LIU, J.

In the

Supreme Court

of the

State of California

S198616

IN RE CIPRO CASES I & II

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

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REPLY TO ANSWERS TO PETITION FOR REVIEW

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INTRODUCTION

Respondents' arguments and justifications do not change the important public interest in this unsettled legal area. Bayer concedes that this appeal involves "high stakes" issues (Bayer at 6), and neither Answer disputes that denial of review would increase the burden on California consumers, health care providers and government agencies at a time of strained budgets and rising prescription drug costs.

Furthermore, the California Attorney General, recognizing the damage to California citizens and California jurisprudence from the decision below, urges this Court to accept review. *See* 1/10/12 AG Amicus Letter, at 1–3 ("The Attorney General believes that the Court of Appeal applied an incorrect standard .... The decision below has changed California law").[1]

ARGUMENT

I. Respondents' Answers Show the Court's Review Is Needed.

A. Respondents Fail to Diminish the Consequential Issues at Stake.

The recent practice where drug companies transfer and share wealth to avoid patent trials, and thereby protect prescription drug monopolies, has bedeviled the antitrust and patent bars, economists, academic commentators and government officials. And for good reason. These agreements harm the public because they prevent price competition on key medicines and the much lower pricing that necessarily results.

Does holding a patent allow a company to pay its competitors hundreds of millions of dollars so that the patent can remain in effect? Can

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[1] Petitioners adopt the arguments made by the Attorney General and by *Amicus Curiae* the American Antitrust Institute in its letter of January 18, 2012.

drug companies collude to share the profits from monopoly pricing under California law? Law enforcers, regulators and commentators are virtually unanimous that the answers are no.

The answers are doubly important as prescription drug prices continue upward. Californians paid $21.7 billion for drugs in 2010. This was about $5 billion more than they paid just five years ago.[2]

Reverse exclusionary payments contribute to this trend. Californians will pay around $4.2 billion in supracompetitive prescription drug costs over the next ten years—unless reverse payments are subjected to antitrust scrutiny.[3]

Proper application of California law will send these claims to a jury. *Fruit Machinery Company v. F. M. Ball & Company* (1953) 118 Cal.App.2d 748, and *Vulcan Powder Company v. Hercules Powder Company* (1892) 96 Cal. 510, teach that a patent holder may not engage in abusive conduct that violates the Cartwright Act. The Generics accurately quote *Fruit Machinery*'s disjunctive holding (Generics at 17 ("... or *abuse*[] any rights or powers"))—but then omit this key language from their subsequent description of the holding. (Generics at 18.) Regarding *Vulcan*, Bayer admits that its federal "analog" is *In re Cardizem CD Antitrust Litigation* (6th Cir. 2003) 332 F.3d 896, which held a similar pay-for-delay agreement *per se* unlawful. (Bayer at 17.) The court below specifically refused to follow *Cardizem* and, therefore, *Vulcan*.

Respondents' agreement is a *per se* violation of the Cartwright Act, which forbids *any* "tampering with prices; they must be determined, we have stated, by the 'interplay of the economic forces of supply and

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[2] *See* 1/10/12 AG Amicus Letter, at 2 (citing Kaiser Family Foundation findings).

[3] *See* 1/10/12 AG Amicus Letter, at 3 (citing FTC findings).

demand.'" *Mailand v. Burckle* (1978) 20 Cal.3d 367, 377.[4] The UCL, too, employs "broad, sweeping language, precisely to enable judicial tribunals to deal with the innumerable new schemes which the fertility of man's invention would contrive." *Cel-Tech Comms., Inc. v. Los Angeles Cellular Tel. Co.* (1999) 20 Cal.4th 163, 181. Reverse payments—though a relatively "new scheme"—belong to an ancient species of antitrust violation. Few business arrangements are more pernicious than a monopolist's payment to another firm to stay out of the entire California market. *Lowell v. Mother's Cake & Cookie Co.* (1978) 79 Cal.App.3d 13, 23.

