absence of prior authority did not stop the Court from summarily reversing and granting summary judgment to the plaintiffs in *Palmer v. BRG of Georgia, Inc.* (1990) 498 U.S. 46 (per curiam), despite the fact that the agreement to end competition occurred in the context of a licensing agreement. So, too, does the rule of *per se* illegality apply to the Cipro agreements, as the California Attorney General recognizes.[12] (See 1/10/12 AG Amicus Letter, at p. 3.)

2. The Court of Appeal's Stated Reasons for Not Applying the *Per Se* Rule Are Insufficient.

The Court of Appeal erred in failing to apply the established *per se* rule. Citing to federal Eleventh Circuit authority, the court reasoned that the *per se* rule did not apply because, "[c]onsidering the important public policies [1] underlying patent law (*Valley Drug, supra*, 344 F.3d at pp. 1307-1308) and [2] favoring the settlement of patent litigation (*Schering, supra*, 402 F.3d at pp. 1074-1075), and [3] the fact that the Cipro agreements did not restrain competition outside the exclusionary zone of the '444 patent, we cannot view the Cipro agreements as lacking any redeeming virtue." (Opinion at p. 33.) Yet, pay-for-delay settlements do *not* promote either the policies of the Patent Act or settlement of patent cases—the only two "redeeming virtues" cited by the lower court. And the limitation of the agreements to Cipro simply means they were not even more anticompetitive; it does not qualify as a "virtue."

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[12] Under *Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Company* (1999) 20 Cal.4th 163, 180-181, the Cipro agreements violate the UCL in addition to the Cartwright Act.

a. Pay-for-Delay Settlements Do Not Promote the Policies of the Patent Act.

Declining to apply the *per se* rule frustrates patent law rather than furthering it. The opinion below misunderstood patent law, allowing a private agreement surrounding an untested—and likely unenforceable—patent to supply the same bulwark against competition as a fully litigated patent upheld on its merits.

A cornerstone of patent policy is "the desirability of *encouraging* licensees to challenge the validity of patents, to further the strong federal policy that only inventions which meet the rigorous requirements of patentability shall be withdrawn from the public domain." (*Aronson v. Quick Point Pencil Co.* (1979) 440 U.S. 257, 265, italics added.) Patent law and policy strongly favor striking illegitimate patents from the economy because they impede competition, innovation, and efficient licensing. "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." (*United States v. Glaxo Group Ltd.* (1973) 410 U.S. 52, 58, quoting *Pope Mfg. Co. v. Gormully* (1892) 144 U.S. 224, 234.) The public stands to gain from the lower aggregate prices that result from adversarial testing of vulnerable patents. Therefore, the law "encourage[s] authoritative testing of patent validity." (*Blonder-Tongue Labs., Inc. v. University of Ill. Found.* (1971) 402 U.S. 313, 343-344, citing in part *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.* (1945) 324 U.S. 806, 816.) The United States Supreme Court has repeatedly "emphasiz[ed] the necessity of protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid," to further the "often expressed policy that 'It is the public interest which is

dominant in the patent system,' *Mercoid Corp. v. Mid-Continent Investment Co.* [1944] 320 U.S. 661, 665, and that the right to challenge 'is not only a private right to the individual, but it is founded on public policy, which is promoted by his making the defence, and contravened by his refusal to make it.' *Pope Mfg. Co. v. Gormully* [1892] 144 U.S. 224, 235." (*Edward Katzinger Co. v. Chicago Metallic Mfg. Co.* (1947) 329 U.S. 394, 400-401; see also *United States v. Line Material Co.* (1948) 333 U.S. 287, 319 (*Line Material*) (conc. opn. of Douglas, J.) [directing courts to condemn patent-based arrangements which create "a powerful inducement for the abandonment of competition, for the cessation of litigation concerning the validity of patents"].)

The Court of Appeal's ruling, contrary to this deeply-rooted policy, lets the owner of an invalid pharmaceutical patent *halt* adversarial testing, and avoid expected invalidity determinations, by offering up some of its monopoly profits to erstwhile challengers.

Repudiating the faulty approach below will encourage the salutary patent testing that benefits the public by weeding out such weak patents. But, it will *not* diminish the patent policy encouraging innovation. (Cf. Opinion at p. 20.)

Not every extra dollar that goes to an inventor promotes innovation. It strains the imagination to think that a scientist's decision to pursue a new line of research depends on whether, decades later, his or her employer will be able to pay a competitor not to challenge a patent obtained from that research. In reality, "patents are but one aspect of innovation policy . . . [and] innovation cannot be maximized without taking antitrust principles into account. A strong antitrust system is an important component of a larger innovation policy because it provides a check on those forms of patent misconduct that also injure competition." (Christopher R. Leslie,

Antitrust and Patent Law as Component Parts of Innovation Policy, 34 J. CORP. L. 1259, 1288 (2009).) A reverse exclusionary payment is a form of patent misconduct, and it excludes the very generic competition that gives branded drug companies an added incentive to develop new products. The Federal Trade Commission found that "[t]he generic competition spurred by Hatch-Waxman has forced brand-name firms to come up with new products to replenish their revenue streams."[13] Reverse payments have precisely the opposite effect, stifling generic competition and thus *undermining* innovation.

The Court of Appeal's ruling cannot be excused on the basis of the procedural presumption of validity. Far from conferring any definite right, a patent reflects only an initial view by a patent examiner that an invention is patentable; it requires a court-approved injunction to be enforced, and can be invalidated. (*Lear, Inc. v. Adkins* (1969) 395 U.S. 653, 670 (*Lear*); *In re Etter* (Fed.Cir. 1985) 756 F.2d 852, 856 (en banc) (*Etter*); *Zenith Radio Corp. v. Hazeltine Research, Inc.* (1969) 395 U.S. 100, 135 ["The heart of his legal monopoly is the right to invoke the State's power to prevent others from utilizing his discovery without his consent."].)

Thus, patents are not definitively valid but only presumptively so. (35 U.S.C. § 282.) And the rebuttable presumption of validity is "a procedural device, not substantive law." (*Stratoflex, Inc. v. Aeroquip Corp.* (Fed.Cir. 1983) 713 F.2d 1530, 1534.) The presumption merely assigns respective burdens to patent litigants and does not "acquire an independent evidentiary role in any proceeding." (*Etter, supra*, 756 F.2d at p. 856.) Moreover, it applies only in a full adjudication on the merits. (See

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[13] (Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy" (Oct. 2003), ch. 3, at p. 11, *available at*: http://www.ftc.gov/os/2003/10/innovationrpt.pdf.)

Nutrition 21 v. United States (Fed.Cir. 1991) 930 F.2d 867, 869.) Courts therefore have denied preliminary injunctions sought by patent holders on the grounds that, at least until a court has ruled on patent validity, the alleged infringer has a "right to compete." (See, e.g., *Illinois Tool Works, Inc. v. Grip-Pak, Inc.* (Fed.Cir. 1990) 906 F.2d 679, 684.)

On the other hand, a rule that admittedly enables the holder of a "fatally weak" patent (*Tamoxifen, supra*, 466 F.3d at p. 212) to maintain and protect its monopoly by bribing the competition *impairs* "the efficient operation of the federal patent system [that] depends upon substantially free trade in publicly known, unpatented design and utilitarian conceptions." (*Bonito Boats, Inc. v. Thunder Craft Boats, Inc.* (1989) 489 U.S. 141, 156.) Such a rule also abrogates California's own "policy favoring free competition, dissemination of ideas and maximum utilization of intellectual resources"—and it should be rejected for our State. (*Sinclair v. Aquarius Elec., Inc.* (1974) 42 Cal.App.3d 216, 224, citation omitted.)

As the leading antitrust treatise observes: "The problematic thing about large exit payments to infringement defendants is that they raise a strong inference that the parties themselves believed the patents in question were either invalid or not infringed." (12 Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* (2d ed. 2005) ¶ 2046c2.) The inference is particularly strong in this setting because about three-quarters of litigated pharmaceutical patents are struck down. (6AA 1177, 9AA 2157, 2045–2136.) Indeed, challenges to prescription drug patents are of special importance. Pharmaceutical patent monopolies have led to skyrocketing prices, which deter patients from buying their

prescribed medicine.[14] Largely for that reason, the American Medical Association urges courts "to stop 'pay for delay' arrangements by pharmaceutical companies." (10AA 2325.)

b. Outlawing Pay-for-Delay Settlements Will Not Inhibit Settlement of Patent Cases.

