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 BRIEF OF RESPONDENTS 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 Defendants Barr Laboratories, Inc., Hoechst Marion Roussel, Inc., The Rugby Group, Inc., and Watson Pharmaceuticals, Inc.

* Admitted *pro hac vice*

Jay P. Lefkowitz, P.C.*
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 Defendant Barr Laboratories, Inc.

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

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

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 BRIEF OF RESPONDENTS 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 Defendants Barr Laboratories, Inc., Hoechst Marion Roussel, Inc., The Rugby Group, Inc., and Watson Pharmaceuticals, Inc.

* Admitted *pro hac vice*

Jay P. Lefkowitz, P.C.*
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 Defendant Barr Laboratories, Inc.

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

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Rules and Statutes

Other Authorities

INTRODUCTION

This case presents the question whether a patent means less in California than anywhere else in the Nation. The answer to that question is no: California law, like federal law, recognizes that a patent confers a lawful monopoly that entitles the patent holder to exclude competition *within* the patent's scope. It follows, as a matter of law and logic, that the patent holder is entitled to settle litigation involving the patent, as long as that settlement does not restrain competition *beyond* the patent's scope. Any restraint on competition within the patent's scope flows not from the settlement, but from the patent itself.

That straightforward point is the beginning and the end of this case. After years of litigation, Bayer and Barr settled their dispute over the validity of Bayer's patent on the antibiotic drug Cipro. That settlement did not restrain any competition beyond the patent's scope—and indeed allowed Barr to launch a competing drug a full year *before* the end of the patent's exclusivity period. Nothing in the settlement limited the ability of other generic drug makers to challenge the validity of the Cipro patent—and several other companies in fact pursued such a challenge and *lost*.

Nonetheless, a number of lawsuits were filed in federal and state court challenging the Cipro settlement under the antitrust laws. Not one of those lawsuits has prevailed for the simple reason that the antitrust laws do not protect competition *within* a patent's scope, and the settlement here did not restrain any competition *beyond* the patent's scope. Thus, both the U.S. Courts of Appeals for the Second Circuit and the Federal Circuit specifically rejected antitrust challenges to the very settlement agreement challenged here, and in both cases the U.S. Supreme Court declined review.

Plaintiffs' effort to impose per se antitrust liability on the Cipro settlement would take California antitrust law far beyond federal antitrust law, and bring it squarely into conflict with federal patent law. This Court need not, and should not, create any such conflict, which would simply result in the preemption of state law. As both the Second and Federal Circuits have recognized, it is entirely possible to harmonize antitrust and patent law by declining to extend antitrust liability to conduct within a patent's scope. That harmonizing approach also has the virtue of comporting with settled California law. (See *Fruit Machinery Co. v. F. M. Ball & Co.* (1953) 118 Cal.App.2d 748

(*Fruit Machinery*).) Accordingly, this Court should affirm the decision of the Court of Appeal, and end this twelve-year-old litigation for once and for all.

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.[1]

A. The Hatch-Waxman Act

Because the process for introducing generic drugs to market is relevant to understanding how the Cipro patent litigation unfolded, the Generic Defendants briefly explain that process here.

The Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Act") established a new procedure for obtaining FDA approval to market generic drugs. (21 U.S.C.

---

[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 brief as "defendants," join in and incorporate by reference the brief filed by defendant Bayer. (See Cal. Rules of Court, rule 8.504(e)(3).)

§ 355 (2000) [text of Food, Drug, and Cosmetic Act, as amended by Hatch-Waxman Act].) The Hatch-Waxman Act is a carefully-drafted statute that balances two primary interests: (1) encouraging the development of generic drugs, and (2) protecting the patent rights of brand-name drug manufacturers to reward their research and development efforts.

The Hatch-Waxman Act made it easier for generic drug companies to introduce competing versions of a brand-name drug by allowing the generic company to rely on the FDA's determination that the brand-name drug is safe and effective. To gain approval, the generic company must file what is known as an Abbreviated New Drug Application ("ANDA"). (See 21 U.S.C. § 355(j).) In the ANDA, the applicant must demonstrate that its generic version of the drug is "bioequivalent" to the branded drug, meaning that it works in the same way and provides the same benefits. (See *ibid.*) To protect the patent rights of the branded manufacturer, however, the Hatch-Waxman Act requires the generic challenger to file one of four certifications concerning any patent that claims the branded product. (See *id.*, § 355(j)(2)(A)(vii).) The certification relevant here is an ANDA IV—a certification either that the generic drug does not infringe

the patent, or that the patent is invalid or unenforceable (see *id.*, § 355(j)(2)(A)(vii)(IV).)