While federal decisions determined the erroneous result below, California's antitrust laws apply more broadly than federal antitrust laws. *See, e.g., Edwards v. Arthur Andersen LLP* (2008) 44 Cal.4th 937, 948-50 (rejecting federal court's attempt to create a "narrow-restraint" exception to California's prohibition of noncompete agreements). The Cartwright Act "reaches deep in proscribing anticompetitive conduct" and "reaches beyond the Sherman Act" in certain instances. (Werdegar, *Conclusion*, COMPETITION (Fall 2008), at 223; *see also Cellular Plus, Inc. v. Super. Ct.* (1993) 14 Cal.App.4th 1224, 1242 ("[T]he Cartwright Act is broader in range and deeper in reach than the Sherman Act.").) The Congressional Record "reveals that [the bill introduced in the U.S. Senate in 1888, later enacted as the Cartwright Act] was designed not to narrow the scope of the Sherman Act but to broaden it.... As shown by the plain meaning of the statutory language, the evident implication of such language, and the manifest purpose of the Act, the Legislature intended to strike as broadly as it could in the Cartwright Act." *Cianci v. Super. Ct.* (1985) 40 Cal.3d 903, 919-21.

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[4] Emphasis is added, and citations omitted, unless otherwise noted.

The Act outlaws anticompetitive behavior in categorical terms: agreements restraining free competition are "absolutely void." Bus. & Prof. Code § 16722. Also unlike the Sherman Act, the Cartwright Act establishes specific categories of *per se* unlawful restraints. It bans all agreements between businesses "to pool, combine or directly or indirectly unite any interests that they may have connected with the sale or transportation of any such article or commodity, that its price *might in any manner* be affected." Bus. & Prof. Code § 16720(e)(4). Respondents pooled their interests in the Cipro monopoly to affect prices, violating the Cartwright Act. *Guild Wineries & Distilleries v. J. Sosnick & Son* (1980) 102 Cal.App.3d 627, 633 (holding competitor agreements to divide up or share markets categorically violate the Cartwright Act); *see also* Bus. & Prof. Code § 16660 ("Except as provided in this chapter, every contract by which anyone is restrained from engaging in a lawful profession, trade, or business of any kind is to that extent void."); *Oden v. Board of Admin.* (1994) 23 Cal.App.4th 194, 202 (describing *in pari materia* canon).

Confronted with its blatant violation of the Act, Bayer argues this is not an ideal case for the Court to accept because Congress amended the federal Hatch-Waxman Act in 2003 and Bayer filed its patent suit against Barr under the pre-amended Act. (Bayer at 5, 27.) In reality, the 2003 amendments do not change the legal analysis of such violations—under the California statutes—or the fact that they contravene the statutory intent. Indeed, with respect to the federal statute, Representative Waxman joined Senator Hatch in condemning reverse payments, stating that "[t]he law has been turned on its head.... We were trying to encourage more generics and through different business arrangements, the reverse has happened." (10AA 2224.)

Neither Bayer's reexamination of the Cipro patent after settling its patent litigation with Barr, nor the subsequent patent litigation under a

revised and narrowed patent, detracts from the importance of the issues presented by this appeal.[5] Those events should not preclude scrutiny of Respondents' earlier anticompetitive agreement. In addition, they prove nothing about Bayer's concealment of prior art and evident calculation that the patent would have been struck down before it was narrowed.

None of the subsequent cases determined the issue of Bayer's inequitable conduct, largely because by the time the issue could have been litigated, the Cipro patent would have expired or nearly expired. The Barr litigation squarely challenged Bayer's inequitable conduct in applying for the patent.[6] Likely successful, Barr's challenge would have rendered the entire patent unenforceable. *See Fox Indus., Inc. v. Structural Preservation Sys., Inc.* (Fed. Cir. 1990) 922 F.2d 801, 803-04. Bayer's reexamination served to limit future patent challenges, but did not (and could not) undo the company's knowing failure to disclose disqualifying German prior art. (7AA 1486; *see also* 1AA 149–50; 8AA 1804–29 (expert summarized Bayer's deceptive acts).) This inescapable evidence of deception points to the anticompetitive nature of the $398.1 million bribe: it was made to protect a patent that—as Bayer knew—was in all likelihood unenforceable. Bayer's interrogatory response, that its patent agents were basically insane when they testified Bayer intentionally failed to disclose the prior art, is

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[5] The trial court erred in admitting evidence of the reexamination and the subsequent litigation, because those events occurred after the challenged restraint. Antitrust analysis "ask[s] whether an agreement promoted enterprise and productivity at the time it was adopted." *In re Sulfuric Acid Antitrust Litig.* (N.D. Ill. 2010) 743 F.Supp.2d 827, 872; *see, e.g., Reazin v. Blue Cross & Blue Shield of Kansas, Inc.* (D. Kan. 1987) 663 F.Supp. 1360, 1433 (excluding FTC decision "rendered months after" challenged restraint). The lone case cited by Bayer on this point, *Blank v. Coffin* (1942) 20 Cal.2d 457, is not an antitrust case and is therefore inapposite.

