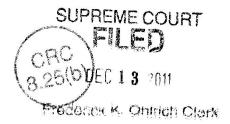
In the

# Supreme Court

of the

### State of California

IN RE CIPRO CASES I & II



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

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#### **ISSUES PRESENTED**

- 1. Does the law of California forbid a pharmaceutical patent holder from paying its competitors hundreds of millions of dollars—part of its monopoly profits—in exchange for their agreement not to sell cheaper competitive generic drugs?
- 2. Do the facts of this case demonstrating egregious patent misuse in the form of a large cash payment, made to head off likely invalidation, that drove up prescription drug prices in an area critical to social welfare, preclude federal preemption of California law?
- 3. Are the trial court and reviewing court required to expressly rule on evidentiary objections raised at summary judgment under this Court's decision in *Reid v. Google, Inc.* (2010) 50 Cal. 4th 512?

#### WHY REVIEW SHOULD BE GRANTED

This Court's review is necessary to establish the law of California with respect to the anticompetitive conduct of pharmaceutical manufacturers under the Cartwright Act, Business and Professions Code section 16700, et seq., and the Unfair Competition Law ("UCL"), Business and Professions Code section 17200, et seq.

This appeal presents issues of vital importance to the people of California. The claims focus on Bayer's \$398.1 million payoff to Barr and others for the explicit purpose of preventing Barr from entering the market and selling generic Cipro at low prices. With prescription drug prices continuing their unchecked rise, drug companies owning prescription drug patents must not be permitted to suppress competition by buying off their would-be rivals. That is why the California Attorney General's Office has denounced anticompetitive agreements like the one at issue here, finding

they cause "collusive delays" to generic drug competition and the availability of affordable prescription medicines.

The Court of Appeal erroneously blessed Bayer's \$398.1 million payment to Barr—made to secure Barr's express agreement not to compete or sell affordable generic versions of the antibiotic Cipro for nearly seven years. The payment was wrong-way or "reverse" in that Barr, the *defendant* in the litigation whose generic formulation allegedly infringed the Cipro patent, *received* massive consideration instead of paying a dime. Bayer made the payment to avoid trial on Barr's invalidity counterclaim and the resulting patent invalidation that would have taken away its monopoly profits. This was wrong.

In affirming a grant of summary judgment to these companies,
Defendants in this action, the Court of Appeal accepted a misdirected line
of recent federal authority that has no place in California jurisprudence.
This Court should grant review to prevent the adoption of this flawed line
of federal decisions as the law of California. If these decisions were to
become the law of California, the aggrieved patients and consumers who
make up this Class, and who paid high prices for Cipro from 1997 to 2004,
would be denied their right to pursue recovery of hundreds of millions of
dollars in illegal overcharges.

Denial of review would pave the way for competitors to continue flaunting California law and public policy. "Pay-for-delay" deals result in American consumers paying an additional \$3.5 billion every year in inflated prescription drug costs.<sup>2</sup> The present case involves the largest such

<sup>&</sup>lt;sup>1</sup> http://ag.ca.gov/publications/biennial\_report\_07-08.pdf, at p. 3 (Appellants' Appendix ("AA"), vol. 10, at 2337).

<sup>&</sup>lt;sup>2</sup> http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf, at p. 2.

deal of all time.<sup>3</sup> There is no better vehicle than this case to safeguard and promote consumer access to reasonably priced prescription drugs.

The Court of Appeal held that Bayer's ownership of a Cipro patent immunized Bayer from Cartwright Act liability, even though the patent had never been upheld in court at the time of Bayer's payment, and even though Bayer's payment allowed it to share its monopoly—and monopoly profits—with its competitors. The Court committed numerous errors. It misapplied California law and gave no weight to the harm Bayer's payment not to compete inflicted on patients and consumers in California. The opinion turned a blind eye to Defendants' naked horizontal market allocation, which led to drastic price increases borne by California citizens. Such agreements are per se illegal under the Cartwright Act. In deferring to recent federal decisions, the opinion failed to address applicable high court authority, including decisions of this Court, and ignored that in legitimate litigation, the patent holder does not pay the alleged infringer to settle. The opinion also misunderstood patent law, allowing a private agreement surrounding an untested—and unenforceable—patent to supply the same bulwark against competition as a fully litigated patent upheld on its merits. Indeed, the \$398.1 million payment to the patent challenger here is the functional equivalent of a victory by the entity asserting the patent was invalid. But consumers gained no benefit and ultimately funded the settlement.

The reasoning and result below are abhorrent to the central purposes of the Cartwright Act: requiring competition and protecting consumers from monopolists. See Bus. & Prof. Code section 16700, et seq.; Marin

<sup>&</sup>lt;sup>3</sup> http://democrats.energycommerce.house.gov/Press\_111/20090331/testimony\_hemphill.pdf, at p. 9 (10AA 2261).

County Bd. of Realtors, Inc. v. Palsson (1976) 16 Cal. 3d 920, 935 ("Antitrust laws are designed primarily to aid the consumer."). The decision also offends the California public policy and public interest with respect to health care. In particular, health care occupies "a special moral status and therefore a particular public interest" in California, as this Court held, and the Legislature declared, "[a]ffordability is critical in providing access to prescription drugs for California residents, particularly the uninsured and those with inadequate insurance." Potvin v. Met. Life (2000) 22 Cal. 4th 1060, 1070; Health & Safety Code § 130500; Stats. 2006, c. 619, s. 1 (A.B. 2911).

Further, if adopted as the law of California, the Court of Appeal's holding would vitiate California's patent abuse doctrine, under which California courts have long recognized that a patent holder can be found to violate the Cartwright Act through unlawful acts, even acts confined to the patent parameters. The doctrine looks to whether a patent was misused in subversion of the public interest. *See* Pages 10–19, *infra*. The Court of Appeal ignored this completely.

A jury could reasonably find that Bayer's payment was made to avoid invalidation of its Cipro patent and the price competition that would have resulted. The size of the payment (far more than Bayer's competitors stood to earn from generic Cipro sales in a competitive market), and the clear proof of Defendants' intent to foreclose competition, raise an inference of unlawful patent abuse and support a finding of Cartwright Act liability.

Payoffs to generic drug competitors are troubling. First, they eliminate competition. Second, they foreclose the testing of patents, a core

focus of the case law regarding patents and patent litigation.<sup>4</sup> Third, they lead to higher drug prices, adversely affecting the public health and welfare.<sup>5</sup> See Brief Amici Curiae of 78 Intellectual Property Law, Antitrust Law, Economics, and Business Professors in Support of Appellant, filed in the Court of Appeal on November 29, 2010. Fourth, in the area of pharmaceutical pricing, such payments blocking generic competition directly undermine the purpose of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), 21 U.S.C. § 355, which was 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.

The California Attorney General's Office, thirty-seven other state attorneys general, the Federal Department of Justice and the Federal Trade Commission have beseeched courts to overrule the rule applied below, as have a broad array of public policy, consumer protection and other non-profit organizations: the American Medical Association; AARP; the American Antitrust Institute; Consumers Union; the National Association of Chain Drug Stores; Prescription Access Litigation; Consumer Federation

<sup>&</sup>lt;sup>4</sup> Far from being sacrosanct, patents, especially pharmaceutical patents, are frequently challenged and invalidated. (6AA 1177.)

<sup>&</sup>lt;sup>5</sup> Scientific studies in peer-reviewed journals have found that many patients do not take some or all of their prescribed medicine when it is too expensive and becomes unaffordable. See, e.g., Emily R. Cox, et al., Medicare Beneficiaries' Management of Capped Prescription Benefits, Medical Care, vol. 3, at 296 (2001) (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) (9AA 1999; see also 9AA 1970–2002).

of America; the Public Patent Foundation; the National Legislative Association for Prescription Drug Prices; and U.S. PIRG.

The Court of Appeal's secondary, wide-reaching federal preemption ruling might be even more disturbing than its unquestioning adoption of the unsound federal standard. The preemption ruling will unwisely and unduly limit the ability of California courts to adjudicate disputes touching upon issues of patent law. *See* Pages 19–24, *infra*. The Court of Appeal incorrectly determined that Petitioners' basis for seeking liability conflicts with federal law. Rather, the Federal Trade Commission has found that, under federal law, these kind of anticompetitive "pay-for-delay" agreements represent "one of the greatest threats American consumers face today."

To counteract that threat, to settle legal issues of vital importance to California patients, consumers and public law enforcement officials, to provide guidance to litigants in California and throughout the United States where California law is applied, and to establish the proper balance between California competition law and federal patent law, this Court should grant review and resolve the question of first impression presented by this appeal. The opinion below should be vacated and the grant of summary judgment reversed so the claims may proceed to trial, consistent with a correct understanding of California law.

#### **BACKGROUND**

These Cartwright Act claims derive from agreements among several competitors. Defendants Bayer AG and Bayer Corp. ("Bayer") held the patent to the blockbuster anti-infection drug ciprofloxacin hydrochloride

<sup>&</sup>lt;sup>6</sup> http://www.ftc.gov/os/testimony/P040101antitrust\_laws.pdf, at p. 4 (10AA 2182).

("Cipro"). In late 1996, Bayer stood at a crossroads. Its internal financial projections showed it would earn at least \$1.614 billion in monopoly profits if it could continue to sell Cipro without competition through December 2003. However, after five years of a patent infringement action against a generic competitor, Defendant Barr Laboratories, Inc. ("Barr"), Bayer faced trial on Barr's counterclaims that the Cipro patent was invalid and unenforceable. Discovery in that case, including the testimony of Bayer's patent lawyers, established that Bayer deliberately concealed prior art from the U.S. Patent and Trademark Office ("PTO"), rendering the Cipro patent void, unenforceable, and incapable of being infringed. Trying to rebut this and other evidence of bad faith, Bayer was reduced to claiming those lawyers suffered from mental infirmities that made their testimony incredible. (7AA 1478–79.)

Confronting the likelihood that it would lose a trial on the merits—and the resulting "patent destruction," the phrase used in a Bayer Board presentation (1AA 150)—Bayer projected that nearly a billion dollars in corporate profits were at risk. Affordable generic medicine would capture 90 percent of the Cipro market within one year, and "there is no credible cost reduction strategy that would overcome such a massive hemorrhage," a Bayer vice-president wrote. (6AA 1283.) Rather than compete, Bayer conspired. Bayer paid Barr and its financial backers a \$398.1 million bribe to drop their patent challenge and terminate their efforts to compete with Bayer. (4AA 701–813.) This was an offer Barr could not refuse: it was more than double the \$148 million to \$177 million Barr predicted it would earn selling generic ciprofloxacin in a competitive market through 2003. (6AA 1203; 10AA 2352–2401.)

After making this large payment to secure the generics' agreement to stay out of the market, Bayer increased the price of Cipro by 16 percent.

(6AA 1167.) Between 1997 and 2003, Bayer gained revenues of approximately \$5.717 billion, and profits of approximately \$4.859 billion, from sales of Cipro tablets including to the California residents who make up the Class here. (6AA 1202.) Pursuant to their agreement, Bayer funded the payment to Barr and others by charging supra-competitive prices for Cipro.

Petitioners represent the certified Class of "hundreds of thousands" of California consumers and third-party payor insurers who purchased Cipro during the Class period. *In re Cipro Cases I and II* (Fourth Dist. 2004) 121 Cal. App. 4th 402, 408. Petitioners filed their consolidated amended complaint on August 5, 2002, alleging violations of the Cartwright Act, the UCL, and the common law doctrine prohibiting monopolistic acts. The case was removed to federal court, then remanded to Superior Court in San Diego.

The Superior Court granted the Defendants' motions for summary judgment on August 21, 2009, entering final judgment on September 24, 2009. The Court of Appeal affirmed, in an opinion issued on October 31, 2011. Neither the Superior Court nor the Court of Appeal applied the antitrust law of California. Instead, they limited the Cartwright Act by adopting the rule from the heavily criticized majority opinion in *In re Tamoxifen Citrate Antitrust Litigation* (2d Cir. 2006) 466 F.3d 187 ("Tamoxifen").

#### **LEGAL ARGUMENT**

Whether California law forbidding payments not to compete should be limited by *Tamoxifen* presents an important question, a question of first impression.

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 (Fourth Dist. 1999) 77 Cal. App. 4th 171, 183 n.9 (citation omitted). The Legislature enacted the Cartwright Act in 1907 "in reaction to perceived ineffectiveness" of the Sherman Act. ABA SECTION OF ANTITRUST LAW, STATE ANTITRUST PRACTICE AND STATUTES, California 6-1 (3d ed. 2004). The Cartwright Act supplies the utmost protection to California citizens, "maximizing effective deterrence of antitrust violations." Clayworth v. Pfizer, Inc. (2010) 49 Cal. 4th 758, 764.

The most recent federal appellate court to have reviewed the *Tamoxifen* standard expressed grave reservations about its soundness: "we believe there are compelling reasons to revisit *Tamoxifen* . . . ." *Arkansas Carpenters Health and Welfare Fund v. Bayer AG* (2d Cir. 2010) 604 F.3d 98, 110. That court, however, was bound by its prior decision in *Tamoxifen*, and thus unable to reach a different conclusion. *Id.* at 108. This Court, on the contrary, is not so bound. This standard cannot be reconciled with long-settled principles of antitrust law and patent law and should be rejected for California.

Additionally, the preemption holding will allow litigants to deny access to California courts simply by invoking a patent law element to otherwise redressable business and consumer disputes.

Finally, the evidentiary ruling overlooks precedent of this Court.

<sup>&</sup>lt;sup>7</sup> Tamoxifen adopted a rule of per se legality that gives a free pass to an exclusion-payment settlement except where: (1) the agreement goes outside the "exclusionary zone" of the patent; (2) the infringement suit was a sham; or (3) the patent was fraudulently procured. 466 F.3d at 213.

# A. The Court of Appeal Wrongly Eliminated the Ability of a Reasonable California Jury to Find the Cipro Market Exclusion Payment Unlawful.

Triable issues of fact exist under the Cartwright Act. Bayer's anticompetitive agreements and \$398.1 million payment violate the Cartwright Act. The agreements obtained more exclusion than was warranted in light of the prospect of patent invalidation. As a result, the agreements unreasonably restrained trade. See Bus. & Prof. Code section 16700, et seq.

The court below erroneously concluded that a patent-based agreement is immune from antitrust scrutiny if the agreement does not affect rights outside the patent's own parameters. See, e.g., Opinion at 38 ("We conclude that because the Cipro agreements undisputedly did not restrain competition beyond the exclusionary scope of the . . . patent, they do not violate the Cartwright Act."). This is incorrect. While a patent may confer a limited monopoly, it also creates opportunities for abuse. When such abuse has occurred, restraints beyond a patent's technical scope are not necessary to a finding of liability. It is settled that the antitrust law prohibits a patent owner from entering into any agreement, even one limited to the patent's scientific and temporal scope, that unreasonably restrains trade. The court below relied on a different, erroneous understanding to foreclose application of the Cartwright Act to address the Cipro agreements' unreasonably anticompetitive purpose and effect.

