No. S198616

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, THE HONORABLE RICHARD E.L. STRAUSS,
JUDICIAL COUNCIL COORDINATION PROCEEDING NOS. 4154 & 4220
(Service Required on Attorney General and District Attorney,
Bus. & Prof. Code § 17209, Cal. Rules of Court, Rule 8.29)

ANSWER TO PETITION FOR REVIEW OF BARR LABORATORIES, INC., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., AND WATSON PHARMACEUTICALS, INC.

Joann Rezzo
(Bar No. 185675)
EDLESON & REZZO
402 West Broadway, Suite 2700
San Diego, CA 92101
(619) 230-0836
jrezzo@san.rr.com

Kathryn E. Karcher
(Bar No. 125073)
KARCHER HARMES LLP
401 B Street, Suite 2450
San Diego, CA 92101
(619) 565-4755
kathryn@karcherappeals.com

Counsel for Respondents Barr Laboratories, Inc., Hoechst Marion Roussel, Inc., The Rugby Group, Inc., and Watson Pharmaceuticals, Inc.

Karen N. Walker, P.C.*
Edwin John U*
Gregory L. Skidmore*
KIRKLAND & ELLIS LLP
655 Fifteenth Street, N.W.
Washington, DC 20005
(202) 879-5000
edwin.u@kirkand.com

Counsel for Respondent Barr Laboratories, Inc.

Heather S. Woodson*
STINSON MORRISON HECKER LLP
1201 Walnut Street, Suite 2900
Kansas City, MO 64106
(816) 842-8600
hwoodson@stinson.com

Counsel for Respondents Hoechst Marion Roussel, Inc., The Rugby Group, Inc., and Watson Pharmaceuticals, Inc.

* *Pro hac vice* pending

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Constitution and Statutes

Other Authorities

WHY REVIEW SHOULD NOT BE GRANTED

Both the Court of Appeal and the superior court correctly recognized that plaintiffs' claims fail under a straightforward application of California law: because a patent is the grant of a statutory monopoly that permits the patent holder to exclude competition, a patent holder and patent challenger are free to settle patent litigation—just as cases settle every day—so long as the settlement does not restrict more competition than the patent itself. Provided a settlement between the patent holder and patent challenger does not exceed the scope of this statutory grant, any impediment to competition flows not from the settlement, but from what the patent already protects. As both the Court of Appeal and the superior court found, all of this dooms plaintiffs' case—especially when the Cipro settlement allowed the challenger to sell a competing product a full year earlier than if it had litigated the patent case to conclusion and lost in court.

While plaintiffs' petition for review is filled with dramatic language attacking the Court of Appeal's and superior court's decisions, one thing that is notably absent is any case adopting their arguments. The reason for that is simple: no such case

exists. California courts have long recognized that, because a patent holder can lawfully restrain competition within the scope of its patent, conduct that extends no further than the patent grant does not violate the Cartwright Act. (See *Fruit Machinery Co. v. F.M. Ball & Co.* (1953) 118 Cal.App.2d 748, 763 (*Fruit Machinery*).) And every decision to consider a Hatch-Waxman patent settlement within the scope of a patent has found such agreements to be lawful. Indeed, the very settlement at issue in this case has been upheld by no fewer than *five courts*, including the two courts below, a federal district court, and the U.S. Courts of Appeals for the Second and Federal Circuits in decisions the U.S. Supreme Court declined to review.

Contrary to what plaintiffs contend, both the Court of Appeal and the superior court evaluated the challenged settlement agreement under traditional Cartwright Act rubrics—first, by considering whether a per se analysis was appropriate; and second, by applying the rule of reason. Both courts ultimately found that because the settlement prevented no more competition than the patent already prohibited, plaintiffs could not satisfy the threshold step of the rule of reason, which requires an actual adverse effect on competition. And, despite plaintiffs'

rhetoric, both opinions demonstrate that this holding is consistent with long-standing California precedent discussing the intersection between antitrust and patent law. Plaintiffs' attempts to point to error in the decision below are neither persuasive nor sufficient grounds to justify review. The petition should be denied.

BACKGROUND[1]

A. Factual Background

This case arises out of the settlement of patent litigation between Bayer—which held the patent on the active ingredient in the prescription antibiotic ciprofloxacin hydrochloride, commonly known as Cipro—and the Generic Defendants. When defendant Barr Laboratories, a generic drug manufacturer, sought FDA approval to introduce a competing generic version of Cipro pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355, Bayer brought a patent infringement action. Because Bayer's patent

---

[1] Barr Laboratories, Inc., Hoechst Marion Roussel, Inc., and the Rugby Group, Inc. (collectively "the Generic Defendants"), along with Watson Pharmaceuticals, Inc., collectively referred to in this answer as "defendants," join in and incorporate by reference the answer filed by defendant Bayer. (See California Rules of Court, rule 8.504(e)(3).)

covered the active ingredient in Cipro, Barr conceded from the start that its generic version would infringe the patent and argued only that the patent was invalid and unenforceable. (See 2RA 356–357.)