Just as holding pay-for-delay settlements *per se* unlawful will not dampen pharmaceutical innovation, such a holding will not prevent pharmaceutical patent cases from settling. Pharmaceutical companies like Bayer, Barr and the other Respondents here are sophisticated businesses,

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[14] Scientific studies included in this appellate record determined that many patients do not take some or all of their prescribed medicine when it is too expensive and becomes unaffordable. (See Stephen B. Soumerai, *et al.*, *Cost-Related Medication Nonadherence Among Elderly and Disabled Medicare Beneficiaries*, Archives of Internal Medicine, vol. 166, pp. 1831, 1834 (2006) (9AA 1973, 1976) [finding that "concern about cost was the predominant reason reported (79.4 percent of [elderly and disabled] respondents) for not filling prescriptions," and that "a substantial proportion of [Medicare] enrollees and almost one quarter of the disabled beneficiaries reported cutting back on basic needs to be able to afford their medications"]; Dawn Klein, *et al.*, *Elders Who Delay Medication Because of Cost: Health Insurance, Demographic, Health, and Financial Correlates*, The Gerontologist, vol. 44, p. 785 (2004) (9AA 1985) [finding that "because of the high cost of some medications, patients may decide that the medication is too costly and that they do not really 'need' the medication, even if they can afford it. . . . [N]oncompliance for any reason may contribute to emergency room visits, inpatient admissions, and overall health care costs."]; Michael A. Steinman, M.D., *et al.*, *Self-Restriction of Medications Due to Cost in Seniors Without Prescription Coverage*, Journal of General Internal Medicine, vol. 16, p. 797 (2001) (9AA 1993) [finding that "[l]ow income and high out-of-pocket drug costs both play an important role in medication restriction, consistent with basic economic principles."]; Emily R. Cox, *et al.*, *Medicare Beneficiaries' Management of Capped Prescription Benefits*, Medical Care, vol. 3, pp. 296, 298 (2001) (9AA 1997, 1999) [finding that 23.6 percent of Medicare beneficiaries who were at risk of reaching their prescription cap took less than the prescribed amount of medication, 16.3 percent stopped using medications, and 14.7 percent went without food, clothing, or shelter].)

perfectly capable of settling patent disputes without exclusionary payments. Between 2000 and 2004—when pay-for-delay settlements were considered to be *per se* illegal under *In re Cardizem CD Antitrust Litigation* (6th Cir. 2003) 332 F.3d 896 (*Cardizem*)—"not one of twenty reported agreements involved a brand firm paying a generic filer to delay entering the market. During this period, parties continued settling their disputes, but in ways less restrictive of competition, such as through licenses allowing early generic entry." (Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 75 (2009).) During this time when such agreements were treated as illegal, and pharmaceutical companies acted accordingly, the patent system continued to operate, innovation did not lag, new products came to market and parties litigated their patent disputes in court, settling virtually all of them and at the same rate. Among other things, this history shows that patent settlements can be negotiated for early entry alone, without pay-for-delay agreements.[15]

In contrast, the retreat by certain federal courts from the *per se* approach of *Cardizem* has opened the pay-for-delay floodgates. Fourteen reverse-payment deals were reached in 2007, 16 in 2008, 19 in 2009, 31 in

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[15] Neither the Court of Appeal nor Respondents can demonstrate that scrutinizing reverse payments would chill patent litigation itself. (*Cf.* Opinion at pp. 35–36.) It would not. Under the Hatch-Waxman procedures, branded drug companies have an overwhelmingly strong incentive to sue generic applicants in order to secure an additional exclusivity period. (See 21 U.S.C. § 355(j)(5)(B)(iii).) Their inability to pay off generic challengers does not vitiate this incentive. Also, given the revenues at stake, generic drug companies will still have every incentive to pursue invalidity judgments and arrive at reasonable settlements with the brands even absent the possibility of gaining a windfall cash payment.

2010, and 28 in 2011.[16] No one seriously disputes that such agreements are anticompetitive and lead to higher prices—pay-for-delay settlements confer no benefit on anyone, except the colluding drug companies. However, settling litigation does not provide *carte blanche* to violate the law. California law:

> does not allow a court to endorse or enforce a provision in a settlement agreement or stipulation which is illegal, contrary to public policy, or unjust. . . . Consequently, even though there is a strong public policy favoring the settlement of litigation, this policy does not excuse a contractual clause that is otherwise illegal or unjust.

(*Timney v. Lin* (2003) 106 Cal.App.4th 1121, 1127; see, e.g., *Union Pacific Corp. v. Wengert* (2000) 79 Cal.App.4th 1444, 1446-1447 [reversing approval of a settlement alleged to be "collusive and against public policy"].[17]) Furthermore, third parties "whose interests are affected" by a settlement agreement can challenge the agreement to obtain a finding of illegality. (*River Garden Farms, Inc. v. Super. Ct.* (1972) 26 Cal.App.3d 986, 1000.)

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[16] (See http://www.ftc.gov/os/2011/10/1110mmachart.pdf.)

[17] The sponsors of the Hatch-Waxman Act have specifically stated that pay-for-delay agreements violate the statutory intent. Senator Hatch has said he thinks such deals are "appalling," and a Senate Judiciary Committee report denounced "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market. Agreeing with smaller rivals to delay or inhibit competition is an *abuse* . . . ." (10AA 2234, 2239, italics added.) According to Representative Waxman, "[t]he law has been turned on its head. . . . We were trying to encourage more generics and through different business arrangements, the reverse has happened." (10AA 2224.)

c. Limitation of the Agreement to Cipro Is Not a Redeeming Virtue and Does Not Justify a Weakened Legal Standard.

The Court of Appeal's third stated reason for refusing to apply the *per se* rule was that the Cipro agreements' terms, while allowing the patent to remain in effect, granted no exclusion other than what was already subsumed within its "exclusionary zone." (Opinion at p. 33.) This is not a "virtue." This reasoning mistakenly treats what is normally a *sufficient* condition for antitrust liability (restraints beyond the patent's claims) as a *necessary* condition. In truth, a court is not absolved of the responsibility to scrutinize the underlying conduct when a patent holder has been sued under the antitrust laws and the alleged restraint does not extend the patent. For a patent holder "may commit patent misuse in improper exploitation of the patent either by violating the antitrust laws *or* extending the patent beyond its lawful scope." (*Transitron Elec. Corp. v. Hughes Aircraft Co.* (D. Mass. 1980) 487 F.Supp. 885, 893, italics added.)

A pertinent example of the former situation arose in *United States v. Masonite Corporation* (1942) 316 U.S. 265, where a patent owner (Masonite) sued its potential competitors for patent infringement and then resolved those disputes by licensing the competing firms to sell its product at a price that it set. (*Id.* at pp. 267-273.) The Supreme Court held these agreements unlawful because Masonite eliminated potential competition by splitting its monopoly rents with its would-be competitors. (*Id.* at pp. 281-282 ["The power of this type of combination to inflict the kind of public injury which the Sherman Act condemns renders it illegal *per se*."].) Notably, the Court reversed the trial court's finding that Masonite's agreements were immune simply because they did not confer any "monopoly or restraint other than the monopoly or restraint granted by the

patents . . . ." (*Id.* at p. 276.) Though the parallel with this case is striking, the Court of Appeal did not cite or discuss *Masonite*.

Several decisions have applied the *per se* antitrust rule to condemn exclusionary agreements taking the form of patent settlements. None of them turned on the fact that the agreement exceeded the patent's "exclusionary zone." In *Vulcan Powder Company v. Hercules Powder Company* (1892) 96 Cal. 510 (*Vulcan*), this Court invalidated a horizontal market allocation contract between competitors who claimed they were merely exchanging their patent rights to dynamite. The Court made it clear that holding a patent does not give a company free rein to enter into anticompetitive contracts, including market allocation contracts with competitors. (*Id.* at pp. 515-516 ["In some text-books and decisions, it has been stated, generally, that the rule about contracts in restraint of trade being void does not apply to patent rights; but as applied in the adjudicated cases, it means only that a trader may sell a patent right, or a secret in his trade or art, and restrain himself generally from the use of it, or from other acts which would lessen the value of the patent sold."].)

The *Vulcan* Court found it significant that the plaintiff and another party to the contract did not own a dynamite patent. The money these parties received did not result from a sale or exchange of patent rights—instead, they received it in exchange for their agreement not to compete. (*Vulcan, supra*, 96 Cal. at p. 515.) The Court held the agreement void under California law, for "no case has been cited in which it has been held that several persons or companies can legally enter into a business combination to control the manufacture, or sale, or price of a staple of commerce merely because some of the contracting parties have letters patent for certain grades of that staple." (*Id.* at p. 516.)

The Court also noted that the restraints at issue, in purporting to affect the dynamite market, went beyond the technological scope of the patent at issue. However, far from being the linchpin of the decision, this was cited as an *aggravating* factor in the antitrust analysis. The Court first analyzed the contract independently of the patent issues, determining that the exclusionary provisions "are clearly in restraint of trade and against public policy; and this conclusion is too obvious to need argument, authorities, or elucidation." (*Vulcan, supra*, 96 Cal. at p. 515.) The Court's subsequent analysis focused on whether the patent holder was receiving consideration for some right it had obtained through the patent, and whether the consideration actually provided by the non-patent holders had any pro-competitive effects. The answer in each instance was no, supporting the conclusion that the provisions were facially unlawful. (*Id.* at pp. 515-516 ["[I]t is obvious that the consideration moving from [the non-patent holders] was their covenant to refrain from competition in the dynamite business, and that they had no patent rights to 'interchange.'"].)

