LIU, J.

S198616

In the

Supreme Court

of the

State of California

S198616
IN RE CIPRO CASES I AND II

KARYN McGAUGHEY, et al.,
Petitioners,

v.

BAYER CORPORATION, et al.,
Respondents.

California Court of Appeal · Fourth Appellate District · Case No. D056361
Superior Court of San Diego County · Hon. Richard E.L. Strauss
Case Nos. JCCP 4154 and JCCP 4220

SERVICE ON ATTORNEY GENERAL AND DISTRICT ATTORNEY REQUIRED UNDER BUS. AND PROF. CODE § 17209 AND CRD 8.29

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**Pro hac vice* pending

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Table of Contents

Table of Authorities

Page

CASES

Page

Page

STATUTES

OTHER AUTHORITIES

Page

INTRODUCTION

The Court of Appeal unanimously affirmed summary judgment for Bayer Corporation (Bayer) and its co-defendants by applying a rule firmly rooted in California law and consistent with unanimous federal authority. Petitioners do not claim any lack of uniformity exists in the appellate decisions bearing on their proposed issues. Nor do Petitioners present issues that require this Court "to settle an important question of law." (Cal. Rules of Court, rule 8.500(b).) Rather, Petitioners argue—and angrily so—that the Court of Appeal erred in a matter involving a potentially large damage award. There are no grounds to justify review of the Court of Appeal's thorough opinion. The petition should be denied.

SUMMARY OF REASONS TO DENY REVIEW

Bayer owned the patent to the antibiotic Cipro. (10AA 2340.) When Barr Laboratories, Inc. (Barr) sought approval under the federal Hatch-Waxman Act to sell a generic version of Cipro, Bayer sued for patent infringement, and Barr counterclaimed that Bayer's patent was invalid. (2AA 243 ¶ 5, 352-358.) Bayer and Barr settled the action. (2AA 246-251.) Under the settlement, Bayer paid Barr money and agreed to allow Barr to enter the market six months before the patent expired. Barr dropped its challenge and agreed not to infringe Bayer's patent. (*Ibid.*)

Petitioners and others filed class actions alleging defendants violated state and federal antitrust laws by settling the patent suit. (Slip. Opn. 8.) Other plaintiffs have mounted similar actions in federal courts against parties who settled Hatch-Waxman suits challenging other drug patents. Patent suits had been settled for many years before the Hatch-Waxman Act

established special procedures to challenge drug patents. Every court to consider the legality of a settlement within a patent's exclusionary effect has reached the same conclusion: If the settlement excludes no more competition than the patent itself, it does not injure competition unless (a) the patent was procured by fraud, or (b) the infringement claim was "objectively baseless." (Slip Opn. 34 [citing, inter alia, *Fruit Machinery Co. v. F.M. Ball & Co.* (1953) 118 Cal.App.2d 748, 762 (*Fruit Machinery*)]; *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (Fed.Cir. 2008) 544 F.3d 1323, 1336 (*Cipro-III*) [citing, inter alia, *Walker, Inc. v. Food Machinery* (1965) 382 U.S. 172, 177-179 (*Walker Process*)]; *In re Tamoxifen Citrate Antitrust Litigation* (2d Cir. 2006) 466 F.3d 187, 210-213 (*Tamoxifen*) [citing *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.* (N.D.Ill. 2003) 289 F.Supp.2d 986 (*Asahi Glass*)]; *Schering-Plough Corp. v. F.T.C.* (11th Cir. 2005) 402 F.3d 1056, 1068 (*Schering-Plough*) [citing *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.* (11th Cir. 2003) 344 F.3d 1294, 1306-1307, 1311 (*Valley Drug*)].)

Applying this "scope of the patent" rule to settlements of Hatch-Waxman litigation, the Court of Appeal joined the Second, Eleventh, and Federal Circuits, as well as numerous federal district courts, in rejecting Petitioners' claims. (See, e.g., ***Second Circuit:*** *Arkansas Carpenters Health & Welfare Fund v. Bayer AG* (2d Cir. 2010) 604 F.3d 98 (*Cipro-IV*); *Tamoxifen*, *supra*, 466 F.3d 187; ***Eleventh Circuit***: *Schering-Plough*, *supra*, 402 F.3d 1056; *Valley Drug*, *supra*, 344 F.3d 1294; ***Federal Circuit***: *Cipro-III*, *supra*, 544 F.3d 1323; accord, e.g., *In re K-Dur Antitrust Litigation*

(D.N.J. Mar. 25, 2010, No. 01-1652) 2010 WL 1172995; *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (E.D.N.Y. 2005) 363 F.Supp.2d 514 (*Cipro-II*); *Asahi Glass*, *supra*, 289 F.Supp.2d 986; Part I, *post*.) In fact, the Court of Appeal is the third appellate court, and the fifth court overall, to reject indistinguishable antitrust claims based on *the same Cipro settlement* at issue here. (Opn. 37-38; 11AA 2665; *Cipro-IV*, *supra*, 604 F.3d 98; *Cipro-III*, *supra*, 544 F.3d 1323; *Cipro-II*, *supra*, 363 F.Supp.2d 514.)

Indirect purchasers of Cipro, situated identically to these Petitioners (including California residents), pursued class claims against defendants in federal multi-district litigation (MDL). (See *Cipro-III*, *supra*, 544 F.3d 1323.) The claims were based on federal and state law, including the Cartwright Act and the California Unfair Competition law. (*Ibid.*) The Federal Circuit affirmed summary judgment for defendants, rejecting the same arguments advanced here, and the United States Supreme Court denied the plaintiffs' petition for certiorari. (*Ibid.*, cert. denied (2009) 129 S.Ct. 2828.) The Second Circuit later affirmed the same summary judgment ruling on an appeal by direct purchasers, and the Supreme Court again denied certiorari. (*Cipro-IV*, *supra*, 604 F.3d 98, cert. denied (2011) 131 S.Ct. 1606.)

The rule that all of these courts have applied arises from principles established in California and elsewhere for over a century: antitrust and unfair competition laws do not protect competition infringing a patent, and the burden is on the antitrust plaintiff to show that the allegedly excluded

competition was lawful. Two undisputed facts of record make the scope of the patent rule dispositive here:

First, Bayer's patent claimed Cipro's active ingredient—the molecule itself. (2AA 243.) Because a generic drug must have the same active ingredient as the pioneer drug it seeks to copy, all generic versions of Cipro infringed Bayer's patent. Here, the generic challenger, Barr, stipulated from the outset of the patent case that its product infringed. (2AA 248.) Thus, the settlement's exclusion of Barr's infringing drug was, by definition, within the patent's scope.

Second, after the settlement, Bayer submitted its patent for reexamination before the Patent and Trademark Office (PTO), which reaffirmed the claims relating to Cipro. (2AA 252.) Bayer then defeated three district court validity challenges by other generics: two on motions for summary judgment, which were affirmed by the Federal Circuit, and one after a bench trial in San Diego, which the losing generic did not appeal. (2AA 253-254, ¶¶ 31-32.) These subsequent patent victories preclude any contention that Bayer's patent claim was "objectively baseless," and may explain why Petitioners' complaint did not attack the validity or enforceability of the patent at all.