In this patent litigation, like all Hatch-Waxman patent litigation, Barr (the generic company) had the ability to obtain a judicial determination whether Bayer's patent was valid before producing and selling its own product. So long as the generic company waits for the ruling before coming to market, it will be liable for few (if any) damages if it loses the patent case, because it will not have made any infringing sales. On the other hand, the branded manufacturer stands to lose a great deal in patent litigation under the Hatch-Waxman framework: if the generic company's challenge to the patent is upheld, the generic company can enter the market immediately and the branded manufacturer will lose its patent monopoly. (See generally *Schering-Plough Corp. v. Federal Trade Com.* (11th Cir. 2005) 402 F.3d 1056, 1074 [*Schering-Plough*]; *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (E.D.N.Y. 2003) 261 F.Supp.2d 188, 251 [*Cipro I*].) Barr and Bayer litigated these patent issues against each other for five years.

As the case approached trial, Bayer and Barr settled their litigation, just as litigants routinely do. Under the Cipro settlement, Barr and its litigation partners received both monetary consideration and a license to sell a competing ciprofloxacin product at least six months before the Cipro patent expired. (4AA 770–775, 788–790.) As Barr's CEO testified, the settlement gave Barr more than if it had *lost* the underlying patent case, but less than it would have earned had its patent challenge succeeded. (See 3RA 670.) Nothing in the settlement purported to preclude other parties from challenging the validity of the Cipro patent; several other generic drug manufacturers proceeded to do so, and none prevailed. (See *Bayer AG v. Schein Pharmaceutical, Inc.* (D.N.J. 2001) 129 F.Supp.2d 705, affd. (Fed.Cir. 2002) 301 F.3d 1306 (*Schein*); *Bayer AG v. Carlsbad Technology, Inc.* (S.D.Cal. June 7, 2002 and Aug. 7, 2002, No. 01CV0867-B); *Bayer AG v. Ranbaxy Pharmaceuticals, Inc.* (D.N.J. Oct. 29, 1999, No. 98-4464).) Bayer also sought re-examination of the Cipro patent by the U.S. Patent & Trademark Office (PTO), which reaffirmed its validity. The Cipro patent expired in 2003.

B. Procedural History

In 2000, direct and indirect purchasers of Cipro sued defendants in various state and federal courts (including this litigation), alleging that the Cipro settlement violated the Sherman Act and/or state antitrust laws, including the Cartwright Act. In 2005, the judge presiding over the coordinated federal cases (Judge Trager) granted the defendants' motions for summary judgment and dismissed the plaintiffs' claims in their entirety. (See *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (E.D.N.Y. 2005) 363 F.Supp.2d 514 [*Cipro II*].) Judge Trager had previously denied plaintiffs' motion for a finding that the settlement was per se illegal. (See *Cipro I*, *supra*, 261 F.Supp.2d 188.)

Plaintiffs appealed both rulings to the U.S. Court of Appeals for the Second Circuit. The Second Circuit transferred the appeal of the indirect purchaser plaintiffs—which included an additional claim for fraud on the PTO—to the U.S. Court of Appeals for the Federal Circuit. The indirect purchasers' complaint in the case before the Federal Circuit—like the complaint in this case—included claims by California consumers suing under California law.

On October 15, 2008, the Federal Circuit unanimously affirmed the district court's grant of summary judgment for defendants on the indirect purchaser plaintiffs' claims. (See *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (Fed.Cir. 2008) 544 F.3d 1323 [*Cipro III*].) The court held that the Cipro settlement was not per se unlawful under the Sherman Act and did not violate the rule of reason. (*Id.* at p. 1340.) In so holding, the Federal Circuit emphasized that the Cipro settlement did not have any anticompetitive effects because it did not restrain trade in areas beyond the lawful monopoly created by Bayer's patent:

- "[T]here was no evidence that the Agreements created a bottleneck on challenges to the [Cipro] patent or otherwise restrained competition outside the 'exclusionary zone' of the patent." (*Id.* at p. 1332.)

- "[T]here is no evidence that the Agreements prevented challenges by other generic drug manufacturers to the validity of the [Cipro] patent. In fact, four other generic manufacturers—Ranbaxy, Mylan, Schein, and Carlsbad— ... initiated challenges of the validity of the patent." (*Id.* at p. 1334.)

- "[T]here 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." (*Id.* at p. 1337.)

The Federal Circuit denied plaintiffs' petition for rehearing en

banc, and the U.S. Supreme Court declined to review the case. (*Cipro III, supra*, 544 F.3d 1323, rehg. en banc den. (Dec. 23, 2008), cert. den. *sub. nom. Arkansas Carpenters Health and Welfare Fund v. Bayer AG* (2009) 129 S.Ct. 2828.)

On April 29, 2010, the Second Circuit, which had retained jurisdiction over the direct purchaser plaintiffs' appeal, issued its own opinion affirming the grant of summary judgment. (*Arkansas Carpenters Health and Welfare Fund v. Bayer AG* (2d Cir. 2010) 604 F.3d 98, rehg. en banc den. (2010) 625 F.3d 779, cert. den. *sub. nom. Louisiana Wholesale Drug Co., Inc. v. Bayer AG* (2011) 131 S.Ct. 1606 [*Cipro IV*].) That court, too, held that the Cipro settlement did not violate the antitrust laws because it did not preclude competition outside of the exclusionary zone of the patent: "Barr's agreement to refrain from marketing generic Cipro encompasses only conduct that would infringe Bayer's patent rights," meaning that there is no antitrust violation. (*Cipro IV, supra*, 604 F.3d at p. 106.) Although the Second Circuit panel queried whether en banc review of the scope of the patent standard adopted in *In re Tamoxifen Citrate Antitrust Litigation* (2d Cir. 2006) 466 F.3d 187 (*Tamoxifen*), would be appropriate, the full court denied plaintiffs' petition for en banc

review on September 7, 2010. Again, the U.S. Supreme Court denied plaintiffs' petition for certiorari. (131 S.Ct. 1606.) The Federal Circuit, the Second Circuit, and the U.S. District Court thus have rejected antitrust challenges to the *exact same settlement agreement* at issue in this case.