Consider four seminal cases that go unmentioned in the Court of Appeal's opinion. First, in *United States v. Univis Lens Company* (1942) 316 U.S. 241, 248-49, the U.S. Supreme Court deemed it "unnecessary" to antitrust liability to determine whether the defendant's patents covered the products subjected to vertical price restraints.

Second, in *United States v. Sealy, Inc.* (1967) 388 U.S. 350, 356 n.3, the Court held that it was "not consequential" whether the scheme to allocate markets affected activity "beyond the protection of the trademark[.]"

Third, the patent-based price-fixing agreement found unlawful in *United States v. Masonite Corp.* (1942) 316 U.S. 265, 376, did not confer any "monopoly or restraint other than the monopoly or restraint granted by the patents[.]" The *Masonite* Court explained that, in cases where antitrust and patent law intersect,

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. That must be the point of departure for decision on the facts of cases such as the present one lest the limited patent privilege be enlarged by private agreements so as to by-pass the Sherman Act. . . . Active and vigorous competition then tend to be impaired not from any preference of the public for the patented product but from the preference of the competitors for a mutual arrangement.

316 U.S. at 278, 281. That aptly describes what happened here.<sup>8</sup>

<sup>&</sup>lt;sup>8</sup> Judge Easterbrook has described *Masonite* in terms particularly appropriate to application in this case: "Several makers of particle board reached an agreement under which all but Masonite retired from the business; those who quit became Masonite's 'del credere agents' and sold its product at fixed prices. This was horizontal in an economically meaningful way. Producers to which consumers might turn for supply suddenly withdrew from the market. With supply down price had to rise, producing a monopoly overcharge. Although the (former) rivals contended that they were just knuckling under to the force of Masonite's patents, the Supreme Court saw a more sinister arrangement—properly so unless the patent was both broad and iron-clad, which could not be known once the former rivals started cooperating." *Illinois Corporate Travel v. American Airlines* (7th Cir. 1989) 889 F.2d 751,753. While the Cipro patent may

Fourth, the Court of Appeal also failed to mention the seminal decision in *United States v. Singer Mfg. Co.* (1963) 374 U.S. 174, involving a clear antitrust violation: American, Italian, and Swiss sewing machine companies arrived at patent settlements to head off an open destructive fight over validity. 374 U.S. at 180, 185. "There is a public interest here," Justice White wrote in concurrence, "which the parties have subordinated to their private ends" through agreements "between business rivals to encroach upon the public domain and usurp it to themselves." *Id.* at 200 (White, J., concurring). That is what happened here.

As these and other cases demonstrate, 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 (emphasis added). The present case involves the former, not the latter situation—and the question of whether Bayer misused its patent is for the jury.

Despite the triable issues arising from the Cipro agreements and from Bayer's \$398.1 million payment to avert competition, the Court of Appeal held that the payment deserves a *presumption of legality* because it was made to settle litigation and the law generally favors settlement. See Opinion at 28–30. To the contrary, California law does *not* authorize or condone settlements that violate public policy, particularly a settlement where competitors are paid off to prevent competition. *Timney v. Lin* (First

have been broad, the evidence shows it was far from iron-clad. Indeed, Bayer paid as much as it did in clear-eyed recognition of the *likelihood of invalidity*.

<sup>&</sup>lt;sup>9</sup> There is no California statute—or for that matter a federal analogue—that specifically authorizes or protects settlements.

Dist. 2003) 106 Cal. App. 4th 1121, 1127; River Garden Farms, Inc. v. Super. Ct. (Third Dist. 1972) 26 Cal. App. 3d 986, 1000; see also Singer, 374 U.S. 174 (patent settlements violated the antitrust laws).

Apparently, the Court of Appeal was concerned that scrutiny of these agreements under antitrust law might chill patent litigation or settlements. See Opinion at 35-36. The concern is entirely misplaced. For example, the record shows that pharmaceutical companies do not need to make cash payments in order to settle patent litigation. Between 2000 and 2004—when such payments were held to be per se illegal under In re Cardizem CD Antitrust Litigation (6th Cir. 2003) 332 F.3d 896—"not one of twenty reported agreements involved a brand firm paying a generic filer to delay entering the market. During this period, parties continued to settle 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 period, when such agreements were treated as illegal and pharmaceutical companies conducted themselves accordingly, the patent system continued to operate, innovation continued. new products came to market and parties litigated their patent disputes in court, settling virtually all of them. In contrast, the subsequent retreat by certain federal courts from the Cardizem regime has led to growing numbers of anti-consumer "pay-for-delay" settlements featuring monetary consideration. Fourteen such deals were reached in 2007, 16 in 2008, 19 in 2009, 31 in 2010, and 28 (to date) in 2011. No one seriously disputes that such agreements are anticompetitive and lead to higher prices.

<sup>10</sup> http://www.ftc.gov/os/2011/10/1110mmachart.pdf.

The Court of Appeal further based its erroneous holding on the rebuttable presumption of patent validity. See Opinion at 31, 33. The Court of Appeal misinterpreted this presumption as irrebuttable, foreclosing plaintiffs from offering evidence to overcome it. Yet a presumption that cannot be rebutted is no presumption at all. The "only effect" of a rebuttable presumption is "to shift the burden of producing evidence with regard to the presumed fact. If that evidence is produced by the adversary, the presumption is spent and disappears." 2 McCormick on Evid. § 344 (6th ed. 2006).

The Court of Appeal wrongly treated patents as *conclusively* valid when they are only presumptively valid. *See* 35 U.S.C. § 282. In fact, the statutory presumption of patent validity is only "a procedural device, not substantive law," and it does not apply except in a full adjudication on the merits. *Stratoflex, Inc. v. Aeroquip Corp.* (Fed. Cir. 1983) 713 F.2d 1530, 1534; *Nutrition 21 v. United States* (Fed. Cir. 1991) 930 F.2d 867, 869.

Nevertheless, adopting *Tamoxifen*, the Court of Appeal held that holders of "fatally weak" patents can maintain their monopolies with cash payments even when those payments violate the Cartwright Act by eliminating competition to an unreasonable degree. 466 F.3d at 212. The "fatally weak" concession reveals *Tamoxifen*'s fatal flaw—its affront to the important principle "that competition should not be repressed by worthless patents[.]" *United States v. Glaxo Group Ltd.* (1973) 410 U.S. 52, 58. In 2009, the United States Department of Justice opposed *Tamoxifen* on this ground, stating it "offers no protection to the public interest in eliminating undeserved patents" and "[t]here is no basis for a standard that treats the presumption of validity as virtually conclusive and allows it to serve as a

substantive basis to limit the application of" antitrust law. 11 See also Tamoxifen, 466 F.3d at 224 (Pooler, J., dissenting) (finding that the majority's rule "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.").

Judge Pooler is correct. The United States Supreme Court has "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

http://www.justice.gov/atr/cases/f247700/247708.htm (11AA 2569, 2572–73). The DOJ has consistently taken the position that *Tamoxifen* should be revisited and overturned. In 2007, Paul Clement—the United States Solicitor General under the Administration of George W. Bush—criticized the *Tamoxifen* standard as "erroneous" and "insufficiently stringent . . . for scrutinizing patent settlements." http://www.justice.gov/osg/briefs/2006/2pet/6invit/2006-0830.pet.ami.inv.pdf, at pp. 12-13.

Likewise, FTC Commissioner Thomas Rosch observed that "[s]ince this issue first arose in 1998, every single member of the Commission, past and present—whether Democrat, Republican, or Independent—has supported the Commission's challenges to anticompetitive 'pay-for-delay' deals. . . . The threat that these agreements pose to our nation's health care system is a matter of pressing national concern. . . . [T]hese settlements are harmful because the parties are resolving their dispute at the expense of consumers." (9AA 2008, 2018.)

In 2009, then-Attorney General Brown joined the FTC in filing antitrust claims against pharmaceutical companies that—through exclusionary settlement agreements—"plotted to keep cheap generic drugs off the market, costing consumers millions. This was a predatory move pure and simple, increasing drug company profits at the expense of critically ill patients." (9AA 2004.)

making the defense, 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, 399-401. The public stands to gain, in the form of lower aggregate prices, from adversarial testing of vulnerable patents; so the law "encourage[s] authoritative testing of patent validity." *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.* (1971) 402 U.S. 313, 343-44 (citing, in part, *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.* (1945) 324 U.S. 806, 816); *see also United States v. Line Material Co.* (1948) 333 U.S. 287, 319 (Douglas, J., concurring) (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"). *Tamoxifen*, on the other hand, allows the owner of an invalid patent to short-circuit adversarial testing of that patent by doling out a large chunk of its monopoly profits.

The sheer enormity of Bayer's payment—more money even than Barr stood to gain from selling generic Cipro—raises a powerful inference that the Cipro patent was a "paper tiger" with no bite or ability to defend Bayer's monopoly. <sup>12</sup> Cardizem, 332 F.3d at 915. Valid patents are enforced against infringers through *injunctions*, not private deals and cash pay-offs. Bayer must not be permitted to *pay* for a monopoly that its patent likely could not sustain. The court below ruled to the contrary.

<sup>&</sup>lt;sup>12</sup> The leading antitrust law treatise concludes that market-exit payments to generic manufacturers disproportionately 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 . . . ." 12 Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 2046, at 333 (2d ed. 2003).

The Court of Appeal mistakenly relied on subsequent litigation in which Bayer defended an amended, "cleaned up" Cipro patent, failing to see that Bayer's intervening petition seeking reexamination of the patent itself raises suspicion that the original Cipro patent would have been found unenforceable. *In re Etter* (Fed. Cir. 1985) 756 F.2d 852, 857-58 (en banc) (purpose of a re-examination petition is to "cur[e] defects" in "patents thought 'doubtful.") (citation omitted). Moreover, the court also ignored that such evidence is inadmissible because it postdates the restraint under scrutiny: Bayer's 1998 bribe. *See* Page 25, *infra*.

Neither the general policy in favor of settlement, nor the rebuttable presumption of patent validity, overcomes the venerable California rule against such cash payments to perpetuate monopolies. "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." Wright v. Ryder (1868) 36 Cal. 342, 359 (emphasis in original) (citations omitted) (nullifying payment made to block a competing steamship firm from entering the California market).

In Vulcan Powder Company v. Hercules Powder Company (1892) 96 Cal. 510, this Court invalidated a horizontal market allocation contract between competitors who claimed they were harmlessly exchanging their patent rights to dynamite. Rejecting this defense, the Court found it significant that the plaintiff and another party to the contract did not own a dynamite patent. This fact established that the money those parties received did not result from their sale or exchange of patent rights. Instead—like Barr in the present case—they received money only in exchange for their agreement not to compete, not because of a valid patent. Id. at 515 ("[I]t is obvious that the consideration moving from them was their covenant to refrain from competition in the dynamite business, and

that they had no patent rights to 'interchange.'"). The Court went on to note that the restraints in question exceeded the technological scope of the patent at issue. This was presented as an aggravating, not a dispositive, factor in the antitrust analysis. *Id*.

The Court of Appeal ignored *Vulcan* and its teachings, while misconstruing another relevant California precedent, Fruit Machinery Company v. F. M. Ball & Company (First Dist. 1953) 118 Cal. App. 2d 748. 13 See Opinion at 34-35. The divergent royalty rates challenged in Fruit Machinery passed scrutiny under the Cartwright Act, 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 762. Indeed, the court acknowledged 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. Id. 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 not accorded them by the patent law or abused any rights or powers accorded them by that law." Opinion at 34 (quoting Fruit Machinery, 118 Cal. App. 2d at 762) (emphasis added).

<sup>&</sup>lt;sup>13</sup> According to the California Court of Appeal, "[t]he leading federal authority" on antitrust injury arising from patent litigation is *Dairy Foods Inc. v. Dairy Maid Prods. Co-op.* (7th Cir. 1961) 297 F.2d 805. *Classen v. Weller* (First Dist. 1983) 145 Cal. App. 3d 27, 38. But elements of the *Tamoxifen* rule upend a key holding in *Dairy Foods*, 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*." 297 F.2d at 809-10 (emphasis added).

Bayer's horizontal allocation of monopoly profits from the likely unenforceable Cipro patent was abusive. Between its oversize cash payment to the alleged infringer, its subsequent price hikes, and its weak defense of its patent (based on contentions that its patent agents were insane), <sup>14</sup> the record here contains strong evidence of abusive conduct, more than enough to reach a jury. Corwin v. Los Angeles Newspaper Serv. Bureau, Inc. (1971) 4 Cal. 3d 842, 855 ("Whether a restraint of trade is reasonable in the context of the Cartwright Act is a question of fact to be determined at trial."). Had the Court of Appeal properly applied California law, a jury could also have concluded that the Cipro agreements lacked "any redeeming virtue." Opinion at 32. <sup>15</sup>

### B. The Preemption Ruling Incorrectly and Imprudently Restricts the Scope of California Law.

Because patents restrain competition, California courts strictly construe the rights of patent holders in light of the California "policy

<sup>&</sup>lt;sup>14</sup> As Petitioners' expert in patent practice, Michael H. Jester, observed, Bayer's assertions that its patent agents "had mental problems and by inference that this somehow demonstrates a lack of intent to deceive, are 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.)

<sup>15</sup> The Court of Appeal's final comment regarding this important question of law (see Opinion at 38, fn. 9) reflects nothing less than a complete abdication of its judicial responsibilities. "[T]he courts are the ultimate arbiters of the construction of a statute." California Ass'n of Psychology Providers v. Rank (1990) 51 Cal. 3d 1, 7. It is clear that the Hatch-Waxman Act was intended to prohibit the agreements at issue here. "As co-author of the [Hatch-Waxman] Act, I can tell you that I find these type of reverse payment collusive arrangements appalling," Senator Hatch said. (10AA 2234.) See Arkansas Carpenters, 604 F.3d at 109 ("[R]emarks by an Act's author do not trigger the typical concern about post-enactment legislative history, namely that 'the losers in the legislative arena hope to persuade the courts to give them the victory after all." (citations omitted)).

favoring free competition, dissemination of ideas and maximum utilization of intellectual resources." *Sinclair v. Aquarius Elec., Inc.* (First Dist. 1974) 42 Cal. App. 3d 216, 224 (citation omitted). The Court of Appeal's preemption ruling, however, threatens to prevent state courts from adjudicating cases touching on patents at all. That is why the attorneys general of thirty-eight States, including California, opposed federal preemption in this context, noting it would "thwart the states' express intention to provide monetary recovery to their consumers for antitrust violations." *Amici Curiae* Brief of Thirty-Eight States, 2008 WL 576744, at \*3 (Fed. Cir. 2008).