Unable to provide appropriate grounds for review, Petitioners mount a rhetorical attack on the Court of Appeal. They state that the court's reasoning is "abhorrent to the central purposes of the Cartwright Act" (Petn. 3), that its 53-page opinion reflects "a complete abdication of its judicial responsibilities" (*id.* 19, fn.15), and that its holding "abandons the citizens

of California." (*Id.* 24.) Petitioners repeatedly invoke general policies in favor of low drug prices and improved healthcare, and ask this Court to bend the law to their service without regard to statutory text or precedent. But the controversy Petitioners attempt to describe does not exist in the courts. It exists only for the disappointed plaintiffs who would prefer a rule that disregards a patent holder's right to exclude infringing competition.

Moreover, even if the question presented raised potential grounds for review, this is the wrong case in which to resolve it. The settlement at issue occurred in 1997, under a version of the Hatch-Waxman Act that was substantially amended in 2003. The U.S. Solicitor General has repeatedly told the U.S. Supreme Court to deny certiorari on non-recurring Hatch-Waxman questions such as this, governed by the old statute. (See, e.g., Brief of United States, *Tamoxifen*, *supra*, 551 U.S. 1144 (No. 06-830), 2007 WL 1511527, at *19-20; Brief of United States, *Cardizem*, *infra*, 543 U.S. 939 (No. 03-779) 2004 WL 1562075, *18-19.)

Finally, Petitioners' additional grounds are unworthy of review. On the question of preemption, Petitioners attack a ruling that the Court of Appeal did not even make. Misconstruing this Court's distinction between "jurisdictional preemption" and "substantive preemption," they ask the Court to transform a jurisdictional preemption finding into one of substantive preemption, and to resolve it without benefit of prior analysis by either lower court. On the question of evidentiary objections, Petitioners present an (incorrect) argument as to the procedure for ruling on objections

without suggesting that a different procedure would have changed the result below.

In sum, review of the decision below is unwarranted. The petition makes no pretense that there is any lack of uniformity. Nor does the settled legal issue presented become "important" under the rules simply because the stakes are high and Petitioners wish the law were different.

STATEMENT OF FACTS

This case arises from the settlement of patent litigation in *Bayer AG and Miles, Inc. v. Barr Laboratories, Inc.* (S.D.N.Y. No. 92 Civ. 0381).

Regulatory and Factual Background. The Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act, governs the interaction between patent protection and generic drugs. (Pub. L. No. 98-417, 98 Stat. 1585, as amended, 21 U.S.C. § 355.) To obtain FDA approval for a generic drug, the manufacturer must file an Abbreviated New Drug Application (ANDA). An ANDA-filer seeking approval prior to the expiration of any patent covering the drug must make a "Paragraph IV" certification that the patent "is invalid or ... will not be infringed by the ... [generic] drug." (21 U.S.C. § 355(j) (2)(A)(vii).)

Any ANDA must show that the "active ingredient of [the proposed] new drug is the same as that of the listed [or, pioneer] drug." (21 U.S.C. § 355(j)(2)(A)(ii)(I).) Claim 12 of the Cipro patent covers the molecule ciprofloxacin hydrochloride, which is the only active ingredient in all ciprofloxacin products, however formulated (tablet, capsule, etc.). (2AA 243, ¶ 2.) Thus, all generic Cipro has ciprofloxacin as its active ingredient

and infringes Bayer's patent. (*In re Ciprofloxacin Hydrochloride Antitrust Litigation* (E.D.N.Y. 2003) 261 F.Supp.2d 188, 249 (*Cipro-I*).)

In December 1991, Barr notified Bayer that it had filed an ANDA on Cipro with a Paragraph IV certification, which under Hatch-Waxman constituted an act of infringement. (2AA 243, ¶ 5; 35 U.S.C. § 271(e)(2); *Cipro-I*, *supra*, 261 F.Supp.2d at p. 251.) Bayer then sued Barr for infringement, even though Barr had made no infringing sales. Barr counterclaimed, asserting patent invalidity. (*Ibid.*) Thus, Bayer faced the risk of losing its patent, while Barr risked only litigation costs.

In January 1997, the parties settled. (2AA 247, ¶ 17.) Barr agreed to a consent judgment affirming the validity of the Cipro patent. (2AA 248, ¶ 19.) Bayer agreed to supply Barr with ciprofloxacin for resale under a license at least six months before patent expiration (see 4AA 768 § 1.01; 4AA 770-774 §§ 3.01-3.03), and to make settlement payments totaling $398.1 million (2AA 251, ¶ 24). The payments represented 6.5% of Bayer's U.S. gross sales of oral Cipro tablets for the payment period. (1RA 39, ¶ 3; 4AA 788 § 4.01(a).)

After settling, Bayer submitted the patent for reexamination. The PTO issued a reexamination certificate in 1999 (2AA 252, ¶ 28), confirming the validity of claims covering ciprofloxacin (*Cipro-II*, *supra*, 363 F.Supp.2d at p. 519).

The settlement and reexamination did not inhibit later ANDA challenges. Bayer filed four Hatch-Waxman lawsuits against subsequent Cipro challengers (Ranbaxy, Schein, Mylan, and Carlsbad). (2AA 252,

¶ 29). The Ranbaxy challenge was later withdrawn. (1RA 231, ¶ 7.) In *Schein* and *Mylan*, Bayer prevailed on summary judgment, and the Federal Circuit affirmed. (2AA 253, ¶ 31; *Bayer AG v. Schein Pharmaceuticals, Inc.* (D.N.J. 2001) 129 F.Supp.2d 705, affd. (Fed.Cir. 2002) 301 F.3d 1306.) Finally, Judge Brewster in San Diego rejected Carlsbad's validity challenge after a nine-day bench trial. (See 2AA 254, ¶ 32; *Bayer AG v. Carlsbad Technologies, Inc.* (S.D. Cal. June 7, 2002 and Aug. 7, 2002, No. 01CV0867-B) (1RA 181-227).) Carlsbad did not appeal.

Barr began selling generic Cipro on June 9, 2003. (2AA 255, ¶ 34.) The Cipro patent expired on December 9, 2003, and Bayer's pediatric exclusivity expired on June 9, 2004. (2AA 243, ¶¶ 3, 4.) Since then, other generic versions have been readily available. (2AA 255, ¶ 35.)

Procedural Background. Plaintiffs filed the operative second amended complaint on April 9, 2003, following removal and remand of several individual actions. (See *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (E.D.N.Y. 2001) 166 F.Supp.2d 740.) Twenty-six federal cases were consolidated in a MDL before the Hon. David Trager. The state and federal cases were litigated in tandem, with the parties agreeing that discovery in each case would apply to the others. (E.g., 6AA 1253.)

In March 2005, Judge Trager granted summary judgment to the MDL defendants, holding: "Unless 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." (*Cipro-II*, *supra*, 363 F.Supp.2d at p. 535.)