After the Federal Circuit's decision, the superior court (Strauss, J.) considered defendants' motions for summary judgment in this litigation. Following extensive briefing and oral argument, the court granted defendants' motions and dismissed the case. (11AA 2665–2677.) Like the three federal courts, the trial court held that the Cipro settlement does not violate the antitrust laws 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 patent; there is no evidence that the patent suit by Bayer against Barr was objectively baseless; and Plaintiff cannot establish that the settlement was otherwise unlawful." (11AA 2671.)

Plaintiffs appealed, and the Court of Appeal, Fourth Appellate District (Nares, Benke, Aaron, JJ.), affirmed in a unanimous 53-page published opinion. The court first rejected plaintiffs' argument that Hatch-Waxman patent settlements are

illegal per se, recognizing that "[u]nder 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*," a designation that is inappropriate for the settlement of litigation and that no court has ever accepted for a settlement within the scope of a patent. (Slip opinion 32.)

The court thus applied a traditional rule-of-reason analysis under the Cartwright Act before "conclud[ing] that the Cipro agreements do not violate the Cartwright Act under rule-of-reason analysis," including the approach taken by federal courts addressing Hatch-Waxman patent settlements specifically. (Slip opinion 33.) In conducting this analysis, the Court of Appeal considered the many cases that have analyzed—and upheld—such settlements under the federal Sherman Act. As the court stated: "We agree with the reasoning of these cases and conclude that it applies equally to antitrust claims under the Cartwright Act." (Slip opinion 32.) "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 Machinery Co. v. F. M. Ball & Co.* (1953) 118

Cal.App.2d 748." (Slip opinion 34.) The court thus concluded "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." (Slip opinion 3.) "Because the Cipro agreements undisputedly did not restrain competition beyond the exclusionary scope of the [Cipro] patent, we conclude they do not violate the Cartwright Act." (Slip opinion 3-4.)

The court also addressed plaintiffs' arguments that Bayer's patent lawsuit was an objectively baseless sham. The court first concluded that plaintiffs did not plead that Bayer's patent infringement lawsuit was an objectively baseless sham in their complaint, meaning they could not raise the argument in response to the defendants' motion for summary judgment. (Slip opinion 40.) The court also found that separate and apart from that deficiency, such a claim was meritless given that Bayer had *defeated* multiple subsequent challenges to the Cipro patent. (Slip opinion 41.) Finally, the court observed that such a cause of action would be preempted by federal law. (Slip opinion 42.) The Court of Appeal also considered and rejected plaintiffs'

arguments that the trial court erred in overruling plaintiffs' evidentiary objections. (Slip opinion 51-52.)

ARGUMENT

I. The Courts Below Correctly Applied Well-Settled California Law in Holding That the Cipro Settlement Does Not Violate the Cartwright Act.

The premise of plaintiffs' petition is that "[n]either the Superior Court nor the Court of Appeal applied the antitrust law of California" (PFR 8, 20), and "review is necessary to establish the law of California" with respect to antitrust review of Hatch-Waxman patent settlements. (PFR 1.) Nothing could be further from the truth.

A. The Court Of Appeal and the Superior Court Correctly Evaluated and Upheld the Cipro Settlement Under the Rule of Reason.

Both the Court of Appeal and the superior court applied well-established antitrust precedent in upholding the Cipro settlement using a traditional rule-of-reason analysis. (See slip opinion 33 ["We further conclude that the Cipro agreements do not violate the Cartwright Act under rule-of-reason analysis ...."]; see also 11AA 2673 [superior court opinion].) As both courts explained, to prove an antitrust violation under the rule of reason, a plaintiff must demonstrate that (1) an alleged restraint

on trade has anticompetitive effects, and (2) the anticompetitive effects outweigh any pro-competitive benefits. (See slip opinion 16; 11AA 2673; accord *Bert G. Gianelli Distributing Co. v. Beck & Co.* (Cal.App. 1985) 172 Cal.App.3d 1020, 1048, disapproved on another ground in *Dore v. Arnold Worldwide, Inc.* (2006) 39 Cal.4th 384, 394, fn. 2; *Marin County Bd. of Realtors v. Palsson* (1976) 16 Cal.3d 920, 934–935.) As the Court of Appeal noted, "[c]ourts have limited the reach of the Cartwright Act to restraints of trade that are *unreasonable*." (Slip opinion 16 [citing *UAS Management, Inc. v. Mater Misericordiae Hospital* (2008) 169 Cal.App.4th 357, 364].) To prove an unreasonable restraint, plaintiffs must show the agreement had a "substantially adverse effect on competition in the relevant market." (*Exxon Corp. v. Superior Court* (1997) 51 Cal.App.4th 1672, 1681.) Plaintiffs acknowledge this standard, conceding that they "can prevail only if they also show that Bayer's $398.1 million payment had anticompetitive intent and effects." (PFR 24.)