The Court of Appeal did not apply California law but instead limited it, based on its wholesale adoption of *Tamoxifen*. The court held that, because the Cipro agreements did not go beyond the scope of the patent (and because Petitioners do not claim fraudulent patent procurement), Petitioners must establish sham litigation to maintain a Cartwright Act claim. The court then held that any effort to establish sham litigation is preempted by federal law. Under this analysis, the scope of the Cartwright Act is—exactly zero. That cannot be.

The court's footnote 15 (see Opinion at 49) will provide small 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 sweeping and unprecedented preemption ruling will shut the courthouse door, at a minimum, to any aggrieved party whose claim involves purportedly baseless infringement litigation.

As an initial matter, *Noerr-Pennington* antitrust immunity and its sham litigation requirement do not belong in this analysis. The decision to apply *Noerr-Pennington* immunity is plainly wrong and alone warrants review. The *Noerr-Pennington* doctrine safeguards the First Amendment

as well as comity between branches of government—neither of which is implicated by Bayer's payoff. Compare Blank v. Kirwan (1985) 39 Cal. 3d 311, 320-28 (discussing the First Amendment and comity interests which justify Noerr-Pennington antitrust immunity), with Tamoxifen, 466 F.3d at 213 (importing the sham litigation requirement from Noerr-Pennington jurisprudence).

A California court should be empowered to adjudicate these damage claims, even if liability depends on whether Bayer's infringement suit was baseless. The claims arise under state law, so jurisdiction exists; and they are not displaced by federal law because they entail separate, extra showings, beyond Bayer's deceptive conduct before the PTO, in order for liability to be established. Under the Cartwright Act, the fact finder would necessarily have to decide whether the payment had anticompetitive effects. But, the fact finder would not need to decide whether the original Cipro patent was unenforceable to find the Cartwright elements satisfied. *Dairy Foods*, 297 F.2d at 809-10.

Unfair competition claims that depend on patent validity determinations can proceed in California court. *Mattel, Inc. v. Luce, Forward, Hamilton & Scripps* (Second Dist. 2002) 99 Cal. App. 4th 1179, 1186 (citing *Miller v. Lucas* (Second Dist. 1975) 51 Cal. App. 3d 774, 776 (citing *American Well Works Co. v. Layne & Bowler Co.* (1916) 241 U.S. 257 (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 Dow Chem. Co. v. Exxon Corp. (Fed. Cir. 1998) 139 F.3d 1470, 1475 ("[A]lthough a state

court is without power to invalidate an issued patent, there is no limitation on the ability of a state court to decide the question of validity when properly raised in a state court proceeding.") (citation omitted); *Lear v. Adkins* (1969) 395 U.S. 653, 675-76 (instructing California courts to resolve patent invalidity defense in state-law breach of contract action); *Kewanee Oil Co. v. Bicron Corp.* (1974) 416 U.S. 470, 492 (vacating and remanding case to "the California Supreme Court . . . to pass on the question of patent validity"). In cases arising under state law, then, California courts have the express authority "to determine matters of title, infringement or validity of patents where such determination is ancillary and necessary to the main action." *Blumenfeld v. Arneson Prods., Inc.* (First Dist. 1971) 172 U.S.P.Q. 76, 78.

Although Petitioners' claims unmistakably arise under California law, the Court of Appeal neglected to apply the "strong presumption against preemption" of California law. In re Farm Raised Salmon Cases (2008) 42 Cal. 4th 1077, 1088 (emphasis added). This presumption applies with particular force to statutes, such as the Cartwright Act, that fall within the State's historic police powers because they deter businesses from taking advantage of consumers. Id.; R.E. Spriggs Co. v. Adolph Coors Co. (Second Dist. 1974) 37 Cal. App. 3d 653, 664-66. Nor did the Court of Appeal even pay lip service to this Court's recent guidance that conflict preemption exists only when "simultaneous compliance with both state and federal directives is impossible," and that California law "will be displaced only when affirmative congressional action compels the conclusion it must be." Viva! Int'l Voice for Animals v. Adidas Promotional Retail Operations, Inc. (2007) 41 Cal. 4th 929, 936; In re Jose C. (2009) 45 Cal. 4th 534, 550.

Applying these standards, the Defendants easily could have complied with both federal law and California law, had they simply refrained from trying to make a \$398.1 million deal to protect a tenuous monopoly and avoid a trial on the weak Cipro patent. As for Congress, it has never suggested that federal law displaces state-law claims against drug companies that transfer millions of dollars to perpetuate dubious monopolies. Senator Hatch has called such deals "appalling," and a Senate Judiciary Committee report strongly condemned "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* . . . ."

That one source of proof in the analysis would be Bayer's inequitable conduct before the PTO scarcely renders these claims preempted. In *Dow*, the court reversed a holding that federal patent law preempted a state-law unfair competition claim grounded in allegations that Exxon had threatened baseless infringement litigation. *Id.* at 1471-72. Even though the claim depended on a showing of Exxon's alleged inequitable conduct before the PTO, the claim did not impermissibly conflict with federal law. The business tort at issue in *Dow*, like the Cartwright Act and UCL claims here,

is not premised upon bad faith misconduct in the PTO, but rather is premised upon bad faith misconduct in the marketplace. . . . [I]t plainly is not a preempted alternative or additional state law remedy for inequitable conduct. Rather it is a long-established independent tort remedy for improprieties in the marketplace.

<sup>&</sup>lt;sup>16</sup> 148 Cong. Rec. S 7566 (daily ed. July 30, 2002) (10AA 2234).

<sup>&</sup>lt;sup>17</sup> Report entitled "The Drug Competition Act of 2001," S. Rep. No. 107-167 (2002), at 4 (emphasis added) (10AA 2239).

Id. at 1477. Moreover, "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 . . . ." Id. at 1477-78 (emphasis here).

Dow is instructive here. Even if Petitioners' Cartwright Act claim were to require proof that Bayer's infringement suit was a sham, and even if such proof, in turn, depended on a showing of Bayer's inequitable conduct before the PTO, Petitioners can prevail only if they also show that Bayer's \$398.1 million payment had anticompetitive intent and effects. See CACI 3411 (Cartwright Act jury instructions setting forth traditional Rule of Reason antitrust analysis). Therefore, the state-law claims here are not coterminous with or dependent upon the federal defense of inequitable conduct, and, like the business competitor claim in Dow, are not preempted.

Petitioners' claims under California law are consistent with the objectives of federal law. See Palmer v. BRG of Ga., Inc. (1990) 498 U.S. 46, 50 (under federal law, an agreement that precludes a potential competitor from market entry is "unlawful on its face."). The Court of Appeal's preemption ruling is not only wrong, but it abandons the citizens of California.

C. The Court of Appeal Misapplied California Supreme
Court Precedent by Condoning the Trial Court's Blanket
Overruling of Petitioners' Evidentiary Objections, and by
Failing to Resolve the Objections.

The Court of Appeal failed to require the trial court to rule on Petitioners' written objections to the evidence, contravening this Court's recent ruling in *Reid v. Google, Inc.* (2010) 50 Cal. 4th 512. In *Reid*, the Court held that "[t]he trial court must rule expressly on" evidentiary objections raised with a motion for summary judgment. *Id.* at 532. The

Court disapproved of *Biljac Associates v. First Interstate Bank* (First Dist. 1990) 218 Cal. App. 3d 1410, "to the extent it permits the trial court to avoid ruling on specific evidentiary objections." *Reid*, 50 Cal. 4th at 532 n.8.

The Court of Appeal failed to hold the trial court to this Court's clear directive in *Reid* that each evidentiary objection must be separately addressed. Instead, the Court of Appeal created a false distinction between sustaining an objection and overruling it, excusing a trial court's blanket ruling so long as it only overrules objections. Opinion at 51–52. This distinction has no basis in law and creates confusion around the Court's ruling in *Reid*.

Petitioners filed 30 evidentiary objections prior to the summary judgment hearing and preserved several specific objections at the hearing. (1AA 233-241; Tr. of Aug. 21, 2009 Hearing, Reporter's Transcript, at 264:8–22.) Petitioners at all times, for example, maintained a specific objection to the admission of evidence concerning Bayer's successful defense of a re-examined Cipro patent in four post-1998 cases. (Opening Br. at 54-55, 65-55; Reply Br. at 22-23, 40-41; MSJ Opp. at 67 (1AA 215).)

This evidence is inadmissible because the trier of fact must weigh a given restraint's effect on active and vigorous competition against the extent to which it "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 (emphasis added); see 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.").

The trial court nevertheless overruled all of Petitioners' objections in a one-line blanket statement: "Plaintiffs' evidentiary objections are

overruled." (11AA 2688.) Neither the trial court nor the Court of Appeal actually ruled on Petitioners' individual objections, and, in finding no error in the trial court's terse blanket overruling, the Court of Appeal seemed to miss the entire 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 52, fn. 16 (emphasis added). Petitioners did not dispute whether the subsequent patent cases occurred, but instead sought to exclude evidence of them as irrelevant and inadmissible. (*See* Opening Br. at 54–55; Reply Br. at 22–23.) Indeed, Petitioners reiterated their position on irrelevancy and inadmissibility in the very responses the Court of Appeal cited. (2AA 253–54.)

To prevent confusion and similar misapplication of law, this Court should grant review and reiterate that courts must rule on specific evidentiary objections.

#### **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 federal courts whose faulty analysis the Court of Appeal adopted do not share this Court's obligation to protect the citizens of California. Adopting Tamoxifen misconstrues the Cartwright Act and the Unfair Competition Law. It imposes a new standard on California, impairing the ability of the State and private citizens to vindicate their rights. The Court should grant review to fulfill its obligation to the People and to settle these important questions of law.

#### Respectfully submitted,

Dated: December 12, 2011

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

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

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Dated: December 12, 2011

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

By: Hend Laven



LIEFF, CABRASER, HEIMANN

J. 61 71:

#### CERTIFIED FOR PUBLICATION

# COURT OF APPEAL, FOURTH APPELLATE DISTRICT

### **DIVISION ONE**

#### STATE OF CALIFORNIA

IN RE CIPRO CASES I & II

D056361

(JCCP Nos. 4154 & 4220) [Nine coordinated cases\*]

APPEAL from a judgment of the Superior Court of San Diego County, Richard E. L. Strauss, Judge. Affirmed.

Lieff, Cabraser, Heimann & Bernstein, Joseph R. Saveri, Eric B. Fastiff, Brendan Glackin, Jordan Elias, Dean M. Harvey; Krause, Kalfayan, Benink & Slavens, Ralph B. Kalfayan; Zwerling, Schachter & Zwerling and Dan Drachler for Plaintiffs and Appellants.

Mark A. Lemley for 78 Law, Economics, Business and Public Policy Professors as Amici Curiae on behalf or Plaintiffs and Appellants.

Edleson & Rezzo, Joann F. Rezzo; and Kathryn E. Karcher for Defendants and Respondents.

Luce, Forward, Hamilton & Scripps, Charles A. Bird, Christopher J. Healey, Todd R. Kinnear; Jones Day, Kevin D. McDonald; Bartlit Beck Herman Palencher & Schott and Peter B. Bensinger, Jr., for Defendant and Respondent Bayer Corporation.

Stinson, Morrison, Hecker, David E. Everson, Heather S. Woodson and Victoria Smith for Defendants and Respondents Hoechst Marion Roussel, Inc., The Rugby Group, Inc., and Watson Pharmaceuticals, Inc.

Kirkland and Ellis, Edwin John U, Karen N. Walker, and Gregory Skidmore for Defendant and Respondent Barr Laboratories, Inc.

The plaintiffs in this coordinated class action proceeding sued brand-name drug manufacturer Bayer AG and its subsidiary Bayer Corporation (collectively Bayer); generic drug manufacturers Barr Laboratories, Inc. (Barr), Hoechst Marion Roussel, Inc. (HMR), and HMR's former subsidiary The Rugby Group, Inc. (Rugby) (collectively the generic defendants); and Watson Pharmaceuticals, Inc. (Watson), which purchased Rugby from HMR. Bayer manufactures and markets Cipro, the brand name for ciprofloxacin hydrochloride (ciprofloxacin), an antibiotic prescribed for the treatment of infections. Bayer owned U.S. Patent No. 4,670,444 (the '444 patent), which claimed the ciprofloxacin hydrochloride molecule, until the patent expired in December 2003. Plaintiffs asserted causes of action against all defendants for violation of the Cartwright Act (Bus. & Prof. Code, § 16720 et seq.); violation of the Unfair Competition Law (UCL) (Bus. & Prof. Code, § 17200 et seq.); and common law monopolization, arising from an agreement settling litigation between Bayer and Barr concerning the validity of Bayer's '444 patent and related agreements involving the other defendants (collectively, the Cipro agreements or Cipro settlement). Plaintiffs appeal from a judgment entered in favor of defendants after the court granted summary judgment motions filed by Bayer, the generic defendants, and Watson.

Plaintiffs contend (1) the court erred by not ruling that the Cipro agreements are unlawful per se; (2) if the Cipro agreements are not unlawful per se, there is a triable issue of fact as to whether they violate the Cartwright Act under the "rule of reason applied in antitrust cases;" (3) the court followed incorrectly decided federal court decisions in ruling that the Cipro agreements were lawful because they did not restrict competition outside the exclusionary zone of the '444 patent; (4) there is a triable issue of fact under the case law the court followed; (5) the court erred in ruling that it did not have jurisdiction to determine whether Bayer engaged in fraud or inequitable conduct in obtaining the '444 patent because that determination involves substantial questions of patent law; (6) the court erred in granting Watson's motion for summary judgment; and (7) the court erred by not providing any explanation for overruling all of plaintiffs' evidentiary objections.

We hold that a settlement of a lawsuit to enforce a patent does not violate the Cartwright Act if the settlement restrains competition only within the scope of the patent, unless the patent was procured by fraud or the suit for its enforcement was objectively baseless. Because the Cipro agreements undisputedly did not restrain competition beyond the exclusionary scope of the '444 patent, we conclude they do not violate the Cartwright Act. We further conclude that plaintiffs' claim that Bayer's infringement suit against Barr was objectively baseless due to Bayer's inequitable conduct before the U.S. Patent and Trademark Office (PTO) in procuring the patent is preempted by federal patent law because plaintiffs' right to relief on that claim necessarily depends on

resolution of a substantial question of federal patent law. Accordingly, we affirm the judgment.

# FACTUAL AND PROCEDURAL BACKGROUND

## A. The '444 Patent

Bayer's '444 patent covers or "claims" the ciprofloxacin hydrochloride molecule, which is the active ingredient in Cipro. The '444 patent expired in December 2003, but the United States Food and Drug Administration (FDA) granted Cipro pediatric exclusivity until June 9, 2004. Consequently, no generic ciprofloxacin product could be lawfully marketed before June 9, 2004, under federal law. (21 U.S.C. § 355a.)