The California parties then agreed to stay this action pending the MDL appeal. (1RA 12.) All MDL plaintiffs appealed to the Second Circuit, but the defendants moved to transfer the appeal to the Federal Circuit, which has exclusive jurisdiction of cases arising under patent law. (*See Cipro-IV*, *supra*, 604 F.3d 98, at p. 103, fn.10.) The Second Circuit transferred the appeal of the indirect purchasers, whose complaint alleged that Bayer committed fraud in obtaining the Cipro patent. (*Ibid.*) The Second Circuit retained the appeal of the direct purchasers, who made no such allegations. (*Ibid.*)

In 2008, the Federal Circuit affirmed Judge Trager's rulings in all respects. (*Cipro-III*, *supra*, 544 F.3d at p. 1336.) The Supreme Court denied certiorari. (*Cipro-III*, *supra*, (2009) 129 S.Ct. 2828.)

After the Federal Circuit's affirmance, the California parties briefed summary judgment. (1RA 16.) In 2009, the superior court ruled for the defendants. Summary judgment was appropriate because, *inter alia*, "California cases ... hold that conduct falling within the scope of a patent is not an antitrust violation." (11AA 2668.) As to plaintiffs' argument that Bayer's patent claim was objectively baseless due to inequitable conduct before the PTO, the court held that "[t]he [Second Amended Complaint] is silent as to allegations [of] non-infringement, invalidity, inequitable conduct, or fraud on the PTO.... Further, this Court lacks jurisdiction to make such determinations." (11AA 2670.)

The Court of Appeal unanimously affirmed this ruling, and Petitioners seek this Court's review.

ARGUMENT

I. THE SCOPE OF THE PATENT RULE IS UNIFORM AND SETTLED

Petitioners do not argue that courts have split on the Cartwright Act question presented in this case.[1] And for good reason. Several California cases, including the decision below, and a long list of federal decisions have settled on a uniform rule: No antitrust liability attaches to conduct *within* the exclusionary scope of a patent absent fraud on the PTO or sham litigation. Only when a patentee acts *outside* the patent's exclusionary scope are such actions subject to antitrust liability. This "scope of the patent" test has been applied repeatedly to reject antitrust claims that arise in the context of Hatch-Waxman patent settlements.

A. Under California Law, Agreements Within the Exclusionary Scope of a Patent Do Not Restrain Trade

The leading California decision is *Fruit Machinery*, *supra*, 118 Cal.App.2d 748. There, a patent owner sued a licensee for failure to pay royalties. (*Id.* at p. 750.) The defendant argued that certain license restrictions were in restraint of trade, precluding enforcement. (*Ibid.*)

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[1] As they did before the Court of Appeal, Petitioners have waived review of the Unfair Competition Law issue by not raising it as a separate issue presented, or presenting argument concerning the relevant cases. (Cf. *In re Conservatorship of Ben C.* (2007) 40 Cal.4th 529, 544 & fn.8.) Accordingly, Bayer will not address the multitude of reasons why such review is unwarranted, which include the waiver below, mootness, abstention, and the application of *Chavez v. Whirlpool Corp.* (2001) 93 Cal.App.4th 363.

Among other things, the licensee claimed that the patentee would be able to discriminate in its royalties, charging rates with no "reasonable relationship" to its costs. (*Id.* at p. 762.)

The Court of Appeal rejected these arguments, finding that the contract terms were "made by plaintiff (as assignee of the patentee) in the exercise and *within the scope*, of the rights given and the protection accorded by the patent." (*Fruit Machinery*, *supra*, 118 Cal.App.2d at p. 758 [emphasis added].) The court distinguished several decisions upon which defendant relied because there "the patentee or his assignee went *beyond that which was necessary or incidental to the scope of his patent* ...." (*Id.* at p. 763 [emphasis added].)

Petitioners attempt to distinguish *Fruit Machinery* by claiming that the court did not rely on the scope of the patent. It ruled for the patentee, they argue, only "because the 'differential in royalty rates' bore a 'reasonable relationship to differences in costs and capital risks ....'" (Petn. 18.) Petitioners misread the case. The court gave a three-step response to the argument about royalty rates. First, it noted that the "unreasonable" discrimination had not actually occurred. (*Fruit Machinery*, *supra*, 118 Cal.App.2d at p. 762 ["a sufficient answer is that such has not happened yet"].) Second, even if discrimination had occurred and that were an antitrust violation, the obligation to pay royalties would remain. (*Ibid.* ["Such a violation ... would not itself abrogate the contract ...."].). But third, the Court emphasized that nothing in its analysis implied

that discriminatory royalties, even if "advantageous" to the patentee, were beyond the scope of the patent:

> We do not mean that it would be legally improper or incompetent for the patentee, his exclusive licensee, and the latter's sub-licensees, by agreements such as these parties have made, to give themselves a commercial advantage over others in industry.

(*Ibid.*)[2] It is thus not surprising that both the Court of Appeal and the superior court below relied expressly on *Fruit Machinery* in applying the scope of the patent rule here. (Opn. at 34 [citing *Fruit Machinery*]; 11AA 2668-2669 [citing *Fruit Machinery*].)

Other California decisions apply the same rule. In *Schering-Plough Cartwright Act Cases* (Ala. Cty. Super. Ct. Dec. 17, 2009) JCCP No. 4559, at *5, the Alameda County Superior Court concluded that "only restrictive conduct *outside the scope of the patent grant* will give rise to an antitrust violation." (Emphasis added.) Applying that rule to a Hatch-Waxman settlement, the court noted that a settlement "within the lawful scope of the patent" does not violate California law "even when the settlement involves a reverse payment from the patent holder to the alleged infringer." (*Ibid.*) Thus, the California cases addressing actions within the scope of a valid patent uniformly conclude that such conduct is lawful.

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[2] Courts are clear that charging differential royalties does not constitute patent misuse, because it does not extend the patent's scope. (*USM Corp. v. SPS Techs., Inc.* (7th Cir. 2003) 694 F.2d 505, 512-514.)

B. Federal Decisions Have Applied The Same Rule To Hatch-Waxman Settlements, Including This Settlement

The California decisions are consistent with longstanding federal authority. Contrary to Petitioners' suggestion, there is nothing new about the scope of the patent test. (E.g., *Mallinckrodt, Inc. v. Medipart, Inc.* (Fed.Cir. 1992) 976 F.2d 700, 708 ["Should the restriction be found to be reasonably within ... the scope of the patent claims, that ends the [antitrust] inquiry."]; *USM Corp., supra*, 694 F.2d at p. 513 [antitrust liability may lie "only upon proof of an anticompetitive effect beyond that implicit in the grant of the patent"]; *United States v. Studiengesellschaft Kohle, m.b.H.* (D.C.Cir. 1981) 670 F.2d 1122, 1128 ["[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by the patent, and is otherwise legal."]; *SCM Corp. v. Xerox Corp.* (2d Cir. 1981) 645 F.2d 1195, 1206 ["[W]here a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger [antitrust] liability"].)