Both the superior court and the Court of Appeal held that the Cipro settlement did not have a substantial adverse effect on competition because the settlement excluded no more competition

than the exclusionary potential of the patent itself. As the superior court stated, "under California law, like federal law, there is only antitrust liability for conduct which goes beyond the exclusionary scope granted by the patent, a salient point [plaintiffs] conveniently ignore." (11AA 2676.) The Court of Appeal affirmed, emphasizing that "a settlement of [a patent] enforcement suit does not violate the Cartwright Act if the settlement restrains competition only within the scope of the patent." (Slip opinion 34.) As a result, both courts recognized, plaintiffs failed to satisfy the first step of the rule of reason under the Cartwright Act: "[A]s a matter of law, [plaintiffs] cannot establish the agreement unreasonably restrains trade because no triable issue of material fact exists that there are no anticompetitive effects on competition beyond the exclusionary scope of the patent itself." (11AA 2676; see also slip opinion 33-34.) Far from "immuniz[ing]" the settlement from antitrust scrutiny or making "the scope of the Cartwright Act ... exactly zero"—as plaintiffs wrongly contend (PFR 3, 20, see also 10)—the Court of Appeal and superior court simply concluded that plaintiffs could not satisfy a threshold requirement of the antitrust inquiry as a matter of law.

The lower courts also correctly rejected plaintiffs' request for a holding that Hatch-Waxman patent settlements are per se unlawful. (PFR 3.) As the Court of Appeal recognized, "[u]nder 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.*" (Slip opinion 32; see also *Morrison v. Viacom, Inc.* (1998) 66 Cal.App.4th 534, 540; *Marin County Bd. of Realtors v. Palsson, supra,* 16 Cal.3d at pp. 930–931.) Hatch-Waxman settlements generally, and the Cipro settlement specifically, do not come close to falling within the narrow and exceptional per se category, as both the Court of Appeal and superior court held. After all, "it is well settled that the law favors settlements and this would extend to patent infringement suits as well." (11AA 2672; accord *Abouab v. City and County of San Francisco* (2006) 141 Cal.App.4th 643, 673 [recognizing that there has "long been a strong public policy favoring settlements" in California, citing *McClure v. McClure* (1893) 100 Cal. 339, 343].) It is likewise not anticompetitive for a patent holder to keep would-be infringers out of the market—both because patents are presumed valid by operation of law (see *Cipro III, supra,* 544 F.3d at p. 1337, citing

35 U.S.C. § 282) and because the Cipro patent itself has repeatedly been upheld. Where, as here, a patent holder could lawfully "restrain" competition within the scope of its patent, conduct that extends no further than the patent grant does not violate the Cartwright Act. (See *Fruit Machinery Co. v. F.M. Ball & Co.*, *supra*, 118 Cal.App.2d at p. 763.)

For these reasons, courts have repeatedly recognized the lawfulness of Hatch-Waxman settlements within the scope of a patent, even when they include monetary consideration from the branded patent holder to the generic patent challenger. (See 11AA 2672–2673 [citing cases]; *Tamoxifen*, *supra*, 466 F.3d at p. 206 [holding that Hatch-Waxman settlements with reverse payments are not per se illegal]; *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.* (11th Cir. 2003) 344 F.3d 1294, 1309–1311 (*Valley Drug*) [same].) Per se treatment would be especially inappropriate for the Cipro settlement, which has been reviewed—and upheld—by five different courts. (See slip opinion 33-34; 11AA 2665–2677; *Cipro IV*, *supra*, 604 F.3d at p. 106; *Cipro III*, *supra*, 544 F.3d at p. 1340; *Cipro II*, *supra*, 363 F.Supp.2d at p. 548.) Given the detailed analyses and conclusions of these courts, a finding that this same settlement

was per se illegal would be remarkable.

B. The Decisions of the Court of Appeal and Superior Court Are Consistent With Both California and Federal Law.

Plaintiffs are also incorrect in asserting that the Court of Appeal "fail[ed] to address applicable high court authority, including decisions of this Court," or "misconstru[ed]" *Fruit Machinery Company v. F. M. Ball & Company* (1953) 118 Cal.App.2d 748. (PFR 3, see also 18.) As the Court of Appeal stated, "[t]he 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 Machinery*]" (Slip opinion 34)—and that decision shows that plaintiffs have no valid grounds for seeking review.

In *Fruit Machinery*, the court held that a patent licensing regime did not "put the arrangement beyond the scope of the patent rights and within the proscription of the antitrust laws," because the parties did not "exercise[] rights or powers not accorded to them by the patent law or abuse[] any rights or powers accorded to them by that law." (*Fruit Machinery*, *supra*, 118 Cal.App.2d at p. 762; see also slip opinion 34.) In distinguishing other cases in which antitrust liability was found,

Fruit Machinery emphasized that "it appeared that the patentee or his assignee [in those other cases] 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 Machinery, supra,* 118 Cal.App.2d at p. 763.) Because the patentee in *Fruit Machinery* did not go beyond the scope of the patent, there was no antitrust violation as a matter of law. All of this underscores the correctness of the lower courts' reasoning in this case.