The Cipro agreements, like the agreement in *Vulcan*, did not license patented rights. Bayer did not *license* its patent or *receive any money* from a license. Instead, it *paid* money to entities that had no patent right, in exchange for their agreement not to compete with the patented product. Patent licenses and other reciprocal business arrangements such as patent pools can have pro-competitive effects by expanding consumer choice. Not so here. A generic drug company's agreement to stay out of the market, like the agreement at issue here, and like the market allocation agreement struck down in *Vulcan*, has *no* pro-competitive effects. Under *Vulcan*, a naked payment from a patent holder to a non-patent holder to abandon its validity challenge and stay out of the market for the patented product, thus ensuring supra-competitive prices, is subject to the rule that agreements not

to compete are *per se* illegal. (See also 12 Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* (2d ed. 2005) ¶ 2046c, at p. 321 ["Potentially anticompetitive IP settlements are entitled to deference when they involve the creation of IP licenses whose scope must be assessed against competitive risks. But when no license is created, no such deference is needed. [Footnote.]"].)

The Court of Appeal ignored *Vulcan* and its teachings entirely, while misconstruing another California precedent, *Fruit Machinery Company v. F. M. Ball & Company* (1953) 118 Cal.App.2d 748 (*Fruit Machinery*).) (See Opinion at pp. 34–35.) The divergent royalty rates challenged in *Fruit Machinery* survived antitrust scrutiny, not because the licenses were restricted to the patented products, but because the "differential in royalty rates" bore "a reasonable relationship to differences in costs and capital risks between the two types of uses" at issue under the licenses. (*Id.* at p. 762.) The court specifically noted that a patent holder can be subjected "to the proscriptions and penalties of the antitrust laws" when the circumstances raise an inference of patent abuse or subversion of public interest.[18] (*Ibid.*) The Court of Appeal in this case quoted *Fruit Machinery*'s disjunctive ruling without recognizing its true import: "Defendant has not shown that the parties . . . exercised rights or powers

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[18] A royalty differential subjecting a patent holder to antitrust liability, presented as a hypothetical in *Fruit Machinery, supra*, 118 Cal.App.2d at p. 762, was found to exist in subsequent cases involving disparate royalties in licenses for shrimp peeling equipment. (See *La Peyre v. F.T.C.* (5th Cir. 1966) 366 F.2d 117; *Peelers Co. v. Wendt* (W.D.Wash. 1966) 260 F.Supp. 193; *Laitram Corp. v. King Crab, Inc.* (D. Alaska 1965) 244 F.Supp. 9, modified, 245 F.Supp. 1019.) The contracts in these cases that were struck down as anticompetitive did not grant any rights other than those granted by the patents themselves. (See also *Besser Mfg. Co. v. United States* (1952) 343 U.S. 444, 449 [listing "recognized remedies" under the antitrust laws for "abuses of patent rights"].)

not accorded them by the patent law *or abused* any rights or powers accorded them by that law." (Opinion at p. 34, quoting *Fruit Machinery, supra*, 118 Cal.App.2d at p. 762, italics added.)

In addition, the Court of Appeal overlooked *United States v. Singer Manufacturing Company* (1963) 374 U.S. 174 (*Singer*). In *Singer*, American, Italian, and Swiss sewing machine companies agreed to settle their various patent disputes, heading off patent challenges partly through a cross-licensing scheme, to collude against Japanese manufacturers. (*Id.* at pp. 180, 185.) Concurring, Justice White declared that the "patent laws do not authorize, and the Sherman Act does not permit," arrangements "between business rivals to encroach upon the public domain and usurp it to themselves." (*Id.* at p. 200 (conc. opn. of White, J.).) The defendants "agreed to settle an interference, at least in part, to prevent an open fight over validity. There is a public interest here, . . . which the parties have subordinated to their private ends . . . ." (*Id.* at p. 199, citations omitted.) According to Justice White, the Court vindicated a "public policy favor[ing] the exposure of invalid patent monopolies before the courts in order to free the public from their effects." (*Id.* at p. 200, fn. 1.) In the aftermath of the landmark *Singer* decision, Congress amended the Patent Act to require parties wishing to settle a patent interference to submit their settlement agreement to the PTO; that provision, 35 U.S.C. § 135(c), and the *Singer* decision, remain good law today. (See Christopher R. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34 J. CORP. L. 1259, 1276-1277 (2009).)

Under *Singer*, *Vulcan*, and *Masonite*, the mere assertion of a patent that came under attack cannot immunize Respondents' settlement agreement that left Californians no choice but to pay monopoly prices for seven years. A patent holder "should not be permitted by legal devices to

impose an unjust charge upon the public in return for the use of it." (*Motion Picture Patents Co. v. Universal Film Mfg. Co.* (1917) 243 U.S. 502, 513.) Contrary to the Court of Appeal's discussion, the rule against restrictions on unrelated products does not logically imply that exclusionary agreements relating to a potentially invalid patent may never give rise to antitrust liability. "Rights conferred by patents are indeed very definite and extensive, but they do not give any more than other rights an universal license against positive prohibitions." (*Standard Sanitary Mfg. Co. v. United States* (1912) 226 U.S. 20, 49.) "Nothing in the Patent Act authorizes a patentee to pay a rival simply to stay out of its market." (Herbert Hovenkamp, *Antitrust and Innovation*, 77 ANTITRUST L.J. 749, 753 (2011).) Simply possessing a patent does not allow a company to engage in any manner of pernicious conduct within its scope, and a patentee that abandons pursuit of a verdict against an alleged infringer, using a large sum of money to buy the exclusion the patent evidently could not furnish, can no longer stake a credible claim to its full protection.

That Respondents' agreement was limited to the patent parameters says nothing about whether the patent actually supplied legitimate grounds for the monopoly. However, the timing (on the eve of the patent trial), size (enormous), and direction (from the patent holder *to the patent challenger*) of Bayer's payment demonstrate that Respondents seriously doubted the patent's actual ability to exclude. California law, as established in *Vulcan* and *Fruit Machinery, supra*, recognizes the distinction between legitimate patent use and the kind of actionable abuse present here.

The basis for *per se* treatment in this case is simple as well as sound. By allocating the entire Cipro market to Bayer, the Cipro agreements precluded generic drug entry, competition and free-market pricing. That the agreements settled a patent dispute does not shield

Respondents' conduct from scrutiny. Their wealth transfer forced California citizens to pay monopoly prices, denying patients and insurers the benefits of the competitive prices they otherwise would have received. Such a horizontal agreement preventing a competitor from entering a market violates California law on its face.

B. The Court of Appeal Incorrectly Adopted a Faulty Federal Standard.

In evaluating Cartwright Act claims, "federal precedents must be used with caution because the acts, although similar, are not coextensive." (*Freeman v. San Diego Ass'n of Realtors* (1999) 77 Cal.App.4th 171, 183, fn. 9, citing *State of Calif. ex rel. Van de Kamp v. Texaco, Inc.* (1988) 46 Cal.3d 1147, 1152-69; see *Cianci v. Super. Ct.* (1985) 40 Cal.3d 903, 919-921 [finding "the Legislature intended to strike as broadly as it could in the Cartwright Act."]; *Edwards v. Arthur Andersen LLP* (2008) 44 Cal.4th 937, 948-950 [rejecting federal court's attempt to create a "narrow-restraint" exception to California's prohibition of noncompete agreements].)

Here the trial court and the Court of Appeal wrongly adopted the most permissive federal standard possible, the flawed *Tamoxifen* rule, as the law of California. *Tamoxifen* is not the only rule that can be adopted from the federal system. The Sixth and D.C. Circuits have properly held pay-for-delay settlements to be *per se* illegal, while the Eleventh Circuit's Rule of Reason analysis looks to the size of the settlement payment in comparison to the profits that the generic drug maker stood to earn. Federal law enforcement authorities have advocated for a rule of presumptive illegality only slightly less stringent than the *per se* rule. As demonstrated below, the federal authorities are not monolithic; any of them is preferable to the standard adopted by the Court of Appeal; and each would require reversal of its decision.

1. The Sixth Circuit and the D.C. Circuit Correctly Hold Pay-for-Delay Agreements *Per Se* Unlawful.

Consistent with basic principles of antitrust law, federal appellate courts have not hesitated to find that the terms of pay-for-delay settlements require *per se* liability. In *Andrx Pharmaceuticals, Inc. v. Biovail Corporation International* (D.C. Cir. 2001) 256 F.3d 799 (*Biovail*), the D.C. Circuit considered allegations that the brand-name company "HMRI paid Andrx 10 million dollars per quarter effectively not to enter the market" to settle Hatch-Waxman litigation over the patent to a hypertension drug. (*Id.* at p. 809.) "One can fairly infer from these facts, which were alleged in the counterclaim, that but for the Agreement, Andrx would have entered the market." (*Ibid.*) Thus, the restraint "could reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions"—language that clearly suggests the availability of *per se* treatment. (*Id.* at p. 811.) Indeed, the *Biovail* court recognized that "[a] payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties entering the agreement and the rent-preserving effect of that agreement." (*Id.* at p. 809, quoting David Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 335 (2000).) The court found that HMRI may have "acted unlawfully when it agreed with a competitor to settle the dispute, suppress information and exclude others from the market." (*Id.* at p. 813, fn. 15, citing *Singer, supra*, 374 U.S. at p. 196.) Therefore, the court remanded the claim to allow the plaintiffs to replead it.