Three federal circuits, in the course of five separate opinions, have applied this rule to reject antitrust claims based on Hatch-Waxman settlements within the patent's exclusionary effects. The first of these was the Eleventh Circuit's decision in *Valley Drug, supra*, 344 F.3d 1294. There, the court reversed a district court decision finding a reverse payment settlement per se unlawful because it failed "to consider the exclusionary power of Abbott's patent in its antitrust analysis." (*Id.* at p. 1306.) The Court explained:

> 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. This is not such a case, however, because one of the parties owned a patent.

(*Ibid.*) The Eleventh Circuit subsequently applied that reasoning in *Schering-Plough*, *supra*, 402 F.3d 1056, to vacate an order by the FTC condemning a settlement due to the presence of reverse payments. The FTC's analysis did not properly consider whether "the challenged agreements restrict competition beyond the exclusionary effects of the ... patent." (*Id.* at 1068.)

The Second Circuit decided *Tamoxifen* not long after Judge Trager issued his opinion in *Cipro-II*, granting summary judgment in the federal MDL with respect to this settlement. *Tamoxifen* cited Judge Trager's opinions seventeen times, and adopted his description of the controlling rule: "'[Absent fraud or a claim that is] 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].)

The Federal Circuit then decided the first of the *Cipro* appeals, by a proposed class of indirect purchasers including California residents. (*Cipro-III*, *supra*, 544 F.3d 1323, cert. denied (2009) 129 S.Ct. 2828.) The Federal Circuit affirmed Judge Trager's result and reasoning:

> [T]he 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.

(*Id.* at p. 1336 [emphasis added].)

In 2010, the Second Circuit likewise upheld Judge Trager's ruling in the direct purchasers' *Cipro* appeal, finding that *Tamoxifen* controlled. (*Cipro-IV*, *supra*, 604 F.3d at p. 106, cert. denied (2011) 131 S.Ct. 1606.) But the *Cipro-IV* panel also invited the losing plaintiffs to seek rehearing en banc, stating that "this case might be appropriate for reexamination by our full Court." (*Id.* at p. 108.)

Petitioners argue that the *Second Circuit* "expressed grave reservations about [*Tamoxifen's*] soundness." (Petn. 9.) But they fail to mention that (1) *Cipro-IV*'s presiding judge, Judge Pooler, was also the dissenting judge in *Tamoxifen*, and (2) the panel's criticism of *Tamoxifen* was based on a mistake of law that the *Cipro-IV* panel later withdrew and corrected in response to Bayer's motion identifying the error.[3] After the correction, the full Second Circuit denied the petition for rehearing en banc without even asking the defendants for a response. (3RA 721-722.) Judge Pooler filed a lone dissent. (3RA 723-727.)

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[3] The initial per curiam opinion invited a petition for rehearing en banc, asserting that "*Tamoxifen* relied on an *unambiguous* mischaracterization" of the Hatch-Waxman Act related to whether a later ANDA filer could succeed to the first ANDA filer's 180 days of market exclusivity. (*Cipro-IV* slip. opn., *supra*, at p. 18, 3RA 693 [emphasis added].) Bayer moved to correct the opinion because the panel had misread and misquoted *Tamoxifen*. (3RA 695-718.) The panel had focused on current law and omitted by ellipses key language from *Tamoxifen* that showed *Tamoxifen* was addressing earlier law that applied only before the 2003 Hatch-Waxman Amendments. (*Ibid.*)

In addition to these appellate courts, numerous district courts have acknowledged the consensus in favor of the scope of the patent rule.[4] Two such opinions were authored by Circuit Judges Richard Posner (Seventh Circuit) and Joseph Greenaway (Third Circuit), sitting by designation in district courts.[5]

C. The Patent Cases on Which Petitioners Rely Underscore The Uniformity of The Scope of The Patent Rule

The only California case involving patents on which Petitioners rely is this Court's decision in *Vulcan Powder Co. v. Hercules Powder Co.* (1892) 96 Cal. 510 (*Vulcan Powder*). (Petn. 17-18.) Yet *Vulcan Powder* provides a perfect example of the rule's application to conduct *outside* the scope of a patent.

Vulcan Powder concerned a contract among several dynamite companies in which they all agreed to produce dynamite only under the agreement and at the prices specified. (*Id.* at p. 514.) Some of the parties had patents on dynamite, but not on all grades. Nonetheless, the agreement proscribed all sales of dynamite, infringing or not. (*Id.* at p. 516.) This

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[4] *In re Androgel Antitrust Litig.* (N.D.Ga. 2010) 687 F.Supp.2d 1371, 1379; *King Drug Co. v. Cephalon, Inc.* (E.D.Pa. 2010) 702 F.Supp.2d 514 [applying rule of *Tamoxifen* and *Cipro-IV*, but denying a motion to dismiss because complaints alleged that the settlements exceeded the patent's scope]; see *Kroger Co. v. Sanofi-Aventis* (S.D.Ohio 2010) 701 F.Supp.2d 938, 954.

[5] See, respectively, *Asahi Glass, supra,* 289 F.Supp.2d 986; *In re K-Dur Antitrust Litigation* (D.N.J. Mar. 25, 2010, No. 01-1652) 2010 WL 1172995 [Order adopting Special Master's Amended Report (Feb. 6, 2009) 2009 WL 508869, at *27].

Court thus found the contract void precisely because it went beyond the scope of the patent. (*Ibid.*)

Petitioners concede that the *Vulcan Powder* court "note[d] that the restraints in question exceeded the technological scope of the patent." (Petn. 18 [citing *Vulcan Powder*, *supra*, 96 Cal. at p. 516].) Still, they argue that the scope of the patent was somehow "not dispositive." (*Ibid.*) This Court, however, could not have been more definite:

> But no case has been cited in which it has been held that several persons or companies can legally enter into a business combination to control ... a staple of commerce merely because some of the contracting parties have letters patent for certain grades of that staple. Indeed, the contract before us *is not confined to dynamite produced under the processes of the named patents.* It speaks ... [of] dynamite generally, and provides that the contract may be terminated if "other party or parties shall begin ... selling dynamite ... in competition to the parties hereto....

(*Vulcan Powder*, *supra*, 96 Cal. at p. 516 [emphasis added].) *Vulcan Powder* establishes that where patents are involved the antitrust inquiry must initially focus, and may ultimately turn, on the patent's exclusionary scope. (See 10A William Mead Fletcher (supp. 2011) *Cyclopedia of the Law of Corporations* § 5027 [citing *Vulcan Powder* to hold that "patent laws do not confer ... immunity from the antitrust laws *as to acts not within the limited scope of the monopoly granted*" (emphasis added)].)