Nor are plaintiffs correct that the lower courts "ignored *Vulcan* [*Powder Company v. Hercules Powder Company* (1892) 96 Cal. 510] and its teachings." (PFR 18.) As the superior court correctly observed, *Vulcan* is wholly inapposite. (11AA 2672.) *Vulcan* addressed a collaboration among industry members (including some that did not even have patent rights) to establish a committee to fix prices (imposing fines on companies that disobeyed). (*Vulcan Powder Co. v. Hercules Powder Co.* (1892) 96 Cal. 510, 513.) "The Court in *Vulcan* found an antitrust violation because the agreement exceeded the scope of the patent. The contract at issue in that case, unlike here, was not confined to the product (dynamite) produced under the patents, and involved a

collaboration among many industry members ... to establish a commitment to fix prices." (11AA 2672.) As the superior court emphasized, the agreement in *Vulcan* in no way resembles the Cipro settlement, in which Bayer and Barr settled their patent litigation (just as countless other patent cases settle every year) in a way that extended no further than the scope of the patent itself. (See 11AA 2672.)

Plaintiffs' attempt to transform the doctrine of patent misuse into a principle of California competition law also fails. (PFR 1, 12 ["the question of whether Bayer misused its patent is for the jury"].) The doctrine of patent misuse is an equitable defense to a patent infringement claim and is distinct from an antitrust inquiry. (*U.S. Philips Corp. v. International Trade Com.* (Fed. Cir. 2006) 424 F.3d 1179, 1184; accord *B. Braun Medical, Inc. v. Abbott Laboratories* (Fed. Cir. 1997) 124 F.3d 1419, 1426 ["The patent misuse doctrine, born from the equitable doctrine of unclean hands, is a method of limiting abuse of patent rights separate from the antitrust laws."].) It thus does not apply here. And even if the patent misuse doctrine could apply, the doctrine is fully consistent with the scope of the patent rule. (See *Princo Corp. v. International Trade Com.* (Fed. Cir. 2010) 616

F.3d 1318, 1328 [en banc] ["Where the patentee has not leveraged its patent beyond the scope of rights granted by the Patent Act, misuse has not been found."].)

The Court of Appeal's holding, and the superior court decision it affirmed, are thus consistent with long-standing California precedent. Neither the Court of Appeal nor the superior court "deferr[ed] to recent federal decisions" as controlling, despite what plaintiffs contend (PFR 3). Instead, the courts properly recognized the persuasiveness of decisions examining the exact same settlement at issue here, under reasoning consistent with California precedent such as *Fruit Machinery*. (Slip opinion 32-34.) As the Court of Appeal noted, "[c]ontrary to [the] assertion that the 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 antirust law." (Slip opinion 37-38 [internal quotation marks and emphasis omitted].) This includes three different federal court decisions

upholding the Cipro settlement, one of which was issued by the Federal Circuit in a case that included California plaintiffs suing under California law and for which the U.S. Supreme Court denied review. (*Cipro IV*, *supra*, 604 F.3d at p. 106 [upholding Cipro settlement]; *Cipro III*, *supra*, 544 F.3d at p. 1337 [same]; *Cipro II*, *supra*, 363 F.Supp.2d at p. 523 [same]; see also *Schering-Plough*, *supra*, 402 F.3d at p. 1074; *Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc.* (N.D.Ill. 2003) 289 F.Supp.2d 986, 995 [Posner, J., sitting by designation] (*Asahi*).) The only courts to reach different conclusions have done so in cases involving settlements that extended *beyond* the scope of the patent grant. (See *Cipro III*, *supra*, 544 F.3d at p. 1335 [distinguishing on this ground *In re Cardizem CD Antitrust Litigation* (6th Cir. 2003) 332 F.3d 896].)[2]

---

[2] The Court of Appeal correctly noted that *Cardizem* is distinguishable because "the reverse payment in *Cardizem* restrained competition beyond the exclusionary zone of the subject patent" (Slip opinion 37), and, in any event, "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." (Slip opinion 37; see also 11AA 2673 [distinguishing *Cardizem* on this ground]; *Cipro III*, *supra*, 544 F.3d at p. 1335 [same].)

Because the decisions below are consistent with both California law and the decisions of the federal courts to have considered this issue—including this same settlement—the petition should be denied.

II. Plaintiffs' Arguments Have Been Rejected by Multiple Courts and Provide No Basis for Granting Review.

Plaintiffs' attempts to create error in the Court of Appeal's opinion fail. The scope of the patent test, as adopted by the superior court, Court of Appeal and the federal courts, is not a "rule of per se legality," despite what plaintiffs wrongly suggest. (PFR 9, fn. 7.) Rather, it is simply a recognition that, so long as a patent settlement does not extend beyond the exclusionary reach of the patent itself, then the settlement excludes nothing more than what the patent already protects—and thus there is no unlawful restraint under the rule of reason. As the Federal Circuit explained in upholding the same settlement:

> [P]atent 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.

(*Cipro III*, *supra*, 544 F.3d at p. 1337, rehg. en banc den. (Dec. 23, 2008); cert. den. *sub. nom. Arkansas Carpenters Health and Welfare Fund v. Bayer AG* (2009) 129 S.Ct. 2828.) The Second Circuit's decision affirming the Cipro settlement followed the same approach, and both the en banc court and the U.S. Supreme Court denied review. (*Cipro IV*, *supra*, 604 F.3d at p. 106, rehg. en banc den. (2010) 625 F.3d 779, cert. den. *sub nom Louisiana Wholesale Drug Co., Inc. v. Bayer AG* (2011) 131 S.Ct. 1606.)