#### B. Hatch-Waxman Act

In 1991 Barr sought FDA approval of a generic version of Cipro under the federal Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) (21 U.S.C. § 355). The Hatch-Waxman Act streamlined the process of obtaining approval of generic versions of branded drugs by allowing a generic manufacturer to file an abbreviated new drug application (ANDA) under 21 United States Code section 355(j). (Merck KGaA v. Integra Lifesciences I, Ltd. (2005) 545 U.S. 193, 196, fn. 1.)

The generic manufacturer does not have to make an independent showing that the generic drug is safe and effective; it need only show that the drug contains the same active ingredients as, and is bioequivalent to, the branded drug. (Ibid., citing 21 U.S.C. § 355(j)(2)(A)(ii) & (iv); § 355(j)(8)(B).)

Regarding any patents that claim the branded drug, the generic manufacturer's ANDA must certify one of the following: "(I) that such patent information has not been

filed, [¶] (II) that such patent has expired, [¶] (III) . . . the date on which such patent will expire, or [¶] (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." (21 U.S.C. § 355(j)(2)(A)(vii).)

A generic manufacturer that files a paragraph IV certification (ANDA IV) must give notice of the certification to any affected patent owners. (21 U.S.C. § 355(j)(2)(B).) The service of the ANDA IV gives an affected patent owner 45 days to file a patent infringement lawsuit against the generic manufacturer. (21 U.S.C. § 355(j)(2)(B)(iii).) If the patent owner files an infringement suit within the 45-day period, FDA approval of the generic manufacturer's ANDA is stayed for 30 months or until a federal district court enters a decision that patent is invalid or not infringed. (21 U.S.C. § 355(j)(2)(B)(iii)(I); In re Ciprofloxacin Hydrochloride Antitrust Litigation (E.D.N.Y. 2003) 261 F.Supp.2d 188, 193 (Cipro I).)

As an incentive for generic manufacturers to file ANDA IV certifications and challenge patents on brand-name drugs, the first ANDA IV filer has the right to exclusively market its generic version of the branded drug for 180 days from the date it begins to commercially market the drug or the date of a final court decision finding the branded drug's patent to be invalid or not infringed. (21 U.S.C. § 355(j)(5)(B)(iv); 21 C.F.R. § 314.07(c)(1) (2009); Cipro I, supra, 261 F.Supp.2d at p. 193.)

C. Barr's ANDA and the Ensuing Patent Litigation

In October 1991 Barr filed an ANDA for a generic version of Cipro with an ANDA IV certification asserting that Bayer's '444 patent was invalid or would not be

infringed by the manufacture, use or sale of Barr's generic ciprofloxacin. After receiving notice of Barr's ANDA IV, Bayer filed a patent infringement suit against Barr in the United States District Court for the Southern District of New York. Barr filed affirmative defenses and counterclaims alleging that the '444 patent was invalid and unenforceable due to Bayer's inequitable conduct before the U.S. Patent and Trademark Office (PTO) in procuring the patent.

In March 1996 Barr and Rugby entered into an agreement under which Rugby agreed to finance a portion of the cost of Barr's patent litigation and Barr agreed to provide Rugby half of the profits from its sale of generic ciprofloxacin. In December 1996 Barr, Rugby, and HMR executed an amendment to that agreement providing that HMR succeeded to all of the rights and obligations of Rugby under the agreement.

# D. The Cipro Agreements

In January 1997, after the district court in the patent litigation had denied cross-motions for partial summary judgment filed by Bayer and Barr and the case had been set for trial, Bayer settled the patent litigation with Barr and other generic drug manufacturers by entering into the Cipro agreements, which consisted of three separate settlement agreements—one with Barr, one with nonparties HMR and Rugby, and one with nonparties Bernard Sherman (Sherman) and Apotex, Inc. (Apotex)—and a "supply agreement" with Barr and HMR.

Under the settlement agreements, Barr, HMR, Rugby, Sherman, and Apotex acknowledged the validity of the '444 patent and related patents held by Bayer. In the settlement agreement between Bayer and Barr, Barr agreed to amend its ANDA to

change its ANDA IV certification to an ANDA III certification, precluding Barr from obtaining FDA approval to market generic Cipro until the '444 patent expired. The agreement also provided for an immediate payment of \$49.1 million from Bayer to a "Barr Escrow Account."

Under the supply agreement, Barr and HMR agreed not to manufacture ciprofloxacin or have it manufactured in the United States. The supply agreement gave Bayer the option of either supplying ciprofloxacin that it manufactured to Barr and HMR for distribution in the United States or making quarterly payments to Barr from January 1998 until the '444 patent expired. Bayer chose to make the payments. By December 2003 when Bayer ceased making payments, its payments to Barr totaled approximately \$398 million, including the initial payment of \$49.1 million.

# E. Reexamination of and Subsequent Challenges to the '444 Patent

After settling the patent litigation, Bayer filed a request for reexamination of the '444 patent with the PTO. The PTO issued a reexamination certificate confirming the patent's validity, including the validity of claim 12, which covered the ciprofloxacin hydrochloride molecule. (See *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (E.D.N.Y. 2005) 363 F.Supp.2d 514, 519 (*Cipro II*).) Subsequently, four generic manufacturers—Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Laboratories Limited (collectively Ranbaxy), Schein Pharmaceutical, Inc., (Schein) Mylan Pharmaceuticals, Inc. and Mylan Laboratories, Inc. (collectively Mylan), and Carlsbad Technology, Inc.—filed ANDAs for ciprofloxacin with ANDA IV certifications and challenged the

validity of the reexamined '444 patent in infringement actions that Bayer filed against them,

Ranbaxy withdrew its ANDA IV certification and stipulated with Bayer to the dismissal of the claims and counterclaims in the patent action between them after entering into a licensing agreement with Bayer. Bayer successfully moved for summary judgment against Schein, Mylan and others on the validity of the '444 patent. (*Bayer AG & Bayer Corp. v. Schein Pharmas*, (D.N.J. 2001) 129 F.Supp.2d 705, affd. (Fed.Cir. 2002) 301 F.3d 1306.) After a bench trial, a federal district court upheld the validity of the '444 patent and ruled in favor of Bayer in its infringement action against Carlsbad Technology, Inc.

## F. Federal Cipro Litigation

In 2000 and 2001, direct and indirect purchasers of Cipro and advocacy groups filed a number of antitrust actions in federal courts challenging the Cipro agreements. The actions were consolidated as "Multidistrict Litigation" (MDL) in the Eastern District of New York. Thereafter, the MDL plaintiffs filed a consolidated complaint against Bayer and the same manufacturers that are generic defendants in the present case, alleging that the Cipro agreements constituted an illegal restraint of trade in violation of the Sherman Act (15 U.S.C. §§ 1-7 et seq.) and various state antitrust and consumer protection laws. (In re Ciprofloxacin Hydrochloride Antitrust Litig. (Fed. Cir. 2008) 544 F.3d 1323, 1329 (Cipro III).) After the district court denied the MDL plaintiffs' motion for partial summary judgment that the Cipro agreements were illegal per se under the Sherman Act and state antitrust laws, the plaintiffs amended their complaint to add a state

law claim that Bayer violated state antitrust law through fraud on the PTO and sham litigation in bringing its patent infringement suit against Barr. 1 (Cipro III, supra, 544 F.3d at pp. 1329-1330.)

The parties filed cross-motions for summary judgment and the district court denied the plaintiffs' motion and granted the defendants' motion. (Cipro II, supra, 363 F.Supp.2d 514.) In the district court's view, the "ultimate question" in the case was "not whether Bayer and Barr had the power to adversely affect competition for ciprofloxacin as a whole, but whether any adverse effects on competition stemming from the [Cipro agreements] were outside the exclusionary zone of the '444 [p]atent." (Id. at p. 523.) The court stated that "[u]nless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." (Id. at p. 535.) The court noted that because "[a]t least four generic companies filed ANDA IVs after Bayer and Barr entered the [Cipro agreements,] . . . it cannot be reasonably argued that the [a]greements created a bottleneck to future generic challenges." (Id. at p. 540.)

The Cipro III court referred to the MDL plaintiffs' fraud-on-the-PTO claim as a "Walker Process type" state law claim. The court explained: "In Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp. [(1965) 382 U.S. 172 (Walker Process)], the Supreme Court held that the enforcement of a patent procured by fraud on the patent office may be a violation of the Sherman Act provided that the other elements necessary to a Sherman Act claim are present. [Citation.] Here, however, the plaintiffs alleged a violation of state antitrust laws." (Cipro III, supra, 544 F.3d at p. 1330, fn. 6.)

The Cipro II court concluded that "in the absence of any evidence that the [Cipro agreements] created a bottleneck on challenges to the '444 [p]atent, or that they otherwise restrained competition beyond the scope of the claims of the '444 [p]atent, the [a]greements have not had any anti-competitive effects on the market for ciprofloxacin beyond that which are permitted under the '444 [p]atent. The fact that Bayer paid what in absolute numbers is a handsome sum to Barr to settle its lawsuit does not necessarily reflect a lack of confidence in the '444 [p]atent, but rather the economic realities of what was at risk. There is simply no precedent for plaintiffs' argument that the parties to a settlement are required to preserve the public's interest in lower prices. Such a rule would only result in parties being less likely to reach settlements, aside from undermining well-settled principles of patent law. Finally, to even attempt to quantify the public's interest in a patent settlement between private parties would require devaluing patents across the board, a result that would contravene the presumption of [patent] validity afforded by Congress and impact the very way patent licenses are handled in countless daily transactions." (Cipro II, supra, 363 F.Supp.2d at pp. 540-541.)

The Cipro II court also granted the defendants' motion to dismiss the indirect purchaser plaintiffs' state law Walker Process type claim on the ground it was preempted by federal patent law (28 U.S.C. § 1338(a)) because it depended entirely on a showing of misconduct before the PTO and rested entirely on patent law. (Cipro II, supra, 363 F.Supp.2d at pp. 542-546.) The court further found that "Bayer's success in its [patent infringement] litigations against Schein, Mylan and Carlsbad forecloses any argument that its lawsuits were shams." (Id. at p. 547.) The court rejected the plaintiffs' argument

that Bayer's success in those actions was immaterial because the '444 patent had undergone reexamination, stating: "[R]eexamination does not cure inequitable conduct, and the defense was available to all of the generic challengers." (Ibid.)

The plaintiffs timely appealed to the Second Circuit Court of Appeals, which retained jurisdiction over the direct purchaser plaintiffs' appeal but transferred the indirect purchaser and advocacy group plaintiffs' appeal to the federal circuit. (Ark. Carpenters Health & Welfare Fund v. Bayer AG (2d Cir. 2010) 604 F.3d 98, 103 (Arkansas Carpenters); Cipro III, supra, 544 F.3d at p. 1327.) The federal circuit affirmed the dismissal of the indirect purchasers' state Walker Process type claims and the "grant of summary judgment . . . that the [Cipro agreements] were not in violation of . . . the Sherman Act because any anti-competitive effects caused by the [a]greements were within the exclusionary zone of the ['444] patent." (Cipro III, supra, 544 F.3d at p. 1341.)

In the direct purchasers' appeal, the Second Circuit likewise affirmed the judgment, noting that most courts considering the issue, including the Second Circuit in In re Tamoxifen Citrate Antitrust Litigation (2nd Cir. 2006) 466 F.3d 187 (Tamoxifen)

"have held that the right to enter into reverse exclusionary payment[2] agreements fall[s]

The Arkansas Carpenters court explained that the terms "reverse exclusionary payment" and "pay-for-delay" refer to a settlement in which "the patent holder (Bayer) agree[s] to pay the alleged infringer to settle the lawsuit, and in exchange, the alleged infringer agree[s] not to enter the market." (Arkansas Carpenters, supra, 604 F.3d at p. 102.) The Tamoxifen court referred to such payments as "reverse payments." (Tamoxifen, supra, 466 F.3d at p. 205.)

within the terms of the exclusionary grant conferred by the branded manufacturer's patent." (Arkansas Carpenters, supra, 604 F.3d at p. 105.) The Arkansas Carpenters court noted that the Tamoxifen court ruled that a reverse payment agreement settling patent litigation between a branded drug manufacturer and a generic drug manufacturer "did not exceed the scope of the patent where (1) there was no restriction on marketing non-infringing products; (2) a generic version of the branded drug would necessarily infringe the branded firm's patent; and (3) the agreement did not bar other generic manufacturers from challenging the patent." (Arkansas Carpenters, supra, 604 F.3d at p. 106, citing Tamoxifen, supra, 466 F.3d at pp. 213-215.) The Arkansas Carpenters court concluded that "as long as Tamoxifen is controlling law, plaintiffs' claims cannot survive." (Arkansas Carpenters, supra, 604 F.3d at p. 110.) The court invited the plaintiffs to file a petition for rehearing en banc (ibid.) and the plaintiffs did so, but the petition was denied. (Ark. Carpenters Health & Welfare Fund v. Bayer AG (2d Cir. 2010) 625 F.3d 779.)

## G. The Present Action

Plaintiffs' operative pleading in this action is a second amended complaint they filed after this and other state actions were removed to federal court and remanded back to state court in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (E.D.N.Y. 2001) 166 F.Supp.2d 740. As noted, the second amended complaint includes causes of action for violation of the Cartwright Act (Bus. & Prof. Code, § 16720 et seq.); violation of the UCL (Bus. & Prof. Code, § 17200 et seq.); and common law monopolization arising from the Cipro agreements. The trial court granted plaintiffs' motion for class certification and

this court upheld a modified certification in *In re Cipro Cases I & II* (2004) 121 Cal.App.4th 402.3

In November 2004 the trial court vacated the trial date and continued the hearing date it had set for defendants' motions for summary judgment pending the federal district court's decision on defense motions for summary judgment filed in the MDL. In March 2005 the district court granted the motions for summary judgment and dismissed the MDL case in the Cipro II decision. The parties in the present action then stipulated to stay the action pending the MDL plaintiffs' appeal of the summary judgment. After the federal circuit issued its decision in Cipro III affirming the summary judgment, the parties stipulated, and the court ordered, that the defendants would file new motions for summary judgment.

The court granted motions for summary judgment filed by Bayer, the generic defendants, and Watson, and entered judgment in favor of defendants. The court ruled that the Cipro agreements did not violate the Cartwright Act because "[t]he undisputed evidence establishes that no triable issue of material fact exists that the agreement did not fall outside the exclusionary scope of the ['444] patent; there is no evidence that the patent suit by Bayer against Barr was objectively baseless; and Plaintiff[s] cannot establish that the settlement was otherwise unlawful." The court ruled the agreements were not illegal per se and did not violate the Cartwright Act under the "rule of reason"

The modification was to exclude all Cipro purchasers who paid a flat copayment and would have paid the same copayment for generic ciprofloxacin under the terms of their health coverage. (In re Cipro Cases I & II, supra, 121 Cal.App.4th at p. 419.)

applied in antitrust cases. The court found that as a matter of law, plaintiffs could not establish that the Cipro settlement unreasonably restrained trade because there was no triable issue of fact as to whether it had "anticompetitive effects on competition beyond the exclusionary scope of the ['444] patent itself." The court stated that "[t]his finding also precludes Plaintiffs' UCL claim and common law monopoly claim as they are based on the same factual allegations that support the Cartwright Act claim."