Similarly, Petitioners' assertion that "[reverse] payments were held to be per se illegal under *In re Cardizem CD Antitrust Litigation* (6th Cir. 2003) 332 F.3d 896" (Petn. 13), is also wrong. *Cardizem* is the federal analog to *Vulcan Powder*. The Sixth Circuit expressly found that the

Hatch-Waxman settlement at issue went beyond the scope of the patent by prohibiting even "non-infringing formulations." (*Cardizem*, *supra*, 322 F.3d at p. 902.) Indeed, Petitioners do not disclose that the *Cardizem* court cited Judge Trager's first *Cipro* opinion, which rejected a claim of per se liability for conduct within the scope of a patent, with approval. (*Id.* at p. 908, fn.13.) Accordingly, the other federal appeals courts have all found *Cardizem* fully consistent with the rule that settlements within the patent's scope do not harm competition. (*Cipro-III*, *supra*, 544 F.3d at p. 1335 [Cardizem agreement "clearly had anticompetitive effects outside the exclusion zone of the patent."]; *Tamoxifen*, *supra*, 466 F.3d at p. 214 [same]; *Valley Drug*, *supra*, 344 F.3d at p. 1311, fn.26 [same].)

In sum, a uniform body of state and federal law protects settlements within the scope of a valid patent. The U.S. Supreme Court has denied certiorari six times in cases raising the issue of Hatch-Waxman settlements, including twice in cases challenging this very settlement. (*Cipro-IV*, *supra*, (2011) 131 S.Ct. 1606; *Cipro-III*, *supra*, (2009) 129 S.Ct. 2828; *Tamoxifen*, *supra*, (2007) 551 U.S. 1144; *Schering-Plough*, *supra*, (2006) 126 S.Ct. 2929; *Cardizem*, *supra*, (2004) 543 U.S. 939; *Valley Drug*, *supra*, (2004) 543 U.S. 939.) The *Cipro-IV* denial came despite a request for review by 32 states, including the California Attorney General. (Amicus Brief of the States of California, et al., *Cipro-IV*, *supra*, 131 S.Ct. 1606 (No. 10-762), 2011 WL96299.)

This Court's review is not "necessary to secure uniformity of decision or to settle an important question of law." (Cal. R. Ct. 8.500(b)(1).) The decisions are uniform and the question settled.

II. REVIEW DOES NOT LIE TO CORRECT ERRORS OR TO ENACT PETITIONERS' POLICY PREFERENCES

Petitioners' real complaint is that all of the California and federal courts are wrong. Even if such arguments could support review, Petitioners would still fail. For the rule applied below is not simply settled; it is also correct.

When conduct is within the scope of a valid patent, an unlawful restraint on competition cannot be shown. The grant of a patent gives the patent-holder a *lawful* monopoly. (35 U.S.C. § 154; *Aetna Casualty & Surety Co. v. Superior Court* (1993) 19 Cal.App.4th 320, 328 ["The grant of a patent is the grant of a statutory monopoly"].) Thus, "the protection of the patent laws and the coverage of the antitrust laws are not separate issues." (*Studiengesellschaft, supra*, 670 F.2d at p. 1128 [citing *Bement v. Nat'l Harrow Co.* (1902) 186 U.S. 70, 91].)

Moreover, it has been established for over a century that "the public [is] not entitled to profit by competition among infringers." (*Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.* (7th Cir. 1907) 154 F. 358, 364.) The antitrust plaintiff therefore bears the burden of showing that the "excluded" competition for which it seeks relief was lawful: "[A]n action under the antitrust laws will not lie where the business conducted by the plaintiff, and alleged to have been restrained by the defendant, was itself unlawful." (*Jenkins v. Greyhound Lines, Inc.* (N.D. Cal. May 4, 1971) No.

C-46141-RHS, 1971 WL 529, at *1; see, e.g., *Meijer, Inc. v. Biovail Corp.* (D.C.Cir. 2008) 533 F.3d 857, 862 [Hatch-Waxman antitrust plaintiff must prove that excluded firm was legally "able" to supply competing drug]; *In re Canadian Import Antitrust Litig.* (8th Cir. 2006) 470 F.3d 785, 790-792 [no liability for conspiring to preclude importation of illegal drugs].)

Applying these principles here is straightforward. Barr admitted infringement, and Petitioners have not even alleged that the Cipro Patent was invalid or unenforceable. Petitioners thus cannot show harm to competition "since if [Bayer-Barr] settlement negotiations fell through and [Bayer] went on to win his suit, competition would be prevented to the same extent." (*Asahi Glass*, *supra*, 289 F.Supp.2d at p. 994.)

A. The Ruling Below Is Fully Consistent With Longstanding U.S. Supreme Court Authority

Petitioners claim that the scope of the patent rule conflicts with "four seminal cases [of the U.S. Supreme Court] that go unmentioned in the Court of Appeal's opinion." (Petn. 10.) As shown here, none of those cases is remotely on point, as all considered conduct *beyond* the scope of the patent (if there even was a patent). But more telling is the U.S. Supreme Court case that goes "unmentioned" in the petition itself: *Walker Process*. As the Eleventh Circuit noted in *Valley Drug*, the *Walker Process* decision represents "[t]he *only* time the Supreme Court has addressed the circumstances under which the patent immunity from antitrust liability can be pierced." (*Valley Drug*, *supra*, 344 F.3d at p. 1307 [emphasis added].)

Walker Process held that proof of actual fraud in securing a patent "would be sufficient to strip [the patentee] of its exemption from the

antitrust laws," and thus allow an antitrust claim for wrongful enforcement. (382 U.S. at p. 177.) Beyond such intentional misconduct in obtaining the patent, however, the court stressed that the patentee's "good faith would furnish a complete defense" to such antitrust claims. (*Ibid.*) In his oft-cited concurrence, Justice Harlan emphasized that antitrust liability does not attach merely on the basis of patent *invalidity* "under one or more of the numerous technicalities attending the issuance of a patent," but only on evidence of actual fraud. (*Id.* at p. 180 [Harlan, J., concurring].)

The scope of the patent rule and its "objectively baseless" exception flow from the *Walker Process* court's insistence that "good faith" reliance on patent rights furnishes a "complete defense" to antitrust liability. (*Walker Process*, *supra*, 382 U.S. at p. 177.) Basing an antitrust claim against parties acting within the scope of a patent on anything less than a sham patent claim would conflict with the express exclusion of private antitrust claims "show[ing] no more than invalidity of the patent." (*Id.* at p. 179 [Harlan, J., concurring].)

Thus, the courts that have already applied the scope of the patent rule to the Cipro settlement have relied on *Walker Process* in doing so. The Federal Circuit stated that its "analysis has been adopted by the Second and the Eleventh Circuits and ... we find it to be completely consistent with Supreme Court precedent." (*Cipro-III*, *supra*, 544 F.3d at p. 1336 [citing only *Walker Process*, *supra*, 382 U.S. at p. 175-177].) Judge Trager warned that plaintiffs' theories "would overstep the bright-line rule adopted by the Supreme Court in *Walker Process*, ... and relied upon by the patent

bar for the past forty years." (*Cipro III*, *supra*, 363 F.Supp.2d at p. 530 [rejecting the same liability theories presented here].) The Court of Appeal's ruling was consistent with *Walker Process* as well. (Opn. 21-22 & 31.)