Plaintiffs insist, however, that the Cipro settlement violated the antitrust laws because the Cipro patent *might have been* invalid. (PFR 10.) According to plaintiffs, the payment from Bayer to Barr in settling the litigation is evidence that the patent was a "'paper tiger' with no bite or ability to defend Bayer's monopoly." (PFR 16.) That assertion is baseless. There are many reasons why parties settle litigation even though they believe they should and will prevail. For one thing, parties cannot know in advance if they will prevail; given the inherent uncertainty of litigation, "[n]o one can be *certain* that he will prevail in a patent suit." (*Asahi*, *supra*, 289 F.Supp.2d 986 at p. 993.) Indeed, "[d]ue to the 'asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its

patent might pay a potential infringer a substantial sum in settlement.'" (*Schering-Plough, supra,* 402 F.3d at p. 1075 [quoting *Valley Drug, supra,* 344 F.3d at p. 1310].) The law does not require parties to litigate every case to final judgment.

Plaintiffs' petition thus asks this court to create a split in the law by being the first court to adopt a presumption of patent *invalidity.* But that argument would turn patent law on its head, and it provides no basis for granting the petition. After all, patents are presumed to be valid under federal law (35 U.S.C. § 282), and there is no basis for undermining that presumption, especially when the Cipro patent has been subject to re-examination (and re-issue) by the PTO, and the patent has been upheld against multiple subsequent challengers. (See *Schein, supra,* 129 F.Supp.2d 705, affd. (Fed.Cir. 2002) 301 F.3d 1306.) These subsequent patent victories also undermine any argument by plaintiffs that Bayer made the payment to "foreclose the testing" of its patent. (PFR 4, see also 15-16.) The settlement of patent litigation resolves claims between the settling parties, but does not preclude *other* parties from challenging the patent's validity, as four other parties did here. None of those challenges prevailed.

Plaintiffs then resort to claiming that the settlement violated the antitrust laws because it included monetary consideration from Bayer, as the patent holder, to Barr, as the patent challenger. According to plaintiffs, such a payment amounted to nothing more than a "bribe" because "in legitimate litigation, the patent holder does not pay the alleged infringer to settle." (PFR 3, 7, 17.) What plaintiffs ignore, however, is that in *all* patent litigation settlements (even outside the Hatch-Waxman context), the alleged infringer typically receives consideration in the deal:

1. The patent owner sues the alleged infringer for selling its infringing product.

2. A loss for the potential infringer could result in potentially crippling damages.

3. To avoid this litigation risk, the alleged infringer typically will pay some amount to the patent holder in exchange for ending the litigation.

4. But the settlement does not require the alleged infringer to give back all of its profits. The alleged infringer will also typically *keep* some amount of profit from its allegedly infringing sales. (See *Tamoxifen, supra*, 466 F.3d at p. 207, fn. 20.)

5. The profits that the alleged infringer retains constitute the value it receives from the settlement.

For this reason, "any settlement agreement can be characterized

as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement." (*Asahi*, *supra*, 289 F.Supp.2d at p. 994; see also *Cipro I*, *supra*, 261 F.Supp.2d at p. 252.)

A settlement payment from a patent holder to a generic challenger is even more logical in the Hatch-Waxman context, where the traditional risks associated with patent litigation are reversed. A generic manufacturer can challenge the patent on a branded drug without actually entering the market. As a result, even if the generic manufacturer is unsuccessful in its challenge, it will be liable for few, if any, monetary damages because it has not yet sold an infringing product. (See *Tamoxifen*, *supra*, 466 F.3d at pp. 206–207.) By contrast, a loss for the branded manufacturer would invalidate its patent, quickly costing it potentially billions of dollars in sales. (See *id.* at p. 210.) Just as the "typical" patent challenger would settle in return for *keeping* a portion of the profits it derived, a Hatch-Waxman challenger would logically settle for a portion of the profits *to be* derived from its generic product. This explains why settlement payments in Hatch-Waxman cases naturally flow from the patent holder to the generic challenger: the generic challenger has the claim of

value in the litigation. (See slip opinion 36 ["We agree ... that reverse payment settlements are a natural byproduct of patent litigation under the Hatch-Waxman Act."]; *Cipro I, supra*, 261 F.Supp.2d at pp. 250–251.)

As the Court of Appeal observed, prohibiting a lawsuit over patent validity from being settled for monetary consideration—a rule that does not exist for any other type of lawsuit—would discourage not only patent settlements but also challenges to patent validity. (Slip opinion 36.) It has long been recognized that, given litigants' differing views about the litigation as well as the parties' different valuations of the case, it often is not possible to settle litigation other than through monetary consideration. (See, e.g., Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy* (2004) 71 Antitrust L.J. 1033, 1034.) This is especially true in the Hatch-Waxman context because the two parties place such vastly different values on the introduction of a competing drug product. For the generic company, an extra day of sales is worth only as much as it would gain at generic prices. For the branded company, however, each lost day of sales is calculated at the higher price of its branded drug. (2RA 387–389.) Each extra day will thus cost the branded manufacturer

more than the generic competitor will gain. The use of monetary consideration allows the two companies to make up this difference and meet in the middle. (2RA 387–389.)