[6] Petitioners do not assert an inequitable conduct claim; however, the evidence of inequitable conduct supports Petitioners' state-law claims.

itself incredible and highlights Bayer's difficulty in defending the patent against Barr's attack. (7AA 1478–79.)

Unable to explain its fanciful response, Bayer changes the subject. It argues that claim 12 of the Cipro patent encompassed the relevant material and was not modified on reexamination, so the reexamined patent was no different. (Bayer at 26.) This new assertion ignores the expert testimony and other record evidence to the contrary:

> [Through the reexamination] Bayer was able to revise and strengthen the original '444 patent so that the IP vulnerabilities identified by Barr in its original litigation were cured .... [T]he exploitation of information shared during settlement negotiations allowed Bayer to alter and increase the scope and strength of the '444 patent in order to ... effectively blockade and foreclose future generic entry.

(6AA 1173, 1209.)

Bayer also now makes the speculative and remarkable suggestion that allowing a jury to evaluate its reverse payment might dampen innovation. (Bayer at 23.) In fact, *reverse payments themselves reduce innovation*, by cutting off the generic competition that gives branded drug companies an added incentive to develop new products.[7]

B. Review Is Necessary to Clarify the Proper Application of California Law in an Unsettled Legal Area.

In attempting to make it appear that federal law in this area is settled, Respondents would have this Court condone adoption of the most permissive and widely criticized rule as the law of California. Federal law is far from settled. The courts have taken at least three different approaches

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[7] *See* http://www.ftc.gov/os/2003/10/innovationrpt.pdf (2003 FTC Report), ch. 3 at 11 ("The generic competition spurred by Hatch-Waxman has forced brand-name firms to come up with new products to replenish their revenue streams.").)

to reverse exclusionary payments, and the U.S. Department of Justice recommends a fourth approach.

The correct standard in California is the traditional *per se* antitrust rule against anticompetitive agreements between horizontal competitors. In *Cardizem*, the court held that a reverse payment agreement was, "at its core, a horizontal agreement to eliminate competition ... a classic example of a *per se* illegal restraint of trade." 332 F.3d at 908. Respondents mischaracterize *Cardizem*. Application of the *per se* rule there did not depend on the agreement restraining trade beyond (as well as within) the scope of the patent but, rather, on the reality that "had [the patent holder] been confident of the independent durability of its patent and the validity of its infringement claim, it would not have paid $89 million to effect what the patent and infringement suit had already accomplished." *Id.* at 915.

A second rule deems reverse payments presumptively unlawful but gives the drug companies the opportunity to rebut this presumption, by, for example, offering evidence that their wealth transfer did not greatly exceed litigation costs. (11AA 2576.) The DOJ supports this approach, as any more permissive rule "treat[s] all but the most obviously invalid patents as equally potent bulwarks against competition from generic drugs. This result seems particularly unacceptable when a substantial payment for an agreement to withdraw a patent validity challenge strongly implies that the payor recognized a significant risk of patent invalidation[.]"[8] (11AA 2573.)

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[8] The drug companies have demonstrated they are perfectly capable of settling patent cases without making payments that forestall generic entry, as shown by the settlements reached from 2000-2004 prior to *Tamoxifen*. (*See* http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf (2006 FTC Report), at 4.)