Petitioners, however, ignore the seminal *Walker Process* case, while castigating the Court of Appeal for ignoring four other inapposite cases:

- *United States v. Univis Lens Co.* (1942) 316 U.S. 241 concerned patent exhaustion. The court itself termed the question presented as "whether the patentee or his licensee, *no longer aided by the patent*, may lawfully exercise" control over "the disposition of the patented article *after the [first] sale*." (*Id.* at p. 250 [emphases added].)

- *United States v. Sealy, Inc.* (1967) 388 U.S. 350, was a trademark, not patent, case. And the court determined that the scope of the trademark was "not consequential" only because the restraint "involved the resale price of a trademarked article," which "cannot be defended as ancillary to [or within the scope of] a trademark licensing scheme." (*Id.* at p. 356 fn.3.)

- *United States v. Masonite Corp.* (1942) 316 U.S. 265, like *Univis Lens*, concerned patent exhaustion. Its holding relied on the express finding that "the patentee *exhausts* his limited privilege when he disposes of the product to the *del credere* agent" and any further restrictions would be "an enlargement [or beyond the scope] of the limited patent privilege." (*Id.* at p. 279.)

- *United States v. Singer Manufacturing Co.* (1963) 374 U.S. 174, expressly did not consider whether "the owner of a lawfully acquired patent can[] use the patent laws to exclude all infringers of the patent." (*Id.* at p. 189.) Instead, it premised its holding on the conclusion that "the limits of the patent monopoly .... have been exceeded in this case." (*Id.* at pp. 196-197.) Moreover, the language from Justice White's concurrence relied on by Petitioners concerned only a conspiracy to commit fraud on the patent office, *i.e.*, conduct that would be outside the scope of the patent rule. (*Id.* at p. 200 [White, J., concurring].)

Although today Petitioners tout the forgoing cases, the failure of identically situated Cipro petitioners to cite them to the U.S. Supreme Court when seeking certiorari shows that the cases are not instructive. When the petitioners in *Cipro-III*, who raised the same Cartwright Act and UCL claims at issue here, sought certiorari to review the Federal Circuit's decision, they did not cite *any* of these four cases. (Petition for Certiorari, *Cipro-III*, 129 S.Ct. 2828 (2009) (No. 08-1194), 2009 WL 797579.) Thus, those Cipro purchasers did not bring these allegedly controlling decisions to the attention of the very court that decided them. The cases are even less relevant here.

B. Petitioners' Policy Arguments Are Unsupported And Unpersuasive

Petitioners urge the Court to disregard the settled scope of the patent rule on grounds of "public policy." (Petn. 2.) All of these assertions go well beyond the record, and none of them changes the fact that the Court of Appeal and the superior court correctly applied settled law. Even by their terms, however, Petitioners' arguments fail.

Initially, Petitioners invoke a strangely one-sided policy: they assume that consumers benefit only when a patent holder loses in court; they assume that the short-term benefits of lower generic prices always outweigh the long-term benefits of newly discovered, life-saving drugs. But such assumptions "ignor[e] the first principle that enforcing valid patents makes a major contribution to consumer welfare by providing the incentive for innovation." (Kent S. Bernard & Willard K. Tom,

Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles (2006) 15 Fed.Cir.B.J. 617, 618.)

To justify these arguments, Petitioners make assertions of non-record facts, relying on public pronouncements by interested parties or on Petitioners' own *ipse dixit*:

Increasing Settlements: Petitioners cite an FTC staff report to argue that judicial intervention is necessary because reverse-payment settlements are increasing. (Petn. 13.) They do not disclose that, after the FTC's attack on reverse payments was rejected in *Schering-Plough*, its Hatch-Waxman reports simply redefined the term "payments" to include settlements with *no cash payments at all*, such as settlements with exclusive licenses.[6] Between 2004 and 2008, while this action was pending in superior court, the reports show only *five* that included cash payments to the generic, and all were small amounts for "litigation" expenses.[7]

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[6] See, e.g., Federal Trade Commission, *Agreements Filed With FTC Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2008* ("FY 2008 Report") 1 n.2 & 2, *available at* http://www.ftc.gov/os/2010/01/100113-mpdim2003rpt.pdf.

[7] See FY 2008 Report at 4 (one settlement); Federal Trade Commission, *Agreements Filed With FTC Under the Medicare Prescription Drug Improvement Act of 2003, Summary of Agreements Filed in FY 2007* ("FY 2007 Report") 4, *available at* http://www.ftc.gov/os/2008/05/mmaact.pdf (one settlement); Federal Trade Commission, *Agreements Filed With FTC Under the Medicare Prescription Drug Improvement Act of 2003, Summary of Agreements Filed in FY 2006* ("FY 2006 Report") at 4, *available at* http://www.ftc.gov/reports/mmact/ MMAreport2006.pdf (three settlements). The reports for FY 2004 and FY 2005 reflect no cash payments.

Reverse Payments: Petitioners' declaration that payments to the infringement defendant in Hatch-Waxman litigation are "wrong" (Petn. 2) ignores the incentive structure the statute created. Under Hatch-Waxman, an ANDA filer infringes simply by filing its Paragraph IV certification. (35 U.S.C. § 271(e)(2)(A).) The generic challenger, with no damages exposure from actual sales, thus "has relatively little to lose ... beyond litigation costs," while the innovator could "be stripped of its patent monopoly." (*Tamoxifen*, *supra*, 466 F.3d at pp. 206-207.) Where the innovator has everything to lose, and the generic challenger has everything to gain, consideration for settlement naturally flows from the innovator to the challenger. (*Ibid.*; accord *Asahi Glass*, *supra*, 289 F.Supp.2d at p. 994 [the generic challenger "would not settle unless he had something to show for the settlement."]; *Schering-Plough*, *supra*, 402 F.3d at pp. 1074-1076.)

Size of Payment: Petitioners contend that "[t]he sheer enormity of Bayer's payment ... raises a powerful inference that the Cipro patent was a 'paper tiger.'" (Petn. 16.) Bayer's payment was enormous only if taken out of context. The settlement amount equaled just over 6% of Bayer's revenue from Cipro sales from 1997 to 2003, a fact that plaintiffs do not and cannot dispute. (See A.A. 20.) Thus, the settlement made sense even if Bayer's chance of winning was 94%. (*Cipro-II*, *supra*, 363 F.Supp.2d at pp. 540-541 ["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 Patent, but rather the economic realities of what was at risk"].) That is well within the risk attendant to any patent case,

no matter how strong the patent. "No one can be certain that he will prevail in a patent suit." (*Asahi Glass*, *supra*, 289 F.Supp.2d at p. 993; see also *California Teachers Assn. v. State of California* (1999) 20 Cal. 4th 327, 343.) Petitioners do not explain why such a settlement should be considered suspect.