The court ruled that its summary judgment ruling as to Bayer and the generic defendants was dispositive as to Watson's summary judgment motion as well. The court additionally found there was no triable issue of fact as to whether Watson did anything to restrain trade as to ciprofloxacin. The court noted, among other facts, that Watson was not involved in the Cipro agreements and had no relationship to HMR or Rugby when those agreements were made.

#### DISCUSSION

"'"Since a summary judgment motion raises only questions of law regarding the construction and effect of the supporting and opposing papers, we independently review them on appeal, applying the same three-step analysis required of the trial court.

[Citations.] First, we identify the issues framed by the pleadings since it is these allegations to which the motion must respond by establishing a complete defense or otherwise showing there is no factual basis for relief on any theory reasonably contemplated by the opponent's pleading. [Citations.] [¶] [Second], we determine whether the moving party's showing has established facts which negate the opponent's claim and justify a judgment in [the] movant's favor. . . . [¶] When a summary judgment

motion prima facie justifies a judgment, the third and final step is to determine whether the opposition demonstrates the existence of a triable, material factual issue." ' "

(Pepperell v. Scottsdale Ins. Co. (1998) 62 Cal.App.4th 1045, 1054.)

# I. Legality of the Cipro Agreements

Plaintiffs first contend the court erred by not ruling that the Cipro agreements are illegal per se under the Cartwright Act. The Cartwright Act (Bus. & Prof. Code, 4 § 16700 et seq.) "prohibits every trust, defined as 'a combination of capital, skill or acts by two or more persons' for specified anticompetitive purposes. (§ 16720.) Section 16720 generally codifies the common law prohibition against restraint of trade.

[Citation.][5] [¶] "The federal Sherman Act prohibits every 'contract, combination... or conspiracy, in restraint of trade.' (15 U.S.C. § 1.) 'The similar language of the two acts reflects their common objective to protect and promote competition. [Citations.] Since the Cartwright Act and the federal Sherman Act share similar language and objectives, California courts often look to federal precedents under the Sherman Act for guidance.' "

(Fisherman's Wharf Bay Cruise Corp. v. Superior Court (2003) 114 Cal.App.4th 309, 334.)

All further statutory references are to the Business & Professions Code unless otherwise noted.

Section 16720, subdivision (a) specifies as a trust purpose a combination "[t]o create or carry out restrictions in trade or commerce." Subdivisions (b) through (e) of section 16720 specify various anticompetitive schemes and agreements constituting trusts, and section 16726 states that, except as otherwise specified in the Cartwright Act, "every trust is unlawful, against public policy and void."

Courts have limited the reach of the Cartwright Act to restraints of trade that are unreasonable. (UAS Management, Inc. v. Mater Misericordiae Hospital (2008) 169

Cal.App.4th 357, 364.) "Generally, in determining whether conduct unreasonably restrains trade, '[a] rule of reason analysis requires a determination of whether . . . its anticompetitive effects outweigh its pro-competitive effects.' " (Bert G. Gianelli Distrib. Co. v. Beck & Co. (1985) 172 Cal.App.3d 1020, 1048, disapproved on other grounds in Dore v. Arnold Worldwide, Inc. (2006) 39 Cal.4th 384, 389-390, 394, fn. 2.) However, " '[c]ertain restraints [of trade] which lack redeeming virtue are conclusively presumed to be unreasonable' " and therefore deemed illegal per se. (UAS Management, Inc. v. Mater Misericordiae Hospital, supra, 169 Cal.App.4th at p. 364; Morrison v. Viacom, Inc. (1998) 66 Cal.App.4th 534, 540.)

Plaintiffs contend the Cipro agreements are illegal per se, and the trial court would have found them so if it had not followed *Tamoxifen* and other federal cases supporting the proposition that a reverse-payment settlement between a patent holder and alleged infringer in Hatch-Waxman litigation is legal as long as the settlement does not restrain competition beyond the exclusionary scope of the patent, and there is no showing that the patent was procured by fraud or that the suit for its infringement was objectively baseless. Plaintiffs contend these cases were wrongly decided. We disagree.

In *Tamoxifen*, branded drug manufacturer and patent holder Zeneca, Inc., and related entities (collectively Zeneca) and generic drug manufacturer Barr entered into a reverse exclusionary payment settlement after a federal district court rendered a judgment declaring Zeneca's patent for the drug tamoxifen invalid, and while Zeneca's appeal of

that judgment was pending. (Tamoxifen, supra, 466 F.3d at pp. 193-194.) The plaintiffs in Tamoxifen alleged the settlement violated antitrust laws. (Id. at pp. 196-197.) Considering the sufficiency of plaintiffs' complaint, the Tamoxifen court declined to conclude, and noted that the plaintiffs did not ask it to conclude, "that reverse payments are per se violations of the Sherman Act such that an allegation of an agreement to make reverse payments suffices to assert an antitrust violation." (Id. at p. 206, original italics.) The Tamoxifen court adopted the holding in Cipro II that " '[u]nless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.' " (Tamoxifen, supra, 466 F.3d at p. 213, quoting Cipro II, supra, 363 F.Supp.2d at p. 535.) Affirming the district court's judgment dismissing the complaint and denying plaintiffs leave to amend, the Tamoxifen court concluded that "in the absence of any plausible allegation that Zeneca's patent infringement lawsuit was baseless or that the Settlement Agreement otherwise restrained competition beyond the scope of the tamoxifen patent, [the plaintiffs'] complaint would fail to state a claim on which relief can be granted." (Tamoxifen, supra, 466 F.3d at p. 221.)

Before *Tamoxifen* was decided, the district court in *Cipro I*, addressing the Cipro settlement challenged here, noted that "per se analysis is reserved for a small number of cases involving agreements in restraint of trade that experience teaches have no redeeming value and a pernicious anticompetitive effect. This case involves the rights of a patent holder whose patent has been scrutinized on reexamination by the PTO and

repeatedly challenged in court, but has never been found invalid. This case also involves the Hatch-Waxman Amendments—a new statutory scheme creating a novel, low-cost method for challenging the validity of drug patents. Lastly, this case involves settlement agreements, the type of agreements, generally speaking, encouraged by the legal system and entered into with great frequency. These circumstances pose significant obstacles to per se treatment of the challenged agreements." (Cipro I, supra, 261 F.Supp.2d at p. 233.)

The Cipro I court stated that "when patents are involved, case law directs that the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is per se illegal. Therefore, the proper analysis in this case is whether the plaintiffs have proven as a matter of law that the challenged agreements restrict competition beyond the exclusionary effects of the 444 Patent." (Cipro I, supra, 261 F.Supp.2d at p. 249.) The court observed that because the '444 patent covered the active ingredient in all Cipro products, until the patent "either is invalidated or expires, it lawfully precludes the manufacture and use of any generic product containing the compound ciprofloxacin hydrochloride regardless of the form or method of delivery. Therefore, the restrictions in the Supply Agreement on manufacturing Cipro appear within the confines of Bayer's lawful patent monopoly." (Id. at p. 250.) The court concluded that the Cipro agreements, including the supply agreement, "do not restrict competition in areas other than those protected by Bayer's 444 Patent and, thus, are not per se illegal under the Sherman Act." (Ibid.)

Noting that the policies underlying patent law and the Sherman Act conflict to some extent, the Cipro I court reasoned that "[t]he flexibility necessary to balance these competing policies, particularly in the context of a new statutory scheme, suggests that a rule of reason rather than a per se analysis should be employed in this case." (Cipro I, supra, 261 F.Supp.2d at p. 255.) The court noted incentives created by the Hatch-Waxman Act "have led to generic investment in product development, patent review and product challenges through litigation. . . . To maximize these incentives, a generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it. Otherwise, the incentives to mount an ANDA IV challenge could be reduced." (Id. at p. 256.)

The Cipro I court also recognized that the public policy favoring the settlement of disputes was an important factor in its analysis, stating: "[T]he American legal process encourages the settlement of lawsuits where possible, and unless the law explicitly states otherwise, neither party is obligated to litigate to a final conclusion. Nothing in the legislative history supports a conclusion that Hatch-Waxman lawsuits cannot be settled. Moreover, a rule that makes it per se illegal to settle a Hatch-Waxman lawsuit, like the Bayer/Barr patent litigation, limits the options available to both generic and brand-name manufacturers. If brand-name manufacturers are unable to control or limit their risk by settling Hatch-Waxman litigation, they, like generic manufacturers, may be less inclined to invest the research and development ('R&D') costs associated with bringing new drugs to the market. The pharmaceutical industry depends greatly on R&D and the economic returns to intellectual property created when a successful new drug is brought to

market.... A rule prohibiting settlements of Hatch-Waxman patent litigation can have grave consequences for R&D and, in turn, severe consequences for consumers." (Cipro I, supra, 261 F.Supp.2d at p. 256.) "Although a policy in favor of settlement of litigation cannot save a per se violation from the [strictures] of the Sherman Act, a rule that too quickly condemns actions as per se illegal, potentially chilling efforts to research and develop new drugs and challenge the patents on brand-name drugs, does competition—and thus, the Sherman Act—a disservice." (Ibid.)

In another decision predating Tamoxifen, the Eleventh Circuit Court of Appeals, considering a reverse payment settlement of a Hatch-Waxman infringement suit that the district court had found to be illegal per se, stated: "If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's order [granting summary judgment]. This is not such a case, however, because one of the parties owned a patent." (Valley Drug Co. v. Geneva Pharms., Inc. (11th Cir. 2003) 344 F.3d 1294, 1304 (Valley Drug).) The Valley Drug court noted that "[a] patent grants its owner the lawful right to exclude others" (ibid.) and that "a patentee can choose to exclude everyone from producing the patented article or can choose to be the sole supplier itself." (Id. at p. 1305.) "Unlike some kinds of agreements that are per se illegal whether engaged in by patentees or anyone else, such as tying or price-fixing, the exclusion of infringing competition is the essence of the patent grant. . . . '[W]hen patents are involved . . . the exclusionary effect of the patent must be considered before making any determination as

to whether the alleged restraint is per se illegal.' " (Id. at p. 1306, quoting Cipro I, supra, 261 F.Supp.2d at p. 249.)

The Valley Drug court noted that the only time the United States Supreme Court "has addressed the circumstances under which the patent immunity from antitrust liability can be pierced, it held that the antitrust claimant must prove that the patentee enforced a patent with the knowledge that the patent was procured by fraud on the Patent Office." (Valley Drug, supra, 344 F.3d at p. 1307, citing Walker Process, supra, 382 U.S. at p. 177.) "Good faith procurement furnishes a complete defense to the antitrust claim. [Citation.] Justice Harlan's concurrence [in Walker Process] explained that the effect of antitrust liability on the incentives for innovation and disclosure created by the patent regime must be taken into account when a court considers whether a patentee is stripped of its immunity from the antitrust laws: [¶] 'It is well also to recognize the rationale underlying this decision, aimed of course at achieving a suitable accommodation in this area between the differing policies of the patent and antitrust laws. To hold, as we do, that private suits may be instituted under § 4 of the Clayton Act to recover damages for Sherman Act monopolization knowingly practiced under the guise of a patent procured by deliberate fraud, cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure. Hence, as to this class of improper patent monopolies, antitrust remedies should be allowed room for full play. On the other hand, to hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill

the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits. Hence, this private antitrust remedy should not be deemed to reach § 2 monopolies carried on under a nonfraudulently procured patent.' " (Valley Drug, supra, 344 F.3d at p. 1307, quoting Walker Process, supra, 382 U.S. at pp. 179-180, conc. opn. of Harlan, J.)

Further addressing the need to balance the conflicting polices behind patent law and antitrust law, the *Valley Drug* court noted that although patent and antitrust laws necessarily clash, " 'the two regimes seek the same object: the welfare of the public . . . Antitrust law forbids certain agreements tending to restrict output and elevate prices and profits above the competitive level. Patent law also serves the interests of consumers by protecting invention against prompt imitation in order to encourage more innovation than would otherwise occur.' " (*Valley Drug, supra,* 344 F.3d at pp. 1307-1308.) The *Valley Drug* court concluded that the fact the district court found the patent at issue in that case to be invalid alone was "insufficient to render the patent's potential exclusionary effects irrelevant to the antitrust analysis." (*Id.* at p. 1309.)

The plaintiffs in Valley Drug argued that patent rights do not include the right to pay infringers—an argument the Valley Drug court viewed as implying "that any exclusion resulting from payment rather than judicial enforcement is not protected from per se antitrust liability by the patent laws." (Valley Drug, supra, 344 F.3d at p. 1309.) The court rejected that argument based on the important role settlement plays in the enforcement of patent rights, stating: "Appellees have not explained why a monetary payment as part of a patent litigation settlement should be flatly prohibited as a per se

violation, particularly where the alleged infringer has not yet caused the patentee any harm and the patentee does not have a damages claim to bargain with. [Citations.] [¶] We cannot conclude that the exclusionary effects of the Agreements not to enter the market were necessarily greater than the exclusionary effects of the '207 patent merely because Abbott paid Geneva and Zenith in return for their respective agreements. If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. The failure to produce the competing terazosin drug, rather than the payment of money, is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement. [Citation.] To hold that an ostensibly reasonable settlement of patent litigation gives rise to per se antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally. We are not persuaded that such a per se rule would be an appropriate accommodation of the competing policies of the patent and antitrust laws." (Ibid.)

Although the *Valley Drug* court stated that the size of a reverse or "exit" payment may raise suspicion that the settling parties lacked faith in the validity of the patent in question, the court also noted that "[g]iven the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent may pay a potential infringer a substantial sum in settlement." (*Valley Drug, supra,* 344 F.3d at p. 1310.) As an example, the court noted the \$398 million that Bayer paid Barr in the Cipro settlement

even "though the ['444] patent was subsequently approved by the PTO on reexamination and unsuccessfully challenged in court three times." (*Ibid.*, citing *Cipro I, supra*, 261 F.Supp.2d at p. 234.)

The *Valley Drug* court, in remanding the case to the district court, concluded that neither per se analysis nor the rule of reason was an appropriate approach for determining whether the settlement at issue violated antitrust law, stating: "Rule of reason and *per se* analysis are both aimed at assessing the anticompetitive effects of particular conduct; what is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects." (*Valley Drug, supra,* 344 F.3d at p. 1311, fn. 27.)