Third, a line of cases in the Eleventh Circuit applied what could be described as a modified Rule of Reason[9] looking to the "scope of the exclusionary potential of the patent" to determine whether antitrust claims can proceed. *Valley Drug Co. v. Geneva Pharms., Inc.* (11th Cir. 2003) 344 F.3d 1294, 1311. This approach differs from *Tamoxifen* in that the concept of "exclusionary potential" incorporates an analysis of the patent's likely ability to exclude infringing use, *i.e.*, its strength. Applying this standard, one court noted that "[t]he exclusionary value of the patent ... cannot be defined by looking at the patent terms in a vacuum," for "[t]he legitimate exclusion value of a pharmaceutical patent ... is the power it actually confers over competition, which is in turn a function of the scope of the patent and its chance of being held valid." *In re Terazosin Hydrochloride Antitrust Litig.* (S.D. Fla. 2005) 352 F.Supp.2d 1279, 1296. After all "a patent does not give the patentee 'the right to exclude,' but rather the more limited 'right to *try* to exclude' by asserting its patent in court." *Id.* (emphasis in original). Therefore a court should evaluate the "likely outcomes of the patent litigation that was pending at the time the parties entered into the Agreement" and assess the risk that the patent would have been nullified. *Id.* at 1299-1301.

Fourth, the Second Circuit immunized reverse payment agreements unless they involve a baseless patent suit or a patent procured by fraud, or contain provisions exceeding the patent's scope. *In re Tamoxifen Citrate Antitrust Litig.* (2d Cir. 2006) 466 F.3d 187. The majority, however, had serious misgivings: "There is something on the face of it that does seem

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[9] Bayer and the Generics each tout their purported "early entry license" on the first page of their respective Answers. The record reveals this limited license to be window dressing. It had no pro-competitive effects. Under it, Barr sold Bayer-manufactured Cipro at prices that were 5-10% higher than Bayer's own supracompetitive prices. (5AA 1037; 6AA 1207–08.)

'suspicious' about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn by winning the lawsuit and entering the newly competitive market in competition with the patent holder." *Id.* at 208. The Federal Circuit agreed with the majority in *Tamoxifen. In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Fed. Cir. 2008) 544 F.3d 1323. In 2010, the Second Circuit again addressed reverse payments, and noting, among other things, that "the United States has itself urged us to repudiate *Tamoxifen*," concluded "there are compelling reasons to revisit *Tamoxifen*[.]" *Arkansas Carpenters Health & Welfare Fund v. Bayer AG* (2d Cir. 2010) 604 F.3d 98, 108-10.

While there may be disagreement about the correct standard, there is agreement about one issue. Virtually everyone except pharmaceutical companies agree that *Tamoxifen*—and now the opinion of the court below—is incorrect.

II. Respondents Fail to Demonstrate Why Review Is Not Justified to Settle the Questions Presented.

A. The Unexamined Assertion of a Patent Cannot Shield Bayer's Noncompete Payment From Scrutiny.

Beyond its failure to apply California antitrust law, the opinion's reasoning has an Achilles' heel. The Court of Appeal "provides a broad immunity to reverse-payment agreements based solely upon the *unexamined assertion* of a patent." (1/10/12 AG Amicus Letter, at 6.) Indeed, the court defers to the mere exclusionary "potential" of a drug patent, even one that came under fundamental attack. (Generics at 14.)

But a rule that yields to a patent's "potential" to exclude—that allows even "fatally weak" patent rights (*Tamoxifen*, 466 F.3d at 212) to survive several additional years when enshrined in a naked payment not to compete, safeguarding billions in profits from vital medicines—offends the

public interest behind California competition law, as well as the "strong ... policy that only inventions which meet the rigorous requirements of patentability shall be withdrawn from the public domain." *Aronson v. Quick Point Pencil Co.* (1979) 440 U.S. 257, 264.

By claiming to focus on the "exclusionary zone" of the patent, while ignoring whether the patent was valid in the first place, the Court of Appeal assumes that a patent holder, by virtue of the patent grant, has an absolute right to pay its competitors to stay out the market. That assumption is false. A patent does not confer a definite right. *In re Etter* (Fed. Cir. 1985) 756 F.2d 852, 856. Instead, it reflects only an *initial view* that an invention is patentable; it requires a court-approved injunction to be enforced, and can be invalidated. *Lear, Inc. v. Adkins* (1969) 395 U.S. 653, 670; *Zenith Radio Corp. v. Hazeltine Research* (1969) 395 U.S. 100, 135 ("The heart of his legal monopoly is the right *to invoke the State's power* to prevent others from utilizing his discovery without his consent.").[10] A patent holder can also reasonably license or assign patent rights. *Id.*

But, it was settled long ago that issuance of a patent does not provide a private right to commit antitrust violations through abusive patent-based dealings, including, as here, unlawful combinations and cash agreements to prolong the life of a weak patent. "Nothing in the Patent Act authorizes a patentee to pay a rival simply to stay out of its market." Herbert Hovenkamp, *Antitrust and Innovation*, 77 ANTITRUST L.J. 749, 753 (2011).