For these reasons, "[a] ban on reverse-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." (*Asahi*, 289 F.Supp.2d at p. 994; see also *Tamoxifen*, *supra*, 466 F.3d at p. 203 ["Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation," citing *Valley Drug*, *supra*, 344 F.3d at p. 1308]; *Schering-Plough*, *supra*, 402 F.3d at p. 1075 ["[T]he 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."].) It is thus plaintiffs' position, not defendants', that would "eliminate competition" and "lead to higher drug prices," thereby "directly undermin[ing] the purpose of the [Hatch-Waxman Act]." (PFR 4-

5.)

The only case law plaintiffs cite is inapposite and thus provides no basis for this court's review. Indeed, the only cases plaintiffs can point to as going "unmentioned" by the Court of Appeal are four *federal* cases. (PFR 10-12 [citing *United States v. Univis Lens Co.* (1942) 316 U.S. 241; *United States v. Sealy* (1967) 388 U.S. 350; *United States v. Masonite Corp.* (1942) 316 U.S. 265; *United States v. Singer Manufacturing Co.* (1963) 374 U.S. 174].) Although plaintiffs argue these cases are "seminal," they provide little analysis of them in the petition. The reason for this is simple: all of the cases support *defendants'* position and the scope of the patent framework, and thus provide no basis for granting review.

Three of the cases—*Masonite*, *Univis* and *Sealy*—involved an agreement to fix prices beyond the initial sale from the patent holder and down the supply chain, which has long been recognized to go beyond the scope of a party's patent rights. (See *United States v. Univis Lens Co.*, *supra*, 316 U.S. at p. 251 ["The added stipulation by the patentee fixing resale prices derives no support from the patent and must stand on the same footing under the Sherman Act as like stipulations with respect to

unpatented commodities."].) The language plaintiffs quote from *Sealy*, for example, comes in a discussion of the "scope" of the intellectual property right (there, a trademark): "A restraint such as is here involved of the resale price of a trademarked article, *not otherwise permitted by law*, cannot be defended as ancillary to a trademark licensing scheme." (*United States v. Sealy, Inc.*, *supra*, 388 U.S. at p. 356, fn. 3, emphasis added.) And the very language plaintiffs quote from *Masonite*, discussing how the "patent privilege" cannot "be enlarged," also is consistent with the scope of the patent framework. (*United States v. Masonite Corp.*, *supra*, 316 U.S. at p. 278.)

Singer similarly fails to support plaintiffs' position. In *Singer*, the Supreme Court found that three sewing machine manufacturers, Singer, Gegauf, and Vigorelli, conspired and acted in concert to suppress competition from Japanese manufacturers. In so holding, the court focused on an "entire course of dealings between the parties" (*United States v. Singer Manufacturing Co.*, *supra*, 374 U.S. at p. 190, fn. 7) where "by entwining itself with Gegauf and Vigorelli in such a program Singer went far beyond its claimed purpose of merely protecting its own 401 machine" on which it had a patent (*id.* at p. 194).

Because no *court* has ever adopted plaintiffs' proposed approach, plaintiffs rely on the *losing* policy positions advocated in briefs by state attorneys general, the Department of Justice and the Federal Trade Commission. As the Court of Appeal properly recognized, however, the courts are not a proper forum for altering what it means to have a patent under the Patent Act. (Slip opinion 38, fn. 9.) This is not an "abdication of judicial responsibility," as plaintiffs claim (PFR 19, fn. 15), but simply a recognition that courts apply the law as written. And that is especially appropriate here because, despite plaintiffs' selective quotations from individual legislators, the U.S. Congress has consistently *rejected* legislation that would alter the patent/antitrust balance and make Hatch-Waxman settlements unlawful. (See Sen. No. 27, 112th Cong. (2011); Sen. No. 3677 (amend.), 111th Cong. (2010); Sen. No. 369, 111th Cong. (2009); Sen. No. 316, 110th Cong. (2009).) Plaintiffs' arguments provide no basis for granting the petition.

III. The Lower Courts Correctly Applied This Court's Precedent in Overruling Plaintiffs' Evidentiary Objections.

In a last-ditch effort to obtain review, plaintiffs argue that the lower court "contraven[ed] this Court's recent ruling in *Reid v. Google, Inc.*" by overruling all of plaintiffs' evidentiary objections in open court and in a written opinion without individually addressing each objection seriatim. (PFR 24.) This secondary issue, which plaintiffs did not even develop below, also does not merit review.

First, plaintiffs' attempt to create a conflict with *Reid v. Google, Inc.* (2010) 50 Cal.4th 512, is telling: they did not even cite that decision in the briefing below. It was *defendants* that cited *Reid* in support of their response. The Court of Appeal agreed with defendants, quoting *Reid*'s holding 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 ....'" (Slip opinion 51-52, quoting *Reid*, at p. 534.) Here, the superior court considered plaintiffs' objections (and defendants' responses) before expressly ruling—in open court and in its written opinion—that those

objections were overruled. (11AA 2677.) Nothing in *Reid* or any other provision of California law requires more.