In Schering-Plough Corp. v. FTC (11th Cir. 2005) 402 F.3d 1056 (Schering), the Eleventh Circuit Court of Appeals vacated a decision by the Federal Trade Commission (FTC) finding that Hatch-Waxman settlements between branded drug manufacturer Schering-Plough Corporation (Schering) and generic manufacturers Upsher-Smith Laboratories, Inc. (Upsher) and ESI Lederle, Inc. (ESI) violated the FTC Act and the Sherman Act. (Id. at p. 1062.) Schering manufactured and marketed an extended release potassium chloride product called K-Dur 20, and owned a formulation patent on the extended-release coating that surrounds the potassium chloride on the product. (Schering, supra, 402 F.3d at p. 1058.) Upsher filed an ANDA IV seeking FDA approval of a generic version of K-Dur 20 and Schering filed a patent infringement suit against Upsher. (Id. at pp. 1058-1059.) Schering and Upsher entered into a settlement of the

infringement suit that included Schering's agreeing to an early entry date for Upsher's generic version of K-Dur, and Uphser's granting Schering licenses to market five other Upsher products, including a time-release niacin product used to reduce cholesterol. (*Id.* at p. 1059.) The settlement involved a "three-part license deal, which called for Schering to pay [Upsher] (1) \$60 million in initial royalty fees; (2) \$10 million in milestone royalty payments; and (3) 10% or 15% royalties on sales." (*Id.* at p. 1060.)

ESI also sought FDA approval for a generic version of K-Dur 20 and was sued by Schering for patent infringement. (*Schering, supra*, 402 F.3d at p. 1060.) Schering and ESI entered into a settlement agreement under which Schering allowed ESI to market its competing generic three years before Schering's patent expired (*ibid.*) and "agreed to pay ESI a \$5 million noncontingent payment, representing legal fees, and an additional \$10 million contingent on ESI's FDA approval. Schering and ESI also entered into a contemporaneous license agreement whereby ESI granted Schering the licenses to [two ESI drugs] in exchange for \$15 million." (*Id.* at p. 1061, fn. 8.)

The FTC filed an administrative complaint challenging the legality of the settlements under the FTC Act and the Sherman Act, and the complaint was tried before an administrative law judge (ALJ) who rejected the FTC's theories that the settlement agreements at issue were anticompetitive. (Schering, supra, 402 F.3d at p. 1061.) Noting that the FTC's theories required either a presumption that Schering's patent in question was invalid or that Upsher's and ESI's generic products did not infringe it, the ALJ ruled that the presumptions had no basis in law or fact. (Ibid.) The ALJ found that the fact the settlements included payments did not make them anticompetitive per se. "Rather, the

strength of the patent itself and its exclusionary power needed to be assessed. The [ALJ's] decision highlighted the FTC's failure to prove that, absent a payment, either better settlement agreements or litigation results would have effected an earlier entry date for the generics. Finally, the ALJ found no proof that Schering maintained an illegal monopoly within the relevant . . . market." (Id. at pp. 1061-1062.)

On appeal of the ALJ's decision to the full Commission, the Commission reversed the ALJ, ruling the settlements included agreements to defer generic entry dates that injured competition and consumers. (*Schering, supra*, 402 F.3d at p. 1062.) Regarding the settlement payments, "the Commission determined that neither the \$60 million to Upsher nor the \$30 million to ESI represented legitimate consideration for the licenses granted by Upsher or ESI's ability to secure FDA approval of its generic. Consequently, the Commission prohibited settlements under which the generic receives anything of value and agrees to defer its own research, development, production or sales activities." (*Id.* at p. 1062, fn. omitted.)

The Schering court noted that both the ALJ and Commission applied the rule of reason in analyzing the Schering settlements, albeit under two different methodologies. (Schering, supra, 402 F.3d at p. 1064.) Following Valley Drug, the court stated: "We think that neither the rule of reason nor the per se analysis is appropriate in this context. We are bound by our decision in Valley Drug where we held both approaches to be ill-suited for an antitrust analysis of patent cases because they seek to determine whether the challenged conduct had an anticompetitive effect on the market. [Citation.] By their nature, patents create an environment of exclusion, and consequently, cripple

competition. The anticompetitive effect is already present. 'What is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects.' [Citation.] Therefore, in line with *Valley Drug*, we think the proper analysis of antitrust liability requires and examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." (*Schering, supra*, 402 F.3d at pp. 1065-1066, fn. omitted.)

The Schering court noted that "[a]lthough the exclusionary power of a patent may seem incongruous with the goals of antitrust law, a delicate balance must be drawn between the two regulatory schemes. Indeed, application of antitrust law to markets affected by the exclusionary statutes set forth in patent law cannot discount the rights of the patent holder. [Citation.] Therefore, a patent holder does not incur antitrust liability when it chooses to exclude others from producing its patented work." (Schering, supra, 402 F.3d at p. 1067.) "What patent law does not do, however, is extend the patentee's monopoly beyond its statutory right to exclude." (Ibid.)

The Schering court also addressed the policy favoring settlement, stating: "The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits. [Citations.] Patent owners should not be in a worse position, by virtue of the patent right, to negotiate and settle surrounding lawsuits. We find the terms of the settlement to be within the patent's exclusionary power, and

'reflect a reasonable implementation' of the protections afforded by patent law." (Schering, supra, 402 F.3d at p. 1072.)

In considering whether the settlements at issue had anticompetitive effects – i.e., were an " 'unfair method of competition' " (Schering, supra, 402 F.3d at p. 1072) – the Schering court elaborated on the policy favoring settlement of litigation and the detriment that would result from a rule prohibiting reverse payment settlements in patent litigation. The court reiterated that "[t]he efficiency-enhancing objectives of a patent settlement are clear, and '[p]ublic policy strongly favors settlement of disputes without litigation.' " (Id. at pp. 1072-1073.) The court stated that "[t]he Commission's inflexible compromise-without-payment theory neglects to understand that '[r]everse payments are a natural by-product of the Hatch-Waxman process.'[6] [Citation.] . . . A prohibition on reverse-

<sup>6</sup> The Tamoxifen court explained that "reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them." (Tamoxifen, supra, 466 F.3d at p. 206.) The court noted that "under the Hatch-Waxman Act, the patent holder ordinarily brings suit shortly after the paragraph IV ANDA has been filed - before the filer has spent substantial sums on the manufacturing, marketing, or distribution of the potentially infringing generic drug. The prospective generic manufacturer therefore has relatively little to lose in litigation precipitated by a paragraph IV certification beyond litigation costs and the opportunity for future profits from selling the generic drug . . . [¶] Accordingly, a generic marketer has few disincentives to file an ANDA with a paragraph IV certification. The incentive [to file and ANDA IV], by contrast, may be immense: the profits it will likely garner in competing with the patent holder without having invested substantially in the development of the drug, and, in addition, possible entitlement to a 180-day period (to be triggered at its inclination) during which it would be the exclusive seller of the generic drug in the market." (Id. at pp. 206-207, fn. omitted.) On the other hand, "[t]he patent holder's risk if it loses the resulting patent suit is correspondingly large: It will be stripped of its patent monopoly. At the same time, it stands to gain little from winning other than the continued protection of its lawful monopoly over the manufacture and sale of the drug in question. [¶] 'Hatch-Waxman essentially redistributes the relative risk

payment settlements would 'reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.' [Citation.] [¶] There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation. [Citation.] Patent litigation breeds a litany of direct and indirect costs, ranging from attorney and expert fees to the expenses associated with discovery compliance.

Other costs accrue for a variety of reasons, be it the result of uncompromising legal positions, differing strategic objectives, heightened emotions, lawyer incompetence, or sheer moxie. [Citations.] [¶] Finally, the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product." (Id. at pp. 1074-1075.)

The Schering court found that the settlement agreements at issue "fell well within the protections of the [subject] patent, and were therefore not illegal." (Schering, supra, 402 F.3d 15 p. 1076.) The court concluded: "Simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law. This alone underscores the need to evaluate the strength of the patent. Our conclusion, to a degree, and we hope that the FTC is mindful of this, reflects policy. Given the costs of lawsuits to the parties, the public

assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, [the generic challengers] gain[] considerable leverage in patent litigation: the exposure to liability amount[s] to litigation costs, but pale[s] in comparison to the immense volume of generic sales and profits.' " (*Ibid.*)

problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements, we fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and, in an ancillary transaction, pays for other products licensed by the generic. Such a result does not represent the confluence of patent and antitrust law." (*Ibid.*)

In the same month that Schering was decided, the district court in Cipro II granted defendant's motions for summary judgment and dismissal. As noted above, the Cipro II judgment was affirmed in Cipro III as to the direct purchaser plaintiffs and Arkansas Carpenters as to the indirect purchaser and advocacy group plaintiffs. The Cipro III court stated: "[I]n cases such as this, wherein all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent." (Cipro III, supra, 544 F.3d at p. 1336, citing Walker Process, supra, 382 U.S. at pp. 175-177 [although the Sherman Act may be violated when a patent is procured by fraud, a patent is an exception to the general rule against monopolies].)

The Cipro III court concluded: "Pursuant to statute, a patent is presumed to be valid, [35 United States Code section 282], and patent law bestows the patent holder with 'the right to exclude others from profiting by the patented invention.' [Citation.] A settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled – a monopoly over the manufacture and distribution of the patented invention. [Citation.] Thus, the district court correctly concluded that there is no legal basis for restricting the right of a patentee to choose its preferred means of enforcement and no support for the notion that the Hatch-Waxman Act was intended to thwart settlements. [Citation.] . . . [I]f 'there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation.' " (Cipro III, supra, 544 F.3d at p. 1337, quoting Asahi Glass Co. v. Pentech Pharms., Inc. (N.D.Ill. 2003) 289 F.Supp.2d 986, 992.) Accordingly, the Cipro III court found "the analysis by the district court to be fully supported in law and to demonstrate that it was cognizant of the legal standards applied by the regional circuits and governmental agencies in addressing agreements involving exclusion payments in the context of the Hatch-Waxman Act." (Cipro III, supra, 544 F.3d at p. 1337.)

The Arkansas Carpenters court likewise affirmed the Cipro II judgment based on the holding in Tamoxifen and other courts that "the right to enter into reverse exclusionary payment agreements fall[s] within the terms of the exclusionary grant conferred by the branded manufacturer's patent." (Arkansas Carpenters, supra, 604 F.3d at p. 105.) The Arkansas Carpenters court followed the Tamoxifen court's analysis that a

reverse payment agreement settling patent litigation between a branded drug manufacturer and a generic drug manufacturer does "not exceed the scope of the patent where (1) there [is] no restriction on marketing non-infringing products; (2) a generic version of the branded drug would necessarily infringe the branded firm's patent; and (3) the agreement [does] not bar other generic manufacturers from challenging the patent."

(Arkansas Carpenters, supra, 604 F.3d at p. 106, citing Tamoxifen, supra, 466 F.3d at pp. 213-215.)

We agree with the reasoning of these cases and conclude that it applies equally to antitrust claims under the Cartwright Act. Under the Cartwright Act, as under the Sherman Act, the "illegal per se" designation is reserved for agreements or practices that have a pernicious effect on competition and lack any redeeming virtue. (Corwin v. Los Angeles Newspaper Service Bureau, Inc. (1971) 4 Cal.3d 842, 853; Morrison v. Viacom, Inc. (1998) 66 Cal.App.4th 534, 540; Macmanus v. A. E. Realty Partners (1983) 146 Cal.App.3d 275, 285.) Considering the important public policies underlying patent law (Valley Drug, supra, 344 F.3d at pp. 1307-1308) and favoring the settlement of patent litigation (Schering, supra, 402 F.3d at pp. 1074-1075) and 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. Accordingly, we conclude they are not unlawful per se.

We further conclude that the Cipro agreements do not violate the Cartwright Act under rule-of-reason analysis or the analysis the Eleventh Circuit Court of Appeals held to be applicable to settlements of Hatch-Waxman litigation in *Valley Drug* and *Schering*,

which requires "examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." (Schering, supra, 402 F.3d at pp. 1065-1066, fn. omitted.) We find the reasoning of the federal cases discussed above regarding the legality of settlements of Hatch-Waxman patent litigation to be sound and applicable to plaintiffs' cause of action under the Cartwright Act. We agree with the Cipro III court that because a patent is presumed to be valid and gives the patent holder the right to exclude others from marketing the patented invention, a settlement of patent infringement litigation "is not unlawful if it serves to protect that to which the patent holder is legally entitled - a monopoly over the manufacture and distribution of the patented invention." (Cipro III, supra, 544 F.3d at p. 1337.) Therefore, in accordance with Cipro II and Tamoxifen, we conclude that unless a patent was procured by fraud, or a suit for its enforcement was objectively baseless, a settlement of the enforcement suit does not violate the Cartwright Act if the settlement restrains competition only within the scope of the patent. (Tamoxifen, supra, 466 F.3d at p. 213; Cipro II, supra, 363 F.Supp.2d at p. 535.)

The principle that an agreement is not unlawful under California and federal antitrust law if it restrains competition only within the exclusionary scope of a patent is reflected in Fruit Machine Co. v. F. M. Ball & Co. (1953) 118 Cal.App.2d 748 (Fruit Machine). In Fruit Machine, the plaintiff licensee of a patent holder successfully sued the defendant for breach of a contractual obligation to pay plaintiff royalties for use of a patented machine, and the defendant claimed it was absolved of that obligation because, among other reasons, the plaintiff had created a monopoly in violation of state and

federal antitrust law. (Fruit Machine, supra, 118 Cal.App.2d at pp. 750, 760.) In rejecting that claim, the Fruit Machine court noted that the licensing arrangement in question was not "beyond the scope of the patent rights and within the proscription of the antitrust laws . . . . " (Id. at p. 762.) The court noted it would not "be legally improper or incompetent for the patentee, his exclusive licensee, and the latter's sublicensees, by agreements such as these parties have made, to give themselves a commercial advantage over others in industry. The very purpose of the patent law is to encourage inventive effort by according the inventor and his assigns control over the invention and protection in the exercise of the rights accorded him as patentee. Defendant has not shown that the parties, in executing and carrying out the sublicense agreement in suit, exercised rights or powers not accorded them by the patent law or abused any rights or powers accorded them by that law." (Ibid., italics added.) The Fruit Machine court found various antitrust law decisions cited by the defendant to be inapplicable, noting that "[t]he greater number of them dealt with situations in which no patent rights were involved. In those in which the exercise of patent rights [was] involved, it appeared that the patentee or his assignee went beyond that which was necessary or incidental to the scope of his patent and brought himself within the proscription of the antitrust laws." (Fruit Machine, supra, 118 Cal.App.2d at pp. 762-763.)