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[10] The Generics cite instances where courts have commented on the patent misuse doctrine that applies as an affirmative defense (Generics at 19–20), but those courts did not overrule cases like *Zenith Radio* or *Besser Manufacturing Company v. United States* (1952) 343 U.S. 444, which hold that antitrust claims can proceed, even based on misuse of an enforceable patent.

> Rights conferred by patents are indeed very definite and extensive, but they do not give any more than other rights an universal license against positive prohibitions. The Sherman law is a limitation of rights, rights which may be pushed to evil consequences and therefore restrained.

Standard Sanitary Mfg. Co. v. United States (1912) 226 U.S. 20, 49; *see also United Shoe Machinery Co. v. La Chapelle* (Mass. 1912) 99 N.E. 289, 292 (Massachusetts Supreme Judicial Court finds "[t]here appears to be no inherent natural distinction between owners of patents and owners of oil which would justify the application of [antitrust law] to one and not to the other."); *United States v. Singer Mfg. Co.* (1963) 374 U.S. 174 (agreements to settle disputes over patent validity violated antitrust laws).

The Cipro patent at the time of Respondents' agreement was of dubious enforceability. Its simple assertion cannot immunize their horizontal agreement to eliminate competition for more than seven years. A patent holder "should not be permitted by legal devices to impose an unjust charge upon the public in return for the use of it." *Motion Picture Patents Co. v. Universal Film Mfg. Co.* (1917) 243 U.S. 502, 513. This has long been true irrespective of whether the illegal conditions fall within the patent's scope. The rule against restrictions on unrelated products does not imply its converse: that agreements relating to a potentially invalid patent may never give rise to antitrust liability. The basic tenet of Respondents' argument—"there was no monopoly or restraint other than the monopoly or restraint granted by the patents"—has been rejected by the U.S. Supreme Court and also should be rejected on these facts. *United States v. Masonite Corp.* (1942) 316 U.S. 265, 276.

That Respondents' agreement was limited to the patent parameters says nothing about whether the patent actually supplied legitimate grounds

for the monopoly. However, the timing (on the eve of the patent trial), size (enormous), and direction (from the patent holder *to the patent challenger*) of Bayer's payment demonstrate that Respondents seriously doubted the patent's actual ability to exclude.[11] California law, as established in *Fruit Machinery* and *Vulcan*, recognizes the distinction between legitimate patent use and the type of actionable abuse present here.

B. The Preemption Ruling Is Flawed.

The Court of Appeal failed to apply the heavy presumption against federal preemption of California law. The Generics do not address preemption while Bayer falls into the same error as the Court of Appeal. The question of whether federal courts have exclusive jurisdiction is separate and distinct from whether federal law preempts state-law claims. The California laws invoked here proscribe different wrongs, and provide for different relief, than patent law. Accordingly, patent law does not displace them. *See TruePosition, Inc. v. Andrew Corp.* (D. Del. 2007) 507 F.Supp.2d 447, 461 (exercising federal jurisdiction yet *refusing* to find a UCL claim preempted; explaining "[f]ederal laws do not bar state law claims that address different wrongs than those proscribed by the patent laws and that also provide for different forms of relief.").

Moreover, as one judge put it, "[t]he sky will not fall on our patent system by our refusal to preempt the state law causes of action ... which plead at their core a substantial question of federal patent law." *Dow Chem. Co. v. Exxon Corp.* (Fed. Cir. 1998) 144 F.3d 1478, 1480

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[11] Bayer contends that it only shared 6 percent of its gross Cipro sales with its would-be competitors, so it must have thought it had a 94 percent chance of prevailing at trial. (Bayer at 25.) Settlement decisions of this magnitude cannot be reduced to fourth grade math. Bayer's comparison to gross sales indicates that its payment amounted to significantly more than 6 percent of its Cipro *profits*—a more accurate measure of its belief the patent would be "destroyed" at trial, as its Board was told. (1AA 150.)