In *In re Cardizem CD Antitrust Litigation* (6th Cir. 2003) 332 F.3d 896, the Sixth Circuit held the same pay-for-delay settlement illegal *per se*. (*Id.* at p. 907.) As the court concluded, "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 p. 908, fn. omitted.) Consumers paid "higher prices" for "drugs as a result of the contractually mandated absence of competition." (*Id.* at p. 904.) The court acknowledged in footnotes 12 and 13 that an earlier district court decision in the federal *Cipro* litigation had distinguished the *Cardizem* district court's ruling on the grounds that the *Cardizem* agreement restrained trade beyond, as well as within, the scientific and technological scope of the patent. Nevertheless, the holding of the Sixth Circuit and the district court in *Cardizem*—like the conclusion reached in *Vulcan, supra*, 96 Cal. at pp. 515-516—did not depend on the fact that the agreement also restrained trade beyond the patent's scope. The appellate court in *Cardizem* appeared to view this fact as, if anything, a "plus" factor that made the illegal deal even more suspect: the court neither qualified nor limited its holding based on the provisions extending the patent, but instead focused on the exclusion achieved in the market for the patented drug:

> There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade. . . . The Agreement whereby HMR paid Andrx $40 million per year not to enter the United States market for Cardizem CD and its generic equivalents is a horizontal market allocation agreement and, as such, is *per se* illegal under the Sherman Act and under the corresponding state antitrust laws.[19]

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[19] The state antitrust laws at issue in the *Cardizem* case included the Cartwright Act. (See *In re Cardizem CD Antitrust Litig.* (E.D.Mich. 2000) 105 F.Supp.2d 618, 625 & fn. 3.)

(*Id.* at pp. 900, 908.) Notably, the court rejected a defense based on the challenged patent's presumed exclusionary effects, recognizing that the patent's validity had not been confirmed because the settlement had foreclosed such testing. (*Id.* at p. 915.) *Per se* liability in *Cardizem* resulted from the nature of the agreement and the fact that, "had [HMR] been confident of the independent durability of its patent and the validity of its infringement claim, it would not have paid $89 million to effect what the patent and infringement suit had already accomplished." (*Ibid.*)

Analogously, Bayer paid its generic competitors an even bigger price—nearly $400 million—to keep out of the Cipro market. Bayer then did it again, settling a later infringement suit, against Ranbaxy, for $60 million. (7AA 1522–30, 1591–93.) These agreements between horizontal competitors produce a harmful effect—the total foreclosure of competition—and have no redeeming value. Here, Bayer sharply increased the price of Cipro and earned windfall monopoly profits for the remainder of the patent term. (See Factual Background, Section 4, *supra*.)

2. The Justice Department and the FTC Believe a Presumption of Illegality Is Warranted.

An alternate rule deems pay-for-delay agreements presumptively unlawful but gives the drug companies the opportunity to rebut this presumption, by, for example, offering evidence that the reverse payment did not greatly exceed litigation costs—*i.e.*, that it settled a nuisance lawsuit. (11AA 2576.) The United States Department of Justice supports this approach:

> There is no basis for a standard that treats the presumption of [patent] validity as virtually conclusive and allows it to serve as a substantive basis to limit the application of the Sherman Act—particularly since many litigated patents, notably in the Hatch-Waxman Act context, are held invalid. The result is to treat all

> but the most obviously invalid patents as equally potent bulwarks against competition from generic drugs. This result seems particularly unacceptable when a substantial payment for an agreement to withdraw a patent validity challenge strongly implies that the payor recognized a significant risk of patent invalidation through litigation.

(11AA 2572-73.)

In the case of a payment like the $398.1 million provided for in the Cipro agreements, "[t]he exchange of money for continued market exclusivity is starkly apparent." (11AA 2578.) "Absent another explanation for it, such a payment is naturally viewed as consideration for the generic's agreement to delay entry beyond the point that would otherwise reflect the parties' shared view of the likelihood that the patentee would ultimately prevail in the litigation. A payment in exchange for such additional exclusion is presumptively violative . . . ." (11AA 2576.)

The Federal Trade Commission takes the same position.[20] Most recently, in a brief filed with the Third Circuit in the *K-Dur* pay-for-delay litigation, the FTC identified a pressing "need for a rule that protects consumers from collusive agreements to stifle generic entry. The most reliable way to effectuate those policies is to recognize a rule of presumptive illegality."[21] As the FTC pointed out,

> where a settlement includes a substantial payment, that payment must be a *quid pro quo* for something; if the challenger is offering a commitment to stay out of the

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[20] (See 9AA 2011–14 [FTC found that the "permissive approaches" of the Second Circuit and the Eleventh Circuit "are misguided and not supported by the law. These holdings disrupt the carefully balanced patent system by overprotecting weak and narrow patents; allowing patent holders to buy protection that their patents cannot provide; and ignoring consumers' interests in competition safeguarded by the antitrust laws."].)

[21] (http://www.ftc.gov/os/2011/05/110518amicusbrief.pdf, at p. 27.)

> market for a specified time, it follows that the payment is to secure exclusion of a potential competitor. Because such an agreement closely parallels market allocation arrangements universally recognized as unlawful, a presumption of antitrust illegality is justified. Such a presumption is bolstered by the policies of Hatch-Waxman and by experience that shows the vulnerability of many pharmaceutical patents, the weakest of which will be the most likely to result in exclusion-payment settlements.[22]

Herbert Hovenkamp, author of the leading treatise on antitrust law, similarly concluded that reverse payments to generic manufacturers substantially larger than the cost of litigation "indicate that the parties harbored significant doubt that the patents in question were valid or infringed, which entails a significant possibility that, if pursued to a judicial outcome, generic competition would have entered the market. Such amounts are presumptively unreasonable, with the presumption defeated only by a showing that alternative challengers are able, both legally and physically, to enter the market immediately." (12 Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* (2d ed. 2005) ¶ 2046c4(B), at p. 333.)

This DOJ-FTC-Hovenkamp approach constitutes a modified Rule of Reason. (Defendants bear the initial burden.) As such, if the Court were to adopt this approach as California law, these claims should be remanded for trial. "Whether a restraint of trade is reasonable in the context of the Cartwright Act is a question of fact to be determined at trial." (*Corwin v. Los Angeles Newspaper Service Bureau, Inc.* (1971) 4 Cal.3d 842, 855.) That is because "motive and intent play leading roles" in "complex antitrust litigation" where "the proof is largely in the hands of the alleged

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[22] (http://www.ftc.gov/os/2011/05/110518amicusbrief.pdf, at pp. 13–14.)

conspirators . . . . It is only when the witnesses are present and subject to cross-examination that their credibility and the weight to be given their testimony can be appraised." (*Id.* at p. 852, internal quotation marks and citation omitted.)

3. The Eleventh Circuit Applies the Rule of Reason.

The Eleventh Circuit applied a more permissive legal standard in a pair of decisions, *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.* (11th Cir. 2003) 344 F.3d 1294 (*Valley Drug*), and *Schering-Plough Corp. v. F.T.C.* (11th Cir. 2005) 402 F.3d 1056 (*Schering-Plough*). The Eleventh Circuit approach looks to the "scope of the exclusionary potential of the patent" to determine whether antitrust claims can proceed. (*Valley Drug, supra*, 344 F.3d at p. 1311.) This approach differs from *Tamoxifen*—discussed in Section I.B.4, *infra*—in that the concept of "exclusionary potential" incorporates an analysis of the patent's likely ability to exclude infringing use, *i.e.*, its strength as tested through patent litigation.

In *Valley Drug*, the Eleventh Circuit considered Abbott's settlement payments of between $3 and $4.5 million per quarter in exchange for delayed generic sales of a prostate drug. (*Valley Drug, supra*, 344 F.3d at p. 1298.) The court rejected *per se* liability "merely" from the fact or size of a reverse payment. (*Id.* at p. 1309.) Instead, the court stressed the relevance of the economics of pay-for-delay agreements and the strength of the underlying patents:

> [I]n the instant case and given the state of the current record, it is difficult to infer from the size of the payments alone that the infringement suits lacked merit. *We do not know, for example, what lost profits Abbott expected from generic competition or what profits Geneva and Zenith expected to gain from entry*, the risk of the defendants' inability to satisfy a judgment, or the litigation costs each side expected to save from settlement.

(*Id.* at p. 1310, italics added.)