Narrowed Patent: Petitioners claim that "Bayer's intervening petition seeking reexamination of the patent itself raises suspicion that the original Cipro patent would have been found unenforceable." (Petn. 17.) But there is no dispute that the relevant claims *for Cipro* were not narrowed. The claims dropped from the earlier patent involved a different class of drugs entirely (naphthyridines), not the quinolones that included Cipro. Thus, the reexamination did not affect the scope of Bayer's patent over the ciprofloxacin compound. (See *Cipro-II*, *supra*, 363 F.Supp.2d at p. 519 ["[C]laim 12 ... was not substantively amended and ... all parties agree [that it] covers ciprofloxacin hydrochloride."].)

In sum, all of Petitioners' policy assertions go well beyond the record. Whatever the Petitioners' legislative desires may be, none of their policy arguments warrant review of the opinion below.

III. THIS CASE IS NOT APPROPRIATE FOR ARTICULATING A NEW RULE TO GOVERN HATCH-WAXMAN PATENT SETTLEMENTS

In all events, this is the wrong case for the Court to resolve the questions raised by Petitioners.

A. Past and Pending Changes To Hatch-Waxman Render Review Inadvisable

In 2003, long after the Bayer-Barr settlement, Congress substantially amended the Hatch-Waxman Act. (See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.) As the Solicitor General noted when opposing certiorari in *Tamoxifen*, these amendments "altered the regulatory dynamic" under which the settlement here is to be evaluated. (Brief of United States, *Tamoxifen*, *supra*, 551 U.S. 1144 (No. 06-830), 2007 WL 1511527, at *19.)

Bayer is aware of no other pending California case concerning a pre-2003 settlement. Thus, this Court would invest its time in making a one-off ruling, rather than addressing any generally applicable question of law. This is why the Solicitor General urged the U.S. Supreme court to wait: "To the extent the Court is inclined to address the validity of th[is] type of settlement in particular, it may be preferable to do so in a case that arises under the current regulatory regime." (Brief of United States, *Tamoxifen*, *supra*, 551 U.S. 1144 (No. 06-830), 2007 WL 1511527, at *20; see also Brief of United States, *Cardizem*, *supra*, 543 U.S. 939 (No. 03-779) 2004 WL 1562075, *18-19.)

In addition, pending legislation could render any decision by this Court wholly academic. Since it lost in *Schering-Plough*, the FTC has campaigned for a statute to outlaw reverse-payment settlements. Bills to this effect have been introduced in the past several Congresses. (E.g., Preserve Access to Affordable Generics Act, S. 27, 112th Cong. (2011); S. 369, 111th Cong. (2009), Protecting Consumer Access to Generic Drugs

Act of 2009, H.R. 1706, 111th Cong. (2009).) Investment of this Court's scarce resources is inadvisable when the governing law for future disputes of this kind may well be different. (Cf. Eugene Gressman et al. (9th ed. 2007) *Supreme Court Practice* 247.)

B. The Strength of Bayer's Patent Confirms The Result Below

The Cipro patent's track record makes this a poor test case for adopting a rule that would limit a patentee's right to settle. Bayer's patent has been vindicated before the PTO on reexamination, in three district court challenges to judgment, and at the Federal Circuit. On the appeal of antitrust claims concerning this settlement, moreover, the Federal Circuit agreed that "no fraud occurred" before the PTO. (*Cipro-III*, *supra*, 544 F.3d at p. 1341.) As Judge Trager stated, "there is something anomalous about the notion that plaintiffs could collect treble damages for settlement of a litigation involving a patent that has been subsequently upheld by the Federal Circuit." (*Cipro-II*, *supra*, 363 F.Supp.2d at p. 530, fn.14.)

Petitioners thus make no argument that any test based on the "strength" or potential invalidity of the patent would change the result *in this case*. (See Petn. 10-19.) This Court should not intervene merely to confirm what each of five other courts to consider this settlement has already concluded.

IV. PETITIONERS' OTHER GROUNDS ARE ALSO UNWORTHY OF REVIEW

A. The Finding of Substantive Preemption that Petitioners Attack Was Never Made, and Is Not Ripe For Review

Review is unwarranted because Petitioners' "preemption" argument attacks a straw-man. Petitioners conjure a conclusion as to substantive preemption that the Court of Appeal did not, in fact, reach. It is true that granting review here would require this Court to address a difficult issue of what this Court calls "obstacle preemption"—whether a California rule imposing liability on a settlement within the scope of a valid patent would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" under the patent laws. (*In re Jose C.* (2009) 45 Cal.4th 534, 551.)

But it is equally true that neither the superior court nor the Court of Appeal reached that question. Instead, after ruling on the merits of Petitioners' claims, both held that Petitioners' invalidity theory would also "arise under" federal patent law, depriving the California courts of jurisdiction. If this Court were to grant review, it would have to consider both the jurisdictional preemption question that the Court of Appeal resolved, as well as the substantive preemption question that it did not. But the jurisdictional question is unchallenged on this petition, while the substantive preemption question is presented without the benefit of analysis by either lower court. Neither is worthy of review.

The issue of exclusive federal jurisdiction arose below because the Petitioners contended for the first time in opposing summary judgment that the Bayer infringement suit against Barr was "objectively baseless." They

argued in their briefs that the patent was unenforceable due to Bayer's alleged inequitable conduct before the PTO. The Court of Appeal rejected Petitioners' contention on several grounds, one of which was that allowing proof that the patent was unenforceable as an element of the state claims would trigger the exclusive jurisdiction of the federal courts. (Opn. 38-43.) Although Bayer had raised the issue of obstacle preemption in its brief, the court did not reach it.

Petitioners now seek to create an issue for review by mischaracterizing the court's finding of jurisdictional preemption. In *In re Jose C.*, *supra*, 45 Cal.4th 534, this Court explained the fundamental distinction between two kinds of federal preemption:

> Congress may preempt state courts from exercising jurisdiction over [federal] matters, or it may preempt state Legislatures from substantively regulating on matters touching upon [those federal matters].

(45 Cal.4th at p. 538.) The Court warned that "whether Congress has preempted state court jurisdiction is not to be confused with whether it has preempted [substantive] state legislative action." (*Id.* at p. 546.) Within "substantive preemption," there are four separate types: "express, conflict, obstacle, and field preemption." (*Id.* at pp. 549-550.) Obstacle preemption occurs when state law conflicts with the "full purposes and objectives of Congress." (*Ibid.*)

Faithful to this distinction, the Court of Appeal decided only the question of *jurisdictional* preemption:

> [W]e 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 patent ... cases." (28 U.S.C. § 1338(a).)

(Opn. 42; see Opn. 44 ["whether inequitable conduct in the procurement of a patent constitutes unfair competition is within the exclusive jurisdiction of the federal Circuit Court of Appeals."]; *ibid.* [rejecting Petitioners' argument as "immaterial to the federal jurisdiction issue"]. Nowhere in the opinion did the court use the term "obstacle" preemption; nowhere did it address whether California law would conflict with federal patent law.