(Clevenger, J., concurring). The Court of Appeal erroneously conflates the two inquiries—"plaintiffs' claim that Bayer's infringement suit against Barr was objectively baseless due to inequitable conduct is preempted by federal patent law because it necessarily depends on resolution of a substantial question of patent law." (Opinion at 44.)

The federal decisions relied on by Bayer and the Court of Appeal interpret the Sherman Act. Neither Bayer nor the Court of Appeal explains how limiting the Sherman Act has any preemptive effect on the Cartwright Act under any of the four well-known theories of preemption: express, field, obstacle, and conflict.[12] *See Farm Raised Salmon Cases* (2008) 42 Cal.4th 1077, 1087-88. California antitrust law can be broader than the Sherman Act. *California v. ARC America Corp.* (1989) 490 U.S. 93, 101 (finding "it is plain that this is an area traditionally regulated by the states.").

Even the trial court did not consider or find preemption. Rather, it found subject matter jurisprudence lacking. This, too, was error.

First, *Tamoxifen*'s sham litigation requirement, on which the jurisdiction and preemption holdings depend, is misplaced—for the different setting of First Amendment petitioning deserves a higher bar to liability than private agreements among rivals not to compete. (Petition at 20–21.) Respondents offer no response to this point, focusing instead on fraud claims under *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corporation* (1965) 382 U.S. 172. (Bayer at 20–22.) *Walker Process* does not limit patent-based antitrust violations to those arising from fraudulent patent procurement, and Petitioners do not assert fraudulent procurement as a basis for liability here.

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[12] There is no such thing as "jurisdictional preemption." (Bayer at 30.)

Second, whether a claim "arises under" patent law "must be determined from what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration, unaided by anything alleged in anticipation of avoidance of defenses which it is thought the defendant may interpose." *Franchise Tax Board of Calif. v. Constr. Laborers Vacation Trust* (1983) 463 U.S. 1, 10. Further, "a claim supported by alternative theories *in the complaint* may not form the basis for" exclusive federal jurisdiction under 28 U.S.C. § 1338 "unless patent law is essential to *each* of those theories." *Christianson v. Colt Indus. Operating Corp.* (1988) 486 U.S. 800, 810.

Petitioners' complaint does not include any claim arising under patent law. Patent law is not essential to Petitioners' allegation that Bayer's payoff violates California law due to its anticompetitive intent and effect. Respondents' sham litigation argument in their defense has no jurisdictional effect. In California, "there is broad state jurisdiction over matters affecting patents, the Supreme Court has clearly blessed such state power, and the federal courts have shown a clear lack of concern with state adjudication of such matters." *Mattel, Inc. v. Luce, Forward, Hamilton & Scripps* (2002) 99 Cal.App.4th 1179, 1186.

C. The Evidentiary Ruling Contravenes *Reid.*

Respondents do not deny that the blanket rulings below, which failed to address Petitioners' specific objections in contravention of *Reid v. Google, Inc.* (2010) 50 Cal.4th 512, 532 & n.8, will result in confusion. Petitioners' objections were not "rote" but challenged the admissibility of specific items of evidence, citing law in support. (*Compare* Bayer at 32, *with* 1AA 233–41.)

CONCLUSION

The decision below will do lasting harm by giving a green light to pharmaceutical companies to ignore California antitrust law, allocate markets, foreclose competition, and perpetuate monopolies to the detriment of California citizens. The Court should grant review to prevent that outcome and settle these important questions of law.

Respectfully submitted,

Dated: January 30, 2012

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Dated: January 30, 2012

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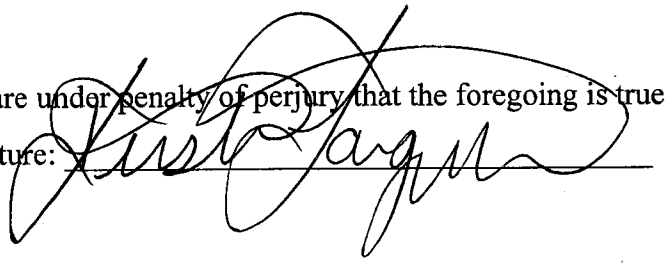
Signature: 

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