The court's next pay-for-delay decision upheld Schering-Plough's $15 million settlement payment in exchange for delayed generic sales of a drug used to treat high blood pressure. (*Schering-Plough, supra*, 402 F.3d at pp. 1058, 1061, fn. 8.) The court declined to apply the *per se* rule, not based on a sound interpretation of antitrust or patent law, but as a matter of "policy." (*Id.* at p. 1076 ["Our conclusion, to a degree, and we hope the FTC is mindful of this, reflects policy."].) Yet the court's policy analysis ascribed undue importance to protecting settlements in order to avoid the "problems associated with over-crowded court dockets." (*Ibid.*) While the court attempted to depict the relatively small settlement at issue as harmless—a characterization manifestly at odds with the record here—none of the "policy" rationales it articulated diminish the force of the logic that (a) patent settlements can always be negotiated for early entry alone, because sophisticated firms like drug manufacturers know how to monetize time on the market, and (b) when a cash payment forms a major part of the consideration for dropping a patent challenge, there is no reason as a matter of economics to be any less skeptical than one would be toward a naked payment not to compete outside the context of patent litigation.

Even so, these Eleventh Circuit decisions do not immunize pay-for-delay settlements from condemnation under the antitrust laws, and cannot be reconciled with (and do not support) the more extreme opinion of the Court of Appeal. The federal district court handling the *Valley Drug* litigation on remand *denied* the defendants' motion for summary judgment on the Sherman Act. (See *In re Terazosin Hydrochloride Antitrust Litig.* (S.D.Fla. 2005) 352 F.Supp.2d 1279.) As that court noted, the Eleventh Circuit "[r]ecogniz[ed] that the patentee's exclusionary right cannot be exploited in every way . . . ." (*Id.* at p. 1292.) Moreover, "[t]he

exclusionary value of the patent" itself "cannot be defined by looking at the patent terms in a vacuum," for "[t]he legitimate exclusion value of a pharmaceutical patent . . . is the power it actually confers over competition, which is in turn a function of the scope of the patent and its chance of being held valid." (*Id.* at p. 1296, citation omitted.) After all, "a patent does not give the patentee 'the right to exclude,' but rather the more limited 'right to *try* to exclude' by asserting its patent in court." (*Ibid.*, italics in original, citation omitted.) So a court applying the Eleventh Circuit approach should evaluate the "likely outcomes of the patent litigation that was pending at the time the parties entered into the Agreement" and assess the risk that the patent would have been nullified. (*Id.* at pp. 1299-1301.)

The $398.1 million payment in this case is the largest pay-for-delay settlement of all time. (10AA 2261.) The magnitude of the payment alone raises triable issues concerning the strength of the patent that the money was spent to protect.[23] The record here, unlike in *Valley Drug*, also contains Bayer's internal financial projections that it would earn at least $1.614 billion in monopoly profits if it could continue to sell Cipro through December 2003 unhindered by competition. (4AA 690.) As for the Generics, the record reveals that the bribe they took constitutes more than three times what they expected to earn in a competitive Cipro market after

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[23] At a *Bayer v. Barr* trial, the original Cipro patent would almost certainly have been nullified. This is the only reasonable conclusion the trier of fact could draw from all the record evidence, including Dr. Ivor R. Elrifi's unrefuted testimony concerning Bayer's deception in applying for the patent (8AA 1804–29; see also 8AA 1852–56), Bayer's patent agents' admissions that the company hid prior art (8AA 1853), Bayer's attempts to label them effectively insane (7AA 1479, 8AA 1917), and the fact that Bayer's Board was advised the patent in all likelihood would be "destroyed" (4AA 691).

winning the patent trial. (6AA 1204, citing Barr documents at 10AA 2353–75, 2377–2401.)

4. ***Tamoxifen*, the Most Permissive Approach, Is Not Soundly Grounded in High Court Precedent and Does Not Adequately Protect Consumer Interests.**

The unsettled nature of federal law multiplied when a 2-1 split decision by a Second Circuit panel approved a $21 million settlement of patent litigation concerning the breast cancer drug Tamoxifen. (See *In re Tamoxifen Citrate Antitrust Litig.* (2d Cir. 2006) 466 F.3d 187.) The majority opinion instituted a rule of presumptive *legality* that immunizes pay-for-delay settlements unless they: (1) involve a patent that was procured by fraud; (2) arise from a patent suit intentionally filed for improper purposes; or (3) contain provisions exceeding the patent's scope. (*Id.* at pp. 208-09 & fn. 22.) The Court of Appeal here adopted this rule.

The *Tamoxifen* majority acknowledged the "troubling dynamic" of exclusion payments that "inevitably protect patent monopolies that are, perhaps, undeserved." (*Tamoxifen, supra*, 466 F.3d at p. 211.) Further, "[t]here is something on the face of it that does seem 'suspicious' about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn by winning the lawsuit and entering the newly competitive market in competition with the patent holder. Why, after all—viewing the settlement through an antitrust lens—should the potential competitor be permitted to receive such a windfall at the ultimate expense of drug purchasers? We think, however, that the suspicion abates upon reflection." (*Id.* at p. 208.) But the majority never explained why its suspicion abated, and hardly seemed sure of itself: "Perhaps it is unwise to protect patent monopolies that rest on such dubious patents. But even if large reverse payments indicate a patent holder's lack

of confidence in its patent's strength or breadth, we doubt the wisdom of deeming a patent effectively invalid on the basis of a patent holder's fear of losing it." (*Id.* at p. 210.)

The majority's ruminations and evident doubt about the propriety of its rule contrast with the clarity and force of Judge Pooler's dissent. She pointed out that "consumers have no ability to affect the settlement, which, in some cases, may benefit both parties beyond any expectation they could have from the litigation itself while harming the consumer. There is a panglossian aspect to the majority's tacit assumption that the settling parties will not act to injure the consumer or competition." (*Id.* at p. 228, fn. 5 (dis. opn. of Pooler, J.).)

> The requirement that—unless an antitrust plaintiff demonstrates that a settlement agreement exceeds the scope of the patent—it must show that the settled litigation was a sham, i.e., objectively baseless, before the settlement can be considered an antitrust violation is not soundly grounded in Supreme Court precedent and is insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws. . . . A more searching inquiry and a less stringent standard are required to properly protect all interests.[24]

(*Id.* at pp. 224, 228.)

A Federal Circuit panel applied *Tamoxifen* in evaluating federal indirect purchaser claims arising from the Cipro agreements. (See *In re*

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[24] Judge Pooler proposed a Rule of Reason analysis that "would rely primarily on the strength of the patent as it appeared at the time at which the parties settled and secondarily on (a) the amount the patent holder paid to keep the generic manufacturer from marketing its product, (b) the amount the generic manufacturer stood to earn during its period of exclusivity, and (c) any ancillary anti-competitive effects of the agreement including the presence or absence of a provision allowing the parties to manipulate the generic's exclusivity period." (*Id.* at p. 228.)

Ciprofloxacin Hydrochloride Antitrust Litig. (Fed.Cir. 2008) 544 F.3d 1323.) The court cited *Tamoxifen* on nearly every page of its opinion (see *id.* at pp. 1333, 1334, 1335, 1336, 1337, 1339)—not once citing *Singer, supra*, 374 U.S. 174, and forgetting that a patent is affected with the public interest. (See *Masonite, supra*, 316 U.S. at p. 278 ["Whilst the remuneration of genius and useful ingenuity is a duty incumbent upon the public, the rights and welfare of the community must be fairly dealt with and effectually guarded. Considerations of individual emolument can never be permitted to operate to the injury of these."], quoting *Kendall v. Winsor* (1859) 62 U.S. 322, 329; see also *Line Material, supra*, 333 U.S. at p. 316 (conc. opn. of Douglas, J.) [stating that the United States Supreme Court, "faithful to the standard of the Constitution, has recognized that the public interest comes first and reward to inventors second, and has refused to let the self-interest of patentees come into the ascendency."].)

In 2010, the Second Circuit again addressed the pay-for-delay issue in connection with federal direct purchaser claims arising from the Cipro agreements. Noting, among other things, that "the United States has itself urged us to repudiate *Tamoxifen*," the court concluded "there are compelling reasons to revisit *Tamoxifen* . . . ." (*Arkansas Carpenters Health & Welfare Fund v. Bayer AG* (2d Cir. 2010) 604 F.3d 98, 108-110.) That court, however, was bound by its prior decision in *Tamoxifen* and thus unable to reach a different conclusion.[25] (*Id.* at p. 108.)

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[25] The plaintiffs' *en banc* petition was denied, over Judge Pooler's dissent. (See *Arkansas Carpenters Health & Welfare Fund v. Bayer AG* (2d Cir. 2010) 625 F.3d 779.) Judge Pooler stated that her dissent reflected not just her views, but also those of "Senior Circuit Judges Jon O. Newman and Barrington D. Parker . . . [who] are not authorized to participate in the *en banc* poll . . . ." (*Id.* at p. 779, fn. 1.)

II. The *Tamoxifen* Interpretation of the Sherman Act Neither Preempts California Law Nor Deprives the California Courts of Jurisdiction to Enforce It.