Plaintiffs and amici curiae<sup>7</sup> focus on the reverse exclusionary payment or pay-for-delay aspect of the Cipro settlement in arguing that the settlement violates antitrust law. Plaintiffs argue that Hatch-Waxman litigation can and should be settled without reverse payments. However, we agree with the *Valley Drug* court's view that deeming an ostensibly reasonable settlement of patent litigation illegal per se under antitrust law if the settlement "involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally." (*Valley Drug, supra,* 344 F.3d at p. 1309.) As the *Schering* court noted, "the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the 'asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent may pay a potential infringer a substantial sum in settlement.' " (*Schering, supra,* 402 F.3d at p. 1075, quoting *Valley Drug, supra,* 344 F.3d at p. 1310.)

We agree with the *Schering* court's observation that reverse payment settlements are a natural byproduct of patent litigation under the Hatch-Waxman Act and that a rule prohibiting them could harm competition by reducing the incentive to challenge patents by reducing the challenger's settlement options in a suit for infringement. (*Schering*, *supra*, 402 F.3d at pp. 1074-1075.) Emphasizing the private and social benefits that the settlement of patent litigation provides, the *Schering* court appropriately concluded that

A group of professors filed an amici curiae brief entitled: "Brief Amici Curiae of 78 Intellectual Property Law, Antitrust Law, Economics, and Business Professors in Support of Appellant."

"[s]imply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law." (*Id.* at p. 1076.)

Plaintiffs and amici curiae point to *In re Cardizem CD Antitrust Litig*. (6th Cir. 2003) 332 F.3d 896 (*Cardizem*) as showing a conflict in the federal circuits regarding the legality of reverse payment settlements of Hatch-Waxman patent litigation. In that case the district court found that a reverse-payment settlement between branded drug manufacturer HMR and generic manufacturer Andrx Pharmaceuticals, Inc., was illegal per se and the *Cardizem* court affirmed. However, the *Cardizem* court noted that in condemning the HMR/Andrx agreement, the district court "'emphasized that the agreement . . . restrained Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation . . . . Thus, the court found that the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem.' " (*Id.* at p. 909, fn. 13, quoting *Cipro I*, *supra*, 261 F.Supp.2d at p. 242.)

In other words, the reverse payment settlement in Cardizem restrained competition beyond the exclusionary zone of the subject patent. As the Cipro III court noted, "although the Sixth Circuit found a per se violation of the antitrust laws in In re Cardizem, the facts of that case are distinguishable from this case and from the other circuit court decisions. In particular, the settlement in that case included, in addition to a reverse payment, an agreement by the generic manufacturer to not relinquish its 180-day exclusivity period, thereby delaying the entry of other generic manufacturers. [Citation.]

Furthermore, the agreement provided that the generic manufacturer would not market non-infringing versions of the generic drug. [Citation.] Thus, the agreement clearly had anticompetitive effects outside the exclusion zone of the patent." (Cipro III, supra, 544 F.3d at p. 1335, italics added.) We further note that unlike the Valley Drug, Schering and Tamoxifen courts, and the trial and appellate courts in the federal Cipro litigation, the Cardizem court did not consider, much less attempt to balance, the competing policies underlying antitrust law and patent law or address the policy favoring settlement of litigation.

Contrary to amici curiae's assertion that "[t]he Second Circuit rule endorsed by the trial court is far outside the mainstream of judicial . . . analysis of exclusionary settlements," every reported decision to date addressing the legality of a reverse-payment settlement of Hatch-Waxman litigation that does not restrain competition beyond the exclusionary scope of the patent has concluded that the settlement does not violate antitrust law. We conclude that because the Cipro agreements undisputedly did not

The Cipro III court added: "To the extent that the Sixth Circuit may have found a per se antitrust violation based solely on the reverse payments, we respectfully disagree." (Cipro III, supra, 544 F.3d at p. 1335.)

restrain competition beyond the exclusionary scope of the '444 patent, they do not violate the Cartwright Act.9

#### II. Sham Litigation Claim

Plaintiffs contend that even if the Cipro settlement does not violate California law unless the '444 patent is shown to have been procured by fraud or a suit for its enforcement is shown to be objectively baseless, the court erred in granting summary judgment because there is as triable issue of fact as to whether Bayer's patent infringement action against Barr was an objectively baseless or "sham" lawsuit. "To prove sham litigation, a plaintiff must show (1) 'the lawsuit [to] be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits,' and (2) that the litigant's 'subjective motivation' for bringing the action was a sham seeking to conceal a knowing attempt to interfere with a competitor." (Cipro II, supra, 363

F. Supp. 2d at p. 547, citing Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc. (1993) 508 U.S. 49, 60-61.) Plaintiffs' position on appeal appears to be that they could show Bayer's patent infringement suit was objectively baseless based on evidence of Bayer's inequitable conduct in procuring the '444 patent—an issue they

We acknowledge that amici curiae, the FTC, and the Department of Justice have advocated various approaches under which reverse-payment settlements of patent infringement litigation under the Hatch-Waxman Act could be deemed to violate antitrust law even when they do not restrain competition beyond the exclusionary scope of a patent. However, considering the necessity of maintaining a proper balance between the competing policies underlying patent law and antitrust law, we believe that any rule prohibiting such settlements of Hatch-Waxman litigation should be made by Congress rather than the courts.

contend was not litigated in Bayer's suits against generic manufacturers for infringement of the '444 patent following the Cipro settlement.

Bayer argues, and the trial court ruled, that plaintiffs' sham litigation claim was not a proper basis for opposing defendants' summary judgment motions because it was not pleaded in plaintiffs' second amended complaint. The trial court further ruled that "[e]ven if such allegations were included in the [second amended complaint], there is no evidence or legal support the suit was objectively baseless or was a sham." The trial court quoted the Cipro II court's finding that "Bayer's success in its [patent infringement] litigations against Schein, Mylan and Carlsbad forecloses any argument that its lawsuits were shams." (Cipro II, supra, 363 F.Supp.2d at p. 547.)

Regarding plaintiffs' inequitable conduct claim, the trial court ruled: "Plaintiffs cannot meet the objectively baseless standard by resorting to allegations of inequitable conduct since the [second amended complaint] does not allege inequitable conduct, much less that Bayer's infringement suit against Barr was objectively baseless or a sham. Even if there were such allegations, inequitable conduct is only an equitable defense to a patent infringement suit which, if proven, can render the entire patent unenforceable. [Citation.] As such, Bayer's alleged inequitable conduct in procuring the patent is not relevant to the case at hand as it pertains to [p]laintiffs' antitrust claims." The trial court also decided that the "determination of . . . inequitable conduct would involve substantial questions of patent law, which this Court does not have jurisdiction to decide."

It is difficult to fault the trial court's ruling that "[p]laintiffs failed to allege that Bayer's infringement suit was objectively baseless, [or] was sham litigation . . . and

[p]laintiffs cannot defeat the motion for summary judgment by doing so now." It is well settled that "the pleadings set the boundaries of the issues to be resolved at summary judgment. [Citations.] A 'plaintiff cannot bring up new, unpleaded issues in his or her opposing papers. [Citation.]' [Citations.] A summary judgment or summary adjudication motion that is otherwise sufficient 'cannot be successfully resisted by counterdeclarations which create immaterial factual conflicts outside the scope of the pleadings; counterdeclarations are no substitute for amended pleadings.' Thus, a plaintiff wishing 'to rely upon unpleaded theories to defeat summary judgment' must move to amend the complaint before the hearing." (Oakland Raiders v. National Football League (2005) 131 Cal.App.4th 621, 648.)

It is a stretch to interpret the second amended complaint as raising the issue of whether Bayer's patent infringement suit against Barr was objectively baseless due to inequitable conduct or for any other reason. The allegations of the second amended complaint reflect plaintiffs' theory that the Cipro agreements injure competition in violation of the Cartwright Act regardless of the validity of Bayer's '444 patent or the merits of its infringement suit against Barr, and merely suggest that the '444 patent might have been ruled invalid but for the Cipro settlement. The second amended complaint alleges that the patent holder and ANDA IV filer "must be adversaries" and that "the former presumes the patent is valid, enforceable and infringed, while the latter must assert that the patent is invalid, unenforceable and/or not infringed." Thus, plaintiffs' allegations that Barr asserted the patent was invalid or unenforceable do not constitute an allegation by plaintiffs that Bayer's infringement suit was baseless; they merely reflect

that Barr assumed the adversarial role it was required to assume in filing an ANDA IV.

The closest the second amended complaint comes to expressly alleging that Bayer's infringement suit lacked merit is the allegation that "[b]ut for the Cipro Agreements and other agreements between Bayer and Barr: . . . the finder-of-fact in the patent litigation could have found that the 444 patent was invalid, unenforceable or not infringed."10 (Italics & underscoring added.) This allegation, which essentially avers that Bayer might have lost its infringement suit had it been litigated to completion, is not reasonably construed as an allegation that the suit was objectively baseless or a sham.

In any event, assuming the complaint sufficiently pleads the claim that Bayer's patent infringement suit was objectively baseless due to inequitable conduct, we agree with the trial court and the Cipro II court that "Bayer's success in its [patent infringement] litigations against Schein, Mylan and Carlsbad forecloses any argument that its lawsuits were shams." [11] (Cipro II, supra, 363 F.Supp.2d at p. 547.) As the Cipro II court noted: "'A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore is not a sham.' " (Ibid., quoting Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., supra, 508 U.S. at p. 61, fn. 5.)

Plaintiffs also suggest that Bayer's infringement suit would not have been successful by alleging that "[b]ut for the Cipro Agreements, generic ciprofloxacin would have been on the United States market by January 1997."

The Cipro II court was addressing Bayer's motion "for summary judgment that Bayer's suits against Barr an the subsequent '444 Patent challengers were not sham litigation as a matter of law." (Cipro II, supra, 363 F.Supp.2d at p. 547.)

Plaintiffs assert that none of the challenges to the '444 patent by generic manufacturers following the Cipro settlement and the patent's reexamination involved the issue of Bayer's inequitable conduct. However, as the Cipro II court noted, "reexamination does not cure inequitable conduct, and the defense was available to all of the generic challengers." (Cipro II, supra, 363 F.Supp.2d at p. 547.) It seems highly unlikely that a generic manufacturer motivated to challenge the '444 patent would overlook or forgo a meritorious defense to Bayer's infringement suit that would render the suit objectively baseless. 12

Further, even if there is evidence creating a triable issue of fact as to whether Bayer's patent infringement suit was objectively baseless due to Bayer's inequitable conduct in procuring the '444 patent, we conclude that plaintiffs' sham-litigation claim is preempted by federal patent law. "The district courts [of the United States] shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents . . . . Such jurisdiction shall be exclusive of the courts of the states in

The Cipro II court addressed this point, stating: "At oral argument, plaintiffs asserted that the court should give little weight to these subsequent failed attacks because none of them raised what plaintiffs believe to be the most forceful attack on the '444 Patent-namely, inequitable conduct. Plaintiffs argue that this defense required extensive discovery and would take a long period of time to prepare and try, and that this explains why none of the subsequent challengers raised this issue. [¶] But this argument is not very convincing in light of the fact that one of the challenges—Carlsbad's, on the ground of obviousness—also required extensive discovery and resulted in a nine-day bench trial. It is difficult to accept the notion that Carlsbad abandoned a stronger argument because it would have presumably required a greater effort, especially since Barr had already done most of the preparatory work on the inequitable conduct issue." (Cipro II, supra, 363 F.Supp.2d at p. 530.)

patent . . . cases." (28 U.S.C. § 1338(a).) Federal jurisdiction over cases arising under patent law "'extend[s] only to those cases in which a well-pleaded complaint establishes either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims.' " (Holiday Matinee, Inc. v. Rambus, Inc. (2004) 118 Cal.App.4th 1413, 1422, quoting Christianson v. Colt Industries Operating Corp. (1988) 486 U.S. 800, 808–809, italics added.)

Plaintiffs' right to relief under the Cartwright Act and UCL, under their sham litigation theory, depends on the resolution of whether Bayer engaged in inequitable conduct in the procurement of its '444 patent that rendered its infringement suit against Barr objectively baseless. When a state law claim involves a patent holder's conduct in obtaining its patent, the claim is preempted by federal patent law unless the plaintiff pleads and proves that the patent holder engaged in fraud before the PTO.13 (Hunter Douglas, Inc. v. Harmonic Design, Inc. (Fed.Cir. 1998) 153 F.3d 1318, 1336-1337, overruled on other grounds in Midwest Industries, Inc. v. Karavan Trailers, Inc. (Fed.Cir. 1999) 175 F.3d 1356, 1358–1359; see also Nobelpharma AB v. Implant Innovations, Inc. (Fed.Cir. 1998) 141 F.3d 1059, 1068 ["[W]hether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law." (Fn. omitted.)].) More specifically, a

Plaintiffs emphasize on appeal that they are not asserting a claim of fraud on the PTO.

determination of whether alleged inequitable conduct in the procurement of a patent constitutes unfair competition is within the exclusive jurisdiction of the Federal Circuit Court of Appeals. (Lockwood v. Sheppard, Mullin, Richter & Hampton (2009) 173

Cal.App.4th 675, 686, citing Pro-Mold & Tool Co. v. Great Lakes Plastics (Fed.Cir. 1996) 75 F.3d 1568, 1574.) Thus, 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 federal patent law – i.e., whether Bayer engaged in inequitable conduct in the procurement of its patent.

Plaintiffs argue they are not seeking to hold Bayer liable for its conduct in procuring or enforcing the '444 patent, but rather are challenging the "collusive payment" that ended the patent suit. However, it is immaterial to the federal jurisdiction issue that plaintiffs' claims do not directly seek to hold Bayer liable for inequitable conduct in procuring the '444 patent; plaintiffs' antitrust and unfair competition claims are preempted by federal patent law because a necessary element of those claims is that Bayer's infringement suit against Barr was objectively baseless due to Bayer's inequitable conduct in the procurement of the patent and, accordingly, the '444 patent was invalid. In their reply brief, plaintiffs similarly contend their claims "are not premised on Bayer's conduct before the [PTO]; they are premised on Bayer's conduct in settling its own patent case with a payment not to compete." (Original boldface.) However, because the payment in question did not restrain competition beyond the exclusionary scope of the '444 patent, it does not subject defendants to antitrust liability unless plaintiffs can

prove their claim that the Bayer's infringement suit was objectively baseless, which claim is premised on Bayer's conduct before the patent office.