Undeterred, Petitioners assert that "[t]he Court of Appeal incorrectly determined that Petitioners' basis for seeking liability conflicts with federal law." (Petn. 6.) They chastise the court for "neglect[ing] to apply the 'strong presumption against preemption,'" (Petn. 22) and for its failure "even to pay lip service to this Court's recent guidance" concerning "conflict preemption" in *Viva! Internat. Voice for Animals v. Adidas Promotional Retail Operations, Inc.* (2007) 41 Cal. 4th 929, 936. (*Ibid.*) But the "presumption" and "guidance" to which Petitioners refer relate to substantive preemption, not to exclusive federal jurisdiction. That is why the Petitioners never cited *Viva!* to either court below.

That is also why Petitioners never cited the *Dow* case, on which they now principally rely (Petn. 21-22 & 23-24 [citing *Dow Chemichal Co. v. Exxon Corp.* (Fed.Cir. 1998) 139 F.3d 1470]), to either court below. In *Cipro-III*, the Federal Circuit rejected the same argument. *Dow* is inapposite because the state claim there was based not on conduct before the PTO, but on the patentee's allegedly false statements to the plaintiff's

customers in the marketplace. (See 139 F.3d at p. 1477.) The Federal Circuit thus rejected plaintiffs' argument that their state claim was based on "elements other than inequitable conduct before the PTO," and held it substantively preempted. (*Cipro-III*, *supra*, 544 F.3d at pp. 1340-1341.)

Petitioners cannot create an issue worthy of review by inventing a holding and then attacking it. To be sure, any state court accepting Petitioners' argument would face a difficult issue of obstacle preemption. The patentee's right to enter agreements within the scope of a valid patent is one of the most fundamental that federal patent law grants. But the Court of Appeal did not address substantive preemption. Review should not be granted for an issue neither developed nor decided below.

B. The Claimed Evidentiary Error Does Not Merit Review

Petitioners' final ground for review is the superior court's alleged failure to rule individually on hundreds of rote objections to evidence in the summary judgment record. As Bayer's co-defendants have demonstrated in their separate Answer to the Petition, that argument misunderstands this Court's decision in *Reid v. Google, Inc.* (2010) 50 Cal.4th 513.[8] Petitioners also waived any claim of error on appeal by failing, with one exception, to "argu[e] that the admission of any specific evidence constituted prejudicial error." (Opn. 52.)

The exception was Petitioners' argument that Bayer's subsequent victories were inadmissible because they post-dated the settlement. (Petn.

[8] Bayer hereby incorporates by reference the Answer of its co-respondents. (Cal. Rules of Court, rule 8.504(e)(3).)

17, 25.) But the timing of Bayer's victories does not make them irrelevant. As Justice Traynor observed: "Evidence of the existence of a particular condition, relationship, or status ... before *and after* an act in question is admissible to indicate the existence of the same status, condition, or relationship at the time of the act." (*Blank v. Coffin* (1942) 20 Cal.2d 457, 463 [emphasis added].) Subsequent findings that the patent's unchanged Claim 12 for Cipro was valid and enforceable are obviously relevant to Petitioners' argument that Bayer's assertion of the identical claim was objectively baseless.

CONCLUSION

The petition for review should be denied.

Respectfully submitted,

Dated: January 10, 2011

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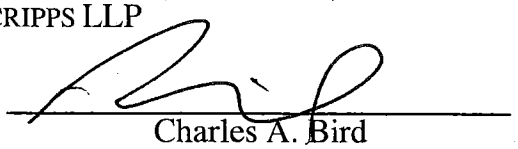
By: 
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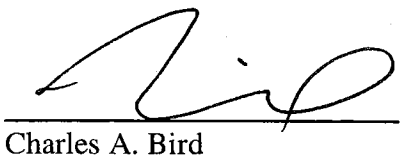
CERTIFICATE OF WORD COUNT

I, Charles A. Bird, counsel for respondent Bayer Corporation, certify that the foregoing brief is prepared in proportionally spaced Times New Roman 13 point type and, based on the word count of the word processing system used to prepare this brief, the brief is 8,390 words long.



Charles A. Bird

PROOF OF SERVICE

In re Cipro Cases I & II, Case No. S198616

At the time of service, I was over 18 years of age and **not a party to this action**. I am employed in the County of San Diego, State of California. My business address is 600 West Broadway, Suite 2600, San Diego, California 92101-3372.

On January 10, 2012, I served true copies of the following document(s) described as: **ANSWER OF RESPONDENT BAYER CORPORATION** on the interested parties in this action as follows:

SEE ATTACHED SERVICE LIST

_X_ **BY MAIL:** I enclosed the document(s) in a sealed envelope or package addressed to the persons at the addresses listed in the Service List and placed the envelope for collection and mailing, following our ordinary business practices. I am readily familiar with Luce, Forward, Hamilton & Scripps LLP's practice for collecting and processing correspondence for mailing. On the same day that the correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service, in a sealed envelope with postage fully prepaid.

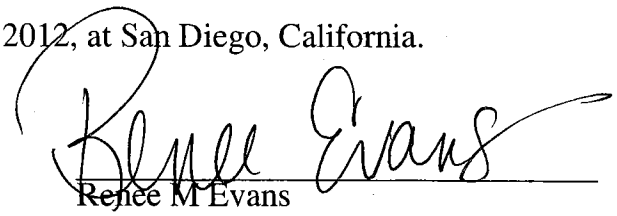
___ **BY FAX TRANSMISSION:** I faxed a copy of the document(s) to the persons at the fax numbers listed in the Service List. No error was reported by the fax machine that I used.

___ **BY FEDEX:** I enclosed said document(s) in an envelope or package provided by FedEx and addressed to the persons at the addresses listed in the Service List. I placed the envelope or package for collection and overnight delivery at an office or a regularly utilized drop box of FedEx or delivered such document(s) to a courier or driver authorized by FedEx to receive documents.

___ **BY HAND DELIVERY:** I caused such envelope(s) to be delivered by hand to the office of the addressee(s).

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

Executed on January 10, 2012, at San Diego, California.



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David E. Everson Victoria Smith STINSON MORRISON HECKER 1201 Walnut, Suite 2600 P.O. Box 419521 Kansas City, MO 64141-6251 Heather S. Woodson STINSON MORRISON HECKER LLP 10975 Benson, Suite 550 12 Corporate Woods Overland Park, KS 66210-2132 Joann F. Rezzo EDELSON & REZZO 402 West Broadway, Suite 2700 San Diego, CA 92101	Defendant and Respondent: Hoechst Marion Roussel, Inc., The Rugby Group, Inc., Barr Laboratories, Inc., Watson Pharmaceuticals, Inc. **By U.S. Mail**
Edwin John U Gregory Skidmore Karen N. Walker KIRKLAND & ELLIS LLP 655 15th Street NW Washington, DC 20005	Defendant and Respondent: Barr Laboratories, Inc. **By U.S. Mail**

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Office Of The District Attorney Appellate Division P. O. Box X-1011 San Diego, CA 92112 Office of the Attorney General P. O. Box 85266 San Diego, CA 92186-5266	The People: **By U.S. Mail**
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