In the trial court below, Petitioners submitted evidence of the objective baselessness of Bayer's defense of its patent that satisfies even the faulty *Tamoxifen* standard. Respondents have in the past contended that the California courts lack *jurisdiction* to consider a claim framed in this fashion because it involves a substantial question of patent law—a position with which Petitioners strongly disagree. The Court of Appeal, however, went a step further, holding that federal law *preempts* any effort to establish sham litigation under the Cartwright Act if it were construed to embrace the faulty *Tamoxifen* standard.[26] (See Opinion at p. 44 [concluding that "plaintiffs' claim that Bayer's infringement suit against Barr was objectively baseless due to inequitable conduct is preempted by federal patent law because it necessarily depends on resolution of a substantial question of patent law."].)

The Court of Appeal confused the concepts of exclusive federal juridical jurisdiction and Supremacy Clause preemption, and in doing so issued a ruling that has the potential to wreak havoc in the California

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[26] Absent the misplaced sham litigation requirement, the basis for the preemption holding falls away. *Noerr-Pennington* immunity and its sham litigation requirement have no place in this analysis. The *Noerr-Pennington* antitrust doctrine safeguards the First Amendment as well as comity between branches of government. Bayer's payoff to a generic entrant simply does not implicate either of these important concerns. (Compare *Blank v. Kirwan* (1985) 39 Cal.3d 311, 320-328 [discussing the First Amendment and comity interests that justify *Noerr-Pennington* antitrust immunity], with *Tamoxifen, supra*, 466 F.3d at p. 213 [importing a sham litigation requirement from *Noerr-Pennington* jurisprudence].) The different setting of First Amendment petitioning deserves a higher bar to liability than private agreements among rivals not to compete.

courts.[27] No rational interpretation of California or federal preemption jurisprudence can support the lower court's preemption holding. Furthermore, the federal courts do not gain exclusive jurisdiction over a Cartwright Act claim just because it involves issues of patent law, and a triable issue exists even under the *Tamoxifen* standard. Bayer's subsequent "defenses" of a narrowed Cipro patent—one of which involved yet another pay-for-delay settlement—are inadmissible, and cannot be used to foreclose this claim as a matter of law and with no examination of the factual record.

A. The Cartwright Act and the UCL Are Not Preempted.

To begin with, the eagerness of the Court of Appeal to deprive Californians of the protection of the Cartwright Act contrasts with this Court's guidance that there is a "strong presumption against preemption" of California law. (*In re Farm Raised Salmon Cases* (2008) 42 Cal.4th 1077, 1088 (*Farm Raised Salmon*); see also *Elsworth v. Beech Aircraft Corp.* (1984) 37 Cal.3d 540, 548 [California courts should be "reluctant to infer preemption"].) This presumption applies with "particular force" to statutes, such as the Cartwright Act and the UCL, that fall within the State's historic police powers because they deter businesses from taking advantage of consumers. (*Farm Raised Salmon, supra*, 42 Cal.4th at p. 1088; see generally *R.E. Spriggs Co. v. Adolph Coors Co.* (1974) 37 Cal.App.3d 653, 664-666 (*Spriggs*); see, e.g., *Paduano v. American Honda Motor Co., Inc.* (2009) 169 Cal.App.4th 1453, 1473-1485 [following *Farm Raised Salmon* to hold a UCL claim not preempted].) The presumption applies with even

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[27] The court's footnote 15 (see Opinion at p. 49) will provide little comfort to future litigants hoping to use California law to vindicate their rights in patent-related disputes. The footnote betrays the court's recognition that its overbroad preemption ruling will deny relief, at minimum, to any aggrieved party whose claim involves purportedly baseless litigation.

greater force in matters related to health and safety, which states have always regulated. (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 485 [recognizing "the historic primacy of state regulation of matters of health and safety."]; see, e.g., *Physicians Committee for Responsible Medicine v. McDonald's Corp.* (2010) 187 Cal.App.4th 554, 564-574 [reversing preemption of Proposition 65's carcinogen disclosure requirement], review den., 2010 Cal. LEXIS 11033; see also *Potvin v. Metropolitan Life Ins. Co.* (2000) 22 Cal.4th 1060, 1070 [holding that health care occupies "'a special moral status and therefore a particular public interest.' [Citation.]"].)

Whether federal law preempts California law "is fundamentally a question whether Congress has intended such a result. [Citations.] ¶ The 'starting presumption' is that Congress has not so intended. [Citations.]" (*Peatros v. Bank of Am.* (2000) 22 Cal.4th 147, 157; see also *California Grocers Assn. v. City of Los Angeles* (2011) 52 Cal.4th 177, 197 [stating that "in any pre-emption analysis, the purpose of Congress is the ultimate touchstone."], citation and internal quotation marks omitted; *Black v. Financial Freedom Senior Funding Corp.* (2001) 92 Cal.App.4th 917, 926 [reversing preemption determination given the absence of "clear and manifest" Congressional intent to displace the UCL].) In addition, "because preemption of state laws by federal law or regulation generally is not favored, the party claiming federal preemption . . . has the burden to show specific state law claims are preempted." (*Smith v. Wells Fargo Bank, N.A.* (2005) 135 Cal.App.4th 1463, 1475.)

Unless Congress signaled its intent to preempt an entire legislative field, a finding of implied preemption must be supported by an actual conflict of law—hypothetical or potential conflicts are insufficient. (*Rice v. Norman Williams Co.* (1982) 458 U.S. 654, 659.) "It is not . . . a mere possibility of inconvenience in the exercise of powers, but an immediate

constitutional repugnancy that can by implication alienate and extinguish a preexisting right of [state] sovereignty."[28] (*Spriggs, supra*, 37 Cal.App.3d at p. 666, quoting *Goldstein v. California* (1973) 412 U.S. 546, 554-555, quoting Hamilton, *The Federalist No. 32.*)

The Court of Appeal failed to undertake the foregoing analysis *in toto*. It neglected to hold Respondents to their burden.[29] It failed to presume the California courts have leeway to resolve these California claims. It failed even to mention—much less determine—Congressional intent. (See footnotes 4 and 17, *supra.*) Nor did the court recognize or apply this Court's holdings that conflict preemption exists only when "simultaneous compliance with both state and federal directives is impossible" (*Viva! Int'l Voice for Animals v. Adidas Promotional Retail Operations, Inc.* (2007) 41 Cal.4th 929, 936), or that California law "will

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[28] For example, in holding that federal narcotics laws do not displace California's medical marijuana laws, the Court of Appeal observed: "It is true that California and the federal government have conflicting views of the potential health benefits of marijuana. But that does not mean the application of state and federal laws are in conflict." (*Qualified Patients Ass'n v. City of Anaheim* (2010) 187 Cal.App.4th 734, 759, review den., 2010 Cal. LEXIS 12082.) There, the court declined to find preemption as California's laws decriminalizing medical marijuana "do not mandate conduct that federal law prohibits, nor pose an obstacle to federal enforcement . . . ." (*Id.* at p. 757.)

[29] Even Respondents did not advocate the flawed view of the Court of Appeal; the Generics did not argue for preemption, while Bayer argued that interpreting the Cartwright Act to be broader than the Sherman Act, by rejecting the *Tamoxifen* standard, would lead to an impermissible conflict with federal law. (See Bayer Appellate Br., at p. 59.) Nevertheless, *California v. ARC America Corporation* (1989) 490 U.S. 93, clearly holds that Cartwright Act remedies may exceed those of the Sherman Act, and the rule of *Tamoxifen* and the federal Cipro decisions are interpretations of the Sherman Act, not of the Patent Act.

be displaced only when affirmative congressional action compels the conclusion it must be." (*In re Jose C.* (2009) 45 Cal.4th 534, 550.)

The mere fact that a state law claim involves a patent or an allegation of sham infringement litigation does not trigger the Supremacy Clause. (*Dow Chem. Co. v. Exxon Corp.* (Fed.Cir. 1998) 139 F.3d 1470, 1471-1472, 1478 (*Dow*) [reversing preemption of a state law, business competitor claim grounded in Exxon's alleged threats to file a sham infringement case: "that the source of proof of bad faith, *just one element* of the tort, was purported inequitable conduct before the PTO, does *not* make this tort a patent issue preempted by federal law"], italics added; see also *Zenith Elecs. Corp. v. Exzec, Inc.* (Fed.Cir. 1999) 182 F.3d 1340, 1351 [noting that the claim in *Dow* was not preempted even though it required proof that the patent had been obtained through inequitable conduct, "because the state law causes of action did not clash with the objectives of the patent laws, and because they included additional elements not found in the patent law remedy."].)

No conflict exists between patent law, which forbids bad faith conduct in applying for a patent, and California antitrust law, which forbids the filing of sham cases to impede competition and requires showings of antitrust injury and damages that are not required by any patent law claim. The Cartwright Act and the UCL proscribe different wrongs, and provide for different relief, than patent law and, consequently, are not displaced. (See *TruePosition, Inc. v. Andrew Corp.* (D. Del. 2007) 507 F.Supp.2d 447, 461 [asserting exclusive federal jurisdiction yet *refusing* to find a UCL claim preempted, because "[f]ederal laws do not bar state law claims that address different wrongs than those proscribed by the patent laws and that also provide for different forms of relief."], citing *Dow, supra*, 139 F.3d at p. 1477.)