Plaintiffs argue that state courts have jurisdiction to determine patent law issues such as patent validity when such determination is ancillary and necessary to the main action, citing, among other authority, Mattel, Inc. v. Luce, Forward, Hamilton & Scripps (2002) 99 Cal.App.4th 1179, 1186. The Mattel court concluded that a state claim against the law firm for malicious prosecution was not preempted by federal copyright law even though the defendant asserted that the underlying trademark infringement action could have been brought only in federal court. The court relied in part on cases holding that " 'if the suit is to enforce or to revoke a patent licensing or other similar agreement, it "is not a suit under the patent laws of the United States, and cannot be maintained in a federal court as such." [Citations.] It follows . . . that in an action in a state court based upon such an agreement, the state court can, where it becomes necessary for it to do so in order to decide the case before it, pass upon the meaning, the scope, the validity, or the infringement of the patent.' " (Id. at p. 1187.) However, the present action is not a contract action seeking to enforce or revoke a patent licensing agreement; it arises from a settlement of patent litigation, and plaintiffs' sham litigation claim requires adjudication of the validity of the patent in the context of the determination of whether Bayer's patent infringement suit against Barr was objectively baseless.

Plaintiffs also rely on *ClearPlay, Inc. v. Abecassis* (Fed.Cir. 2010) 602 F.3d 1364, which involved state law claims by ClearPlay, Inc. (ClearPlay), a manufacturer of DVD players against patent holder Nissim Corp. (Nissim) arising from a patent licensing

agreement that the parties entered into in settlement of a patent infringement suit that Nissim brought against ClearPlay. Nissim claimed that ClearPlay breached the license agreement and filed a motion to enforce the parties' settlement. While that motion was pending, Nissim informed retailers selling ClearPlay's products that the products were not licensed and the retailer's continuing to sell them could constitute patent infringement. (Id. at pp. 1364-1365.) ClearPlay responded by bringing a state law action against Nissim that included claims for tortious interference with contractual relationships, tortious interference with potentially advantageous business relationships, breach of the license agreement by interfering with ClearPlay's business operations, breach of the covenant of good faith and fair dealing, and violation of Florida's Deceptive and Unfair Trade Practices Act. (Id. at pp. 1365, 1367-1368.) The ClearPlay court decided that although "questions of patent infringement are addressed at various points in the communications that are at issue in ClearPlay's complaint, and while it is possible that patent law issues could arise in the course of litigating any one of ClearPlay's claims, it is equally clear that none of those claims necessarily turns on an issue of patent law. That is, in the case of each asserted claim, there is at least one theory of relief that would not require the resolution of a patent law issue." (Id. at p. 1368.) ClearPlay is inapposite. Because the Cipro settlement did not restrain competition beyond the exclusionary scope of the '444 patent, plaintiffs' claims here, unlike state law claims in ClearPlay, necessarily turn on the patent law issue of whether Bayer's infringement suit was objectively baseless due to inequitable conduct.

Plaintiffs argue it is error to revisit the federal jurisdiction issue decided by the district court in In re Ciprofloxacin Hydrochloride Antitrust Litigation, supra, 166 F.Supp.2d 740, when it remanded this action to state court. However, as this court explained in Moreau v. San Diego Transit Corp. (1989) 210 Cal. App.3d 614 (Moreau): "In making its jurisdictional determination on a motion for remand, the [federal] district court looks no further than the complaint and the motion for removal. This limitation is one aspect of the 'well-pled complaint' rule which holds a plaintiff is the 'master' of his complaint and he may craft his causes of action, if he so desires, to exclude federal jurisdiction. Under the rule a federal question must appear from the complaint and not from any preemption defense which might be raised in state court and which might ultimately defeat the cause of action. [Citation.] [¶] However, an independent corollary to the 'well-pled complaint' rule is the 'artful pleading' rule or the 'doctrine of complete preemption.' This doctrine states that while couched in state contract or tort terms, federal jurisdiction exists if the issues actually raise an essentially federal question. . . . [¶] When a federal court grants a motion for remand in the present context, it does nothing more than determine the complaint fails, either directly or by operation of the 'artful pleading' doctrine, to state a question arising under federal law. It does not determine whether a preemption defense can be successfully offered in state court when the entire case is considered." (Id. at pp. 620-621, italics added; accord, Ruiz v. Sysco Food Services (2004) 122 Cal. App. 4th 520, 531-532 ["[T]he trial court was not required or allowed to accord any collateral estoppel effect to the federal district court's remand order, which was not a final judgment but rather a procedural order concerning the

appropriate forum."]; McCormick v. Travelers Ins. Co. (2001) 86 Cal.App.4th 404 [after removal of state tort claims to federal court and federal court's subsequent remand to state court, state court properly granted defendant's motion for judgment on the pleadings on the ground of federal preemption]; AT&T Communications, Inc. v. Superior Court (1994) 21 Cal.App.4th 1673, 1680 [doctrine of law of the case applies only to appellate court decisions and a remand ruling is a jurisdictional ruling, not a final judgment on the merits of a preemption defense]; United Airlines, Inc. v. Superior Court (1991) 234 Cal.App.3d 1085, 1090 ["The exercise of a federal district court's unreviewable power to remand claims to state court . . . is not necessarily the same as a determination of whether those claims on their merits—even though not removable to federal court—would nonetheless be preempted by federal law if asserted by way of defense in state court."]; Coker v. Purdue Pharma Co. (Tenn.Ct.App., Nov. 30, 2006, No. W2005-02525-COA-R3-CV) 2006 Tenn. App. LEXIS 757 [after federal court remanded case to state court on the ground the complaint's allegations of misrepresentation to the PTO in the procurement of a patent could be proven without resorting to question of federal law, state trial court properly determined federal preemption was a valid defense to the misrepresentation claims and granted judgment on the pleadings].)14

Although it is not essential to our preemption analysis, we note that the theory of liability alleged in plaintiffs' second amended complaint that caused the federal district court to remand this case to state court in *In re Ciprofloxacin Hydrochloride Antitrust Litigation, supra*, 166 F.Supp.2d 740 lacks merit, as the district court later acknowledged. The court remanded the case based on its conclusion "that plaintiffs have asserted at least one theory by which they may establish state antitrust violations without resorting to a determination of patent law. Plaintiffs' complaints allege there would have been generic

Plaintiffs' contention that there is a triable issue of fact as to whether Bayer's infringement suit against Barr was objectively baseless due to inequitable conduct in procuring the '444 patent is not a basis to reverse the judgment. To the extent a shamlitigation claim is sufficiently pleaded in plaintiffs' second amended complaint, it arises from and is preempted by federal patent law. 15

competition in the market for ciprofloxacin prior to the expiration of Bayer's patent if Bayer had not reached an unreasonably anti-competitive agreement with Barr, HMR, and Rugby. . . . [Plaintiffs] asserted that, as a matter of fact, Bayer would have authorized Barr to distribute ciprofloxacin by granting Barr a license, or by other means, had Barr not agreed to drop its challenge to the validity of the '444 patent in exchange for large cash payments." (*Id.* at p. 748.)

This theory of liability fails because any restraint on competition resulting from Bayer's decision to enter into the Cipro agreements instead of some other licensing agreement was within the exclusionary zone of the '444 patent and thus is not a basis for imposing antitrust or unfair competition liability on defendants. As the Cipro II court explained: "[P]laintiffs' assertion that Bayer's payment to Barr is anti-competitive because, without it, Bayer and Barr would have agreed on an earlier entry date for Barr or would have otherwise fashioned a more pro-competitive agreement must also fail. This assertion ignores the fact that, if defendants were within their rights (more specifically, the patent right) in reaching the settlement they did, consumers have no right to secondguess whether some different agreement would have been more palatable." (Cipro II, supra, 363 F.Supp.2d at p. 536.) Regarding its basis for remanding the case, the district court stated that "[u]pon further reflection, I have concluded that patent law imposes no such restriction against cash payments by a patent holder, and, accordingly, antitrust law does not impose such a restriction." (Id. at p. 536, fn. 21.) In other words, Bayer was not restricted by patent or antitrust law to settlement options more favorable to competition than the settlement it reached.

We do not hold that the issue of whether a patent infringement suit is objectively baseless can never be decided by a state court; there may be cases where a suit can be shown to be objectively baseless without the necessity of resolving a substantial question of federal patent law.

## III. Unfair Competition and Common Law Monopoly Claims

Our conclusion that defendants are not liable under the Cartwright Act for entering into the Cipro agreements is also dispositive of plaintiffs' causes of action for violation of the UCL and common law monopolization. "The purpose of federal and state antitrust laws is to protect and promote competition for the benefit of consumers. [Citations.] Antitrust laws are designed to prohibit only unreasonable restraints of trade, meaning conduct that unreasonably impairs competition and harms consumers. [Citations.] If the same conduct is alleged to be both an antitrust violation and an 'unfair' business act or practice for the same reason - because it unreasonably restrains competition and harms consumers - the determination that the conduct is not an unreasonable restraint of trade necessarily implies that the conduct is not 'unfair' toward consumers. To permit a separate inquiry into essentially the same question under the unfair competition law would only invite conflict and uncertainty and could lead to the enjoining of procompetitive conduct." (Chavez v. Whirlpool Corp. (2001) 93 Cal.App.4th 363, 375; accord, Drum v. San Fernando Valley Bar Assn. (2010) 182 Cal.App.4th 247, 254 [conduct that is deemed reasonable and condoned under antitrust law does not violate the UCL].)

Regarding plaintiffs' cause of action for common law monopolization, it is questionable whether such a cause of action exists under California law. The federal district court in *In re Intel Corp. Microprocessor Antitrust Litigation* (D.Del. 2007) 496 F.Supp.2d 404 dismissed a common law monopolization claim on the ground that "the common law tort of monopolization is not cognizable under California law . . . . " (*Id.* at

p. 420; accord, Lorenzo v. Qualcomm, Inc. (S.D.Cal. 2009) 603 F.Supp.2d 1291; Luxpro Corp. v. Apple, Inc (W.D.Ark. 2009) 658 F.Supp.2d 921, 933.) To the extent such a cause of action is cognizable under California law, it fails for the same reason plaintiffs' UCL cause of action fails—i.e., because it is based on the same conduct alleged to be a violation of the Cartwright Act. Conduct that has been determined not to unreasonably restrain competition under statutory antitrust law cannot logically be deemed to unreasonably restrain competition under a common law monopolization theory.

The trial court properly granted summary judgment on plaintiffs' causes of action for violation of the UCL and common law monopolization as well as their cause of action for violation of the Cartwright Act. The court also properly ruled that its summary judgment ruling as to Bayer and the generic defendants was also dispositive as to Watson's summary judgment motion, since plaintiffs sought to hold Watson liable solely as a conspirator for the allegedly unlawful conduct of the other defendants.

### IV. Evidentiary Objections

Plaintiffs contend the court erred by not providing any explanation for overruling all of their evidentiary objections, relying on Nazir v. United Airlines, Inc. (2009) 178 Cal.App.4th 243, 254-257 (Nazir) in which the Court of Appeal held that the trial court abused its discretion by issuing a blanket ruling sustaining all but one of defendants' 764 evidentiary objections in a summary judgment proceeding.

Here, the court did not sustain the evidentiary objections in question; it overruled them. In *Reid v. Google, Inc.* (2010) 50 Cal.4th 512, 534, the California Supreme Court held that when a trial court ruling on a summary judgment motion "fails to rule expressly

on specific evidentiary objections, it is presumed that the objections have been overruled, the trial court considered the evidence in ruling on the merits of a summary judgment motion, and the objections are preserved on appeal." Thus, the trial court's blanket ruling overruling plaintiffs' evidentiary objections left plaintiffs in no worse a position than they would have been in if the court had failed to issue any ruling at all on the objections. The objections were preserved on appeal and plaintiffs were free to challenge the trial court's consideration of specific items of objected-to evidence on appeal. Because plaintiffs have not argued that the admission of any specific evidence constituted prejudicial error, the court's ruling on plaintiffs' evidentiary objections provides no basis to disturb the judgment. 16

We note that plaintiffs complain that the court improperly considered evidence concerning the litigation challenging the '444 patent that occurred after the Cipro settlement and the reexamination of the patent. We do not find the admission of this evidence to be prejudicial, however, 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.

## **DISPOSITION**

The judgment is affirmed.

Taces NARES, J.

WE CONCUR:

Benke BENKE, Acting P. J. Jawa AARON, J.



## Court of Appeal

FOURTH APPELLATE DISTRICT 750 B STREET, SUITE 300 SAN DIEGO, CA 92101-8196

October 31, 2011

RECEIVED

LIEFF, CABRASER, HEIMANN & BERNSTEIN

To: ALL PARTIES

Re: D056361, In re Cipro Cases I & II

An asterisked footnote was inadvertently omitted from the opinion in the above case filed on October 31, 2011. It should have appeared at the bottom of page 1, reading as follows:

> McGaughey v. Bayer Corporation (Super. Ct. San Diego County, No. GIC752290); Relles v. Bayer Corporation (Super. Ct. L.A. County, No. BC239083); Samole v. Bayer AG (Super. Ct. S.F. City and County, No. 316349); Garber v. Bayer AG (Super. Ct. S.F. City and County, No. 316518); Lee v. Bayer AG (Super. Ct. S.F. City and County, No. 316670); Patane v. Bayer AG (Super. Ct. S.F. City and County, No. 318457); Moore v. Bayer Corporation (Super. Ct. Sonoma County, No. SCZ228356); Moore v. Bayer Corporation (Super. Ct. Sonoma County, No. 228384); Senior Action Network v. Bayer AG (Super. Ct. S.F. City and County, No. 400750).

> > Very truly yours,

Sandra Feery

Sandra Feeny Judicial Assistant



## RECEIVED

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LIEFF, CABRASER, HEIMANN & BERNSTEIN



# Court of Appeal

FOURTH APPELLATE DISTRICT 750 8 STREET, SUITE 300 SAN DIEGO, CA 92101-8196

November 23, 2011

To: ALL COUNSEL

Re: D056361, In re Cipro Cases I & II, filed October 31, 2011

#### Dear Counsel:

The second sentence of the second paragraph beginning at page 30 of the opinion in the above case inadvertently reversed the positions of the direct purchaser plaintiffs and the indirect purchaser and advocacy group plaintiffs. That sentence should read:

As noted above, the Cipro II judgment was affirmed in Cipro III as to the indirect purchaser and advocacy group plaintiffs and Arkansas Carpenters as to the direct purchaser plaintiffs.

Also due to clerical error, on page 29 in footnote 6, the word "and" in the bracket "[to file and ANDA IV]" should read: [to file an ANDA IV].

An additional correction should be made to the citation in the paragraph beginning on page 34. That citation should read *Fruit Machinery Co. v. F. M. Ball & Co.* (1953) 118 Cal.App.2d 748 (*Fruit Machinery*). Subsequent references should be to "*Fruit Machinery*"— not "*Fruit Machine.*"

Very truly yours.

Sandra Feeny
Sandra Feeny

**Judicial Assistant** 

cc: All parties

State of California ) County of Los Angeles ) )	Proof of Service by: ✓ US Postal Service
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I declare under penalty of perjury that the foregoing is true and correct:

Signature

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