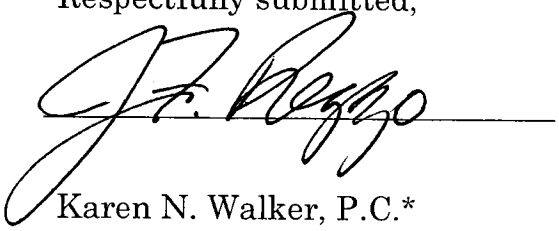
And, in any event, plaintiffs cannot seek review of this issue because they waived it in the Court of Appeal. As that court noted, "plaintiffs have not argued that the admission of any specific evidence constituted prejudicial error," except for a cursory reference to how the superior court should have ignored undisputed evidence of Bayer's subsequent patent victories. (Slip opinion 52 and fn. 16.) But neither plaintiffs' opening brief nor reply brief in the Court of Appeal made any argument as to why any of their objections should have been sustained, what impact the challenged evidence had on the ultimate result, and how any alleged error was prejudicial. (Cal. Const., art. VI, § 13; see also *Soto v. State of California* (1997) 56 Cal.App.4th 196, 202.) This failure constituted waiver in the Court of Appeal (see *Shaw v. Hughes Aircraft Co.* (2000) 83 Cal.App.4th 1336, 1345, fn. 6; *Mission Shores Assn. v. Pheil* (2008) 166 Cal.App.4th 789, 796), and it precludes plaintiffs from developing the issue for the first time here.

CONCLUSION

The petition for review should be denied.

January 10, 2012

Respectfully submitted,



Joann Rezzo
EDLESON & REZZO
402 West Broadway, Suite 2700
San Diego, CA 92101
(619) 230-0836

Kathryn E. Karcher
KARCHER HARMES LLP
401 B Street, Suite 2450
San Diego, CA 92101
(619) 565-4755

Counsel for Respondents Barr Laboratories, Inc., Hoechst Marion Roussel, Inc., The Rugby Group, Inc., and Watson Pharmaceuticals, Inc.

Karen N. Walker, P.C.*
Edwin John U*
Gregory L. Skidmore*
KIRKLAND & ELLIS LLP
655 Fifteenth Street, N.W.
Washington, DC 20005
(202) 879-5000

Counsel for Respondent Barr Laboratories, Inc.

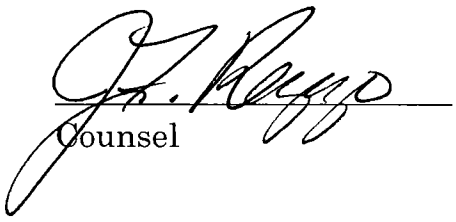
Heather S. Woodson*
STINSON MORRISON HECKER LLP
1201 Walnut Street, Suite 2900
Kansas City, MO 64106
(816) 842-8600

Counsel for Respondents Hoechst Marion Roussel, Inc., The Rugby Group, Inc., and Watson Pharmaceuticals, Inc.

* *Pro hac vice* pending

CERTIFICATE OF WORD COUNT

Pursuant to California Rules of Court, rule 8.504(d)(1), the undersigned certifies that the foregoing brief contains 6,569 words, exclusive of tables, certificates and attachments, as counted by the Word Count feature of Microsoft Word.



Counsel

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

PROOF OF SERVICE

I am a resident of the State of California, over the age of eighteen years, and not a party to this action. My business address is 402 W. Broadway, Suite 2700, San Diego, CA 92101. On January 9, 2012, I served the following document(s):

ANSWER TO PETITION FOR REVIEW OF BARR LABORATORIES, INC., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., AND WATSON PHARMACEUTICALS, INC.

X by placing the document(s) listed above in a sealed envelope with postage fully prepaid, in the United States mail at 402 W. Broadway, Suite 2700, San Diego, California addressed as set forth below.

I declare under penalty of perjury under the laws of the State of California that the above is true and correct. Dated January 9, 2012.

Anne Donovan

SERVICE LIST	
Attorney	**Party**
Dan Drachler ZWERLING, SCHACTER & ZWERLING 1904 Third Avenue, Suite 1030 Seattle, WA 98101 Ralph B. Kalfayan KRAUSE, KALFAYAN, BENINK & SLAVENS, LLP 550 W. C Street, Suite 530 San Diego, CA 92101 Joseph Richard Saveri LIEFF CABRASER LLP 275 Battery St., 29 FL San Francisco, CA 94111	Counsel for Plaintiff/Appellant: Kayrn McGaughey, Barbara Hymes Cohen, Deborah Patane, Donna Moore, IUOE Stationary Engineers Local 39 Health & Welfare Plan, Sheet Metal Workers Health Plan of Southern California **By U.S. Mail**

SERVICE LIST	
Peter B. Bensinger BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP 54 W. Hubbard Street Suite 300 Chicago, Il 60654 Kevin D. McDonald JONES DAY 51 Louisiana Avenue, N.W. Washington, DC 20001 Christopher J. Healey Charles Bird Todd Kinnear LUCE, FORWARD, HAMILTON & SCRIPPS LLP 600 West Broadway Suite 2600 San Diego, CA 92101	Counsel for Defendant/Respondent Bayer Corporation: **By U.S. Mail**
Mark Alan Lemley Stanford Law School 550 Nathan Abbot Way Stanford, CA 94305	78 Law, Economics, Business and Public Policy Professors; Amicus Curiae for Appellant in the Court of Appeal **By U.S. Mail**

SERVICE LIST	
Administrative Office Of The Courts Attn: Carlotta Tillman 455 Golden Gate Avenue 6th Floor San Francisco, CA 94102	**By U.S. Mail**
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	**By U.S. Mail**
Superior Court of California Clerk of San Diego County Superior Court 330 W. Broadway San Diego, CA 92101	**By U.S. Mail**
California Court of Appeal Fourth Appellate District, Division One Symphony Towers 750 B Street, Suite 300 San Diego, CA 92101	**By U.S. Mail**