The Court of Appeal's preemption decision is, respectfully, nonsensical. There is no conceivable conflict between the Cartwright Act and federal law even if the Cartwright Act is construed to be no broader than the most permissive interpretation of the Sherman Act—*i.e.*, if the *Tamoxifen* standard were to apply. Nor is there any conflict if the Cartwright Act could be seen as broader than the Sherman Act because the traditional *per se* rule applies. (See *California v. ARC America Corp.* (1989) 490 U.S. 93, 101 [holding that the Sherman Act did not preempt the broader remedies of the Cartwright Act, finding "it is plain that this is an area traditionally regulated by the states," and clarifying that state antitrust law may not be preempted absent the "clear and manifest purpose of Congress."], citation omitted.) Congress has never suggested that federal law can preempt state law claims against drug companies that transfer millions of dollars to perpetuate monopolies.

B. The California Courts Can Properly Adjudicate These State Law Claims.

Even if the Court of Appeal's preemption holding were interpreted as resulting from a finding that the California courts lack jurisdiction, the holding would still be erroneous. Just as the People of California have the right to regulate pay-for-delay settlements through the Cartwright Act, so do our courts have jurisdiction to enforce this law.

Exclusive federal jurisdiction over patent-related claims does not lie except where the claims "aris[e] under" patent law itself. (28 U.S.C. § 1338(a).) Whether a claim "arises under" federal patent law "must be determined from what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration, unaided by anything alleged in anticipation of avoidance of defenses which it is thought the defendant may interpose. [Citation.]" (*Franchise Tax Board of Calif. v. Constr. Laborers*

Vacation Trust (1983) 463 U.S. 1, 10 (*Franchise Tax Board*).) This Court has clarified that section 1338 "does not purport to cover all patent right 'question[s]' which may arise in some other kind of an 'action' or 'case' such as one based upon common law or equity; the latter actions manifestly are within the jurisdiction of the state courts." (*H. J. Heinz Co. v. Super. Ct.* (1954) 42 Cal.2d 164, 172-173, quoting *Pratt v. Paris Gas Light & Coke Co.* (1897) 168 U.S. 255, 259.) Moreover, a claim "supported by alternative theories in the complaint may not form the basis for" exclusive federal jurisdiction under section 1338 "unless patent law is essential to *each of those theories*." (*Christianson v. Colt Indus. Operating Corp.* (1988) 486 U.S. 800, 810, italics added.)

Petitioners assert no claim arising under patent law. Patent law is not essential to Petitioners' theory that Respondents' horizontal agreement violates the Cartwright Act *per se* because of its anticompetitive intent and effect. Respondents' sham litigation argument in defense cannot divest the California courts of jurisdiction. (*Franchise Tax Board, supra*, 463 U.S. at p. 10.)

It bears emphasis that these claims can be resolved without the need to determine whether the original Cipro patent was unenforceable. The *per se* rule makes any inquiry into the strength of the patent unnecessary, while the other possible rules, including *Tamoxifen*, do not require a finding of unenforceability. (See *Dairy Foods Inc. v. Dairy Maid Prods. Co-op.* (7th Cir. 1961) 297 F.2d 805, 809-810 [holding that an "adjudication that claimed patent rights are unenforceable is not an element prerequisite to the maintenance of an antitrust action for damages or injunctive relief based on misuse of the patent."], cited with approval in *Classen v. Weller* (1983) 145 Cal.App.3d 27, 38.) Given that unfair competition claims dependent upon patent validity determinations can proceed in California courts, it follows

that state law claims requiring an inquiry into the strength of a patent, but no actual finding of invalidity or unenforceability, also may proceed here.

An "antitrust action is basically a suit to recover 'for a tort[.]'" (*Associated General Contractors of California, Inc. v. California State Council of Carpenters* (1983) 459 U.S. 519, 547, fn. 2, quoting *Karseal Corp. v. Richfield Oil Corp.* (9th Cir. 1955) 221 F.2d 358, 363.) It is settled that "[p]atent matters primarily concerned with . . . tortious wrongdoing may be tried in state courts and where such a suit is brought, validity of a patent or its infringement may properly be considered by a state court." (*Miller v. Lucas* (1975) 51 Cal.App.3d 774, 776 (*Miller*).) Indeed, in California "there is broad state jurisdiction over matters affecting patents, the Supreme Court has clearly blessed such state power, and the federal courts have shown a clear lack of concern with state adjudication of such matters." (*Mattel, Inc. v. Luce, Forward, Hamilton & Scripps* (2002) 99 Cal.App.4th 1179, 1186, citing *Miller, supra*, 51 Cal.App.3d at p. 776, citing *American Well Works Co. v. Layne & Bowler Co.* (1916) 241 U.S. 257, 260 (Holmes, J.) [allowing a state law competitor claim to proceed where the defendant allegedly filed baseless patent infringement suits for business advantage; explaining "[t]he fact that the justification may involve the validity and infringement of a patent is no more material to the question under what law the suit is brought than it would be in an action of contract . . . . The State is master of the whole matter . . . ."]; see also *Lear, supra*, 395 U.S. at pp. 675-676 [remanding case to "the California Supreme Court . . . to pass on the question of patent validity"].)

In sum, Petitioners may police this conduct in California court. State jurisdiction exists because the claims arise under state, not federal, law. The federal patent laws do not displace the Cartwright Act claims because these bodies of law do not conflict, but in fact complement one

another. They target different conduct, impose different duties, and require different proof.

III. Triable Issues of Fact Exist Under the *Tamoxifen* Standard.

Because the California courts have jurisdiction to hear these claims even under *Tamoxifen*, in the event this Court agrees with that standard it should consider whether the facts and the economics of the $398.1 million payment create at least a triable question of fact on the question of whether Bayer's infringement suit against Barr was a sham. They do.

Barr's evidence of Bayer's bad faith conduct was powerful and convincing. Michael Jester, a patent attorney of 30 years' experience retained as an expert in this case, testified he had no doubt that Barr's evidence would have satisfied the clear and convincing standard for nullifying the Cipro patent. (8AA 1843–46.) Dr. Simon, Bayer's German patent agent, *admitted* that the German '850 patent application constituted prior art and the company knew about it. (8AA 1853.) Bayer, however, deceived the PTO. It intentionally failed to disclose the German applications in over six years of prosecuting its claim to Cipro.[30] (8AA 1804–29, 1852–56.)

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[30] Although Petitioners did not assert a fraud claim under *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corporation* (1965) 382 U.S. 172, the evidence in the record of Bayer's bad faith—a subset of the evidence demonstrating the objective baselessness of its patent suit—generally corresponds to the evidence that would support an affirmative claim under *Walker Process*. That decision permits a trier of fact to apply antitrust scrutiny to such evidence. (*Id.* at p. 177 ["Walker's counterclaim alleged that Food Machinery obtained the patent by knowingly and willfully misrepresenting facts to the Patent Office. Proof of this assertion would be sufficient to strip Food Machinery of its exemption from the antitrust laws. [Footnote.]"].)

Bayer's response to these admissions and the other evidence of its deception is telling. In effect, it mounted an insanity defense, claiming that its agent Dr. Simon suffered from "[d]epression serious enough to require treatment with tricyclic antidepressants," which supposedly impaired his ability to perform his job as a lawyer in Bayer's patent department. (7AA 1479.) Either the anti-depressants or some kind of "confused thinking," Bayer attested, might explain the failure of its patent department to disclose the prior art. (7AA 1479.) Or perhaps the problem was Dr. Simon's mental state when he testified about Bayer's bad faith. Bayer contended that

> the testimony of Dr. Simon, so extensively relied on by Barr, is irrelevant . . . . Dr. Simon was 72 years old and had been retired for almost 10 years with health problems when he testified in deposition about events 14 years earlier. Dr. Simon had a cerebral hemorrhage after he retired which affected his memory and overall health. He was not able to give a full day of testimony because of these problems.

(8AA 1917.)

As for the other employees who should have insisted upon disclosing the prior art, Bayer claimed that they, too, suffered from incapacitating mental problems. For instance, another of Bayer's patent lawyers, Joseph Kolodny, "suffered from Parkinson's or a related degenerative disease involving extreme mental degeneration. Parkinson's is a progressive disease and may have effects even before complete incapacitation results." (7AA 1479.)

In his expert report, Jester aptly described these contentions as "incredible and unbelievable. No person could perform such meticulous and complex legal work involving sophisticated pharmaceutical chemistry

over such an extended period of time without comprehending the consequences of his intended actions." (8AA 1856.)

Neither the trial court nor the Court of Appeal paid any attention to these facts. Rather, both found that Bayer's successful resolution of subsequent lawsuits challenging the Cipro patent "forecloses any argument" on this point as a matter of law. (Opinion at p. 41.) The approach of both lower courts turns the summary judgment standard upside down: instead of considering the evidence of Petitioners and drawing all reasonable inferences in their favor, both courts considered the (inadmissible) evidence of Respondents and gave no weight to Petitioners' facts at all.[31] (Compare, e.g., *Truong v. Glasser* (2009) 181 Cal.App.4th 102, 109-110 [court must "liberally construe *the evidence* in support of the party opposing summary judgment . . . and assess whether *the evidence* would, if credited, permit the trier of fact to find in favor of the party opposing summary judgment under the applicable legal standards."], italics

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[31] Citing *Oakland Raiders v. National Football League* (2005) 131 Cal.App.4th 621, the Superior Court made the absurd holding that it could not consider the evidence of Bayer's sham litigation because Petitioners' complaint did not set forth all of this evidence. (Order at p. 5 (11AA 2686).) The Court of Appeal discussed this issue but avoided making a holding on it. (See Opinion at pp. 40–41.) The Superior Court's holding is erroneous for at least four reasons: (1) it would improperly limit a summary judgment opposition to the facts pleaded in the complaint—drafted before any discovery; (2) Petitioners did not submit counterdeclarations, assert different claims, or invoke new legal duties in opposing summary judgment, unlike the plaintiff in *Oakland Raiders, supra*, 131 Cal.App.4th at pp. 648-649; (3) Respondents were the ones who raised sham litigation for the first time, as an affirmative defense at summary judgment, and cannot complain that Petitioners cited record evidence to contravene the defense; (4) no appellate court had endorsed the sham litigation requirement of *Tamoxifen* when Petitioners filed their operative complaint, in August 2002, and it is unreasonable to expect them to have predicted the future.

added, citing *Wiener v. Southcoast Childcare Centers, Inc.* (2004) 32 Cal.4th 1138, 1142, and *Aguilar, supra*, 25 Cal.4th at p. 850.)

Both lower courts ignored law submitted by Petitioners holding that the legality of an agreement under the antitrust laws must be evaluated as of the time it is struck, not based on *post-hoc* rationalizations for it. (See, e.g., *International Travel Arrangers v. NWA, Inc.* (8th Cir. 1993) 991 F.2d 1389, 1400 [holding that a government study of airline competition was "properly excluded as irrelevant because it dealt with a time subsequent to the events involved in this case."]; *Reazin v. Blue Cross & Blue Shield of Kansas, Inc.* (D. Kan. 1987) 663 F.Supp. 1360, 1433 [excluding a Federal Trade Commission decision because it was "rendered months after" the challenged restraint].) This law includes the very pay-for-delay federal decisions relied on by Respondents and the lower courts. (See *Valley Drug, supra*, 344 F.3d at p. 1306 ["We begin with the proposition that the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into."].)

In disregarding this principle of antitrust law, the Court of Appeal simultaneously failed to hold the trial court to the directive in *Reid v. Google, Inc.* (2010) 50 Cal.4th 512, that each evidentiary objection must be separately addressed. In *Reid*, this Court held that "[t]he trial court must rule expressly on" evidentiary objections raised in connection with a motion for summary judgment. (*Id.* at p. 532.) The Court disapproved of *Biljac Associates v. First Interstate Bank* (1990) 218 Cal.App.3d 1410, "to the extent it permits the trial court to avoid ruling on specific evidentiary objections." (*Reid, supra*, 50 Cal.4th at p. 532, fn. 8.)

Petitioners filed 30 written objections prior to the summary judgment hearing and preserved several specific objections at the hearing. (1AA 233–41; Tr. of Aug. 21, 2009 Hearing, at p. 264:8–22.) Petitioners at

all times, for example, maintained a specific objection to the admission of evidence concerning Bayer's defense of a narrowed Cipro patent in four post-1997 suits. (See Opening Br. at pp. 54–55; Reply Br. at pp. 22–23, 40–41; MSJ Opp. at p. 67 (1AA 215).) This evidence is inadmissible, as noted, because antitrust analysis considers whether an alleged restraint "promoted enterprise and productivity at the time it was adopted." (*Polk Bros., Inc. v. Forest City Enters., Inc.* (7th Cir. 1985) 776 F.2d 185, 189.)

The trial court overruled all of Petitioners' objections with a one-line, blanket statement: "Plaintiffs' evidentiary objections are overruled." (11AA 2688.) The Court of Appeal avoided applying *Reid* by resorting to a false distinction between sustaining an objection and overruling it, excusing the Superior Court's blanket ruling on the grounds that it *denied* Petitioners' objections to the evidence that Respondents submitted. (See Opinion at pp. 51–52.) This distinction has no legal basis and creates confusion around the holding in *Reid.*

The Court of Appeal also seemed to miss the point of Petitioners' objections to Bayer's subsequent patent cases: "We do not find the admission of this evidence to be prejudicial, . . . because the essential *facts* of those suits were established as undisputed by plaintiffs' responses to Bayer's separate statement of undisputed facts in support of its motion for summary judgment, Nos. 29-33." (Opinion at p. 52, fn. 16, italics added.) However, Petitioners do not dispute whether the subsequent cases occurred but, rather, seek to exclude evidence of them as inadmissible and irrelevant. (See Opening Br. at pp. 54–55; Reply Br. at pp. 22–23.) The very responses that the Court of Appeal referenced set forth the legal basis for these objections. (2AA 253–54.)

Finally, even if the facts surrounding the subsequent actions were admissible and relevant, they do not controvert or "foreclose" the facts

offered by Petitioners to show the objective baselessness of Bayer's suit. (Opinion at p. 41.) Four other potential generic competitors—Ranbaxy, Schein, Mylan, and Carlsbad—challenged the validity of a narrowed, re-examined Cipro patent in actions filed after the Cipro agreements resolved the *Bayer v. Barr* litigation.[32] Whether Bayer purposely misled the PTO was not determined in any of these suits. Bayer paid Ranbaxy over $60 million to abandon its Hatch-Waxman challenge before any issue was litigated to conclusion—protecting Cipro via yet another pay-for-delay settlement. (7AA 1522–30, 1583–84, 1586–1589, 1591–93.) Mylan withdrew its inequitable conduct defense because the company lacked sufficient time to litigate it before the '444 patent expired. (6AA 1365, 1368, 1398–99.) Neither Schein nor Carlsbad raised the defense or counterclaim of inequitable conduct. (7AA 1596, 1459, 1602.)

The Court of Appeal speculated that it "seems highly unlikely" that subsequent challengers of the Cipro patent would have abandoned the inequitable conduct issue had it been meritorious. (Opinion at p. 42.) This speculation runs contrary to the actual facts submitted by Petitioners that the challengers did not raise this issue because they lacked sufficient time to litigate it before the patent expired. (6AA 1365, 1368, 1399.)

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[32] On July 25, 1997, Bayer petitioned the PTO to re-examine the '444 Cipro patent. In its petition, Bayer voluntarily cancelled certain claims, narrowed other claims, added new claims, and belatedly disclosed the German '070 and '850 applications that it had previously failed to disclose. (7AA 1471–75, 1482–88.) Bayer thus "was able to revise and strengthen the original '444 patent so that the IP vulnerabilities identified by Barr in its original litigation were cured by Bayer." (6AA 1173, 1209; see also *Etter, supra*, 756 F.2d at pp. 857-858 [petitions for reexamination focus "on curing defects" of "patents thought 'doubtful.'"], quoting H.R. No. 66-1307, 96th Cong., 2d Sess., p. 3 (1980).)

CONCLUSION

"Consumer welfare is a principal, if not the sole, goal" of California's antitrust laws. (*Cianci v. Super. Ct.* (1985) 40 Cal.3d 903, 918.) The Cartwright Act promotes the interests of consumers by ensuring free markets, open competition and lower prices. The federal courts whose deficient analysis the Court of Appeal adopted do not share this Court's duty to protect the citizens of California. The lower court in this case misconstrued the Cartwright Act and the Unfair Competition Law. It imposed a new standard on California, frustrating the ability of the State and private citizens to obtain redress and vindicate their rights. The Court should correct the law, reverse the grant of summary judgment, and remand the claims for trial.

Respectfully submitted,

Dated: March 16, 2012

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CERTIFICATE OF WORD COUNT

[California Rule of Court 8.204(c)(1)]

Counsel of Record hereby certifies that pursuant to the California Rules of Court, this Brief of Petitioners uses 13-point Roman type and contains 18,738 words, including footnotes, which is the amount of words requested in Petitioners' Application for Leave to File an Oversized Brief, submitted herewith pursuant to Rule 8.204(c)(5). Counsel relies on the count of the computer program used to prepare this Brief.

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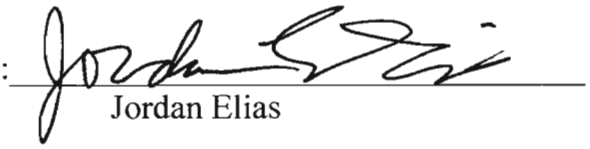
By: 
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