Because an ANDA IV amounts to an assertion by the generic company that the patent on a brand-name drug should not be enforced, filing an ANDA IV is considered a technical act of patent infringement (see 35 U.S.C. § 271(e)), which allows the branded manufacturer to sue immediately rather than waiting until the generic company introduces its drug into the market. Through the resulting litigation, a generic company can obtain a judicial determination of whether the patent is valid before producing and selling its competing product. So long as the generic company waits for the ruling before coming to market, it does not risk paying damages if it loses the patent case, because it will not have made any infringing sales. By contrast, the branded manufacturer stands to lose a great deal in the litigation: 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*).)

B. Factual Background

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, and filed an ANDA IV. In response, Bayer brought a patent infringement action. Because Bayer's patent 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. (2 RA 356–357.)

The parties engaged in five years of litigation and discovery. Although plaintiffs attempt to exaggerate the strength of Barr's patent challenge by stating that the judge presiding over the patent litigation denied Bayer's motion for partial summary judgment (POB 10), plaintiffs fail to point out that the judge also denied *Barr's* cross-motion for summary judgment. (See *Bayer AG v. Barr Laboratories, Inc.* (S.D.N.Y. June 5, 1996, No. 92 Civ. 0381-WK) 1996 WL 304544.) In fact, the court had previously granted partial summary judgment in Bayer's favor at the start of the case and accordingly dismissed one of Barr's threshold patent claims. (2 AA 260, ¶ 8.) As Barr's CEO testified

during his deposition, he "was troubled that some of these claims were dismissed—one or more of the claims were dismissed on summary judgment. That didn't bode well [for Barr], in my opinion." (2 RA 359.)

As the case approached trial, the district judge expressed concern about the complex scientific issues presented. (See 1 RA 27.) The magistrate judge, meanwhile, "inquired about the parties' willingness to settle the case and urged the parties to meet for that purpose." (2 RA 361.) At that point, Bayer and Barr settled their litigation, 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. (4 AA 770–775, 788–790.) Barr's CEO testified that 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. (3 RA 670.)

Nothing in the settlement purported to preclude other parties from challenging the validity of the Cipro patent. Several other generic drug companies did so, but none prevailed. (See *Bayer AG v. Schein Pharmaceutical, Inc.* (D.N.J. 2001) 129

F.Supp.2d 705 [rejecting validity challenges by Mylan and Schein on summary judgment], affd. (Fed.Cir. 2002) 301 F.3d 1306; *Bayer AG v. Carlsbad Technology, Inc.* (S.D.Cal. June 7, 2002 and Aug. 7, 2002, No. 01CV0867-B) [rejecting Carlsbad's validity challenge after bench trial; opinions available at 1 RA 181–193, 195–227]; *Bayer AG v. Ranbaxy Pharmaceuticals, Inc.* (D.N.J. Oct. 29, 1999, No. 98-4464) [dismissing Ranbaxy's challenge as moot; stipulation of dismissal available at 1 RA 229–231].) Bayer also sought re-examination of the Cipro patent by the U.S. Patent & Trademark Office (PTO), which reaffirmed its validity in 1999.

In June 2003, six months before the Cipro patent expired, Bayer began to supply ciprofloxacin that Barr could sell as a competing product. (2 RA 374–377 [deposition of Barr sales and marketing executive].) Because the FDA had, in the interim, granted Bayer a six-month extension of its exclusivity in light of a study on Cipro's effectiveness in children (see 21 U.S.C. § 355a; 2 AA 243, ¶ 4), the Cipro settlement enabled Barr to enter the market and sell a lower-priced ciprofloxacin product *a full year*

earlier than the law otherwise would have permitted.[2] (2 RA 374–377.)

C. Cipro Litigation

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 antitrust and consumer protection laws. 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. (*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. (*Cipro I, supra*, 261 F.Supp.2d 188.)

Plaintiffs appealed both rulings to the U.S. Court of

---

[2] Plaintiffs therefore err by asserting that "[t]he Cipro agreements ... did not license patented rights." (POB 33.) (See *Arkansas Carpenters Health and Welfare Fund v. Bayer AG* (2d Cir. 2010) 604 F.3d 98, 102 [noting that the settlement agreement "provide[d] the generic manufacturers a guaranteed license to sell brand-name Cipro at a reduced rate for six months prior to the patent's expiration"].)

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.

In 2008, the Federal Circuit unanimously affirmed the district court's grant of summary judgment for defendants on the indirect purchaser plaintiffs' claims. (*In re Ciprofloxacin Hydrochloride Antitrust Litigation* (Fed.Cir. 2008) 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 [*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. (129 S.Ct. 2828.)

In 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 manufacturing generic Cipro encompasses only conduct that would infringe Bayer's patent rights," meaning that there is no antitrust violation. (*Cipro IV*, 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 without even asking for a response from the defendants. (625 F.3d 779.) 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. (11 AA 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." (11 AA 2671.)

Plaintiffs appealed, and the Court of Appeal, Fourth Appellate District, Division One (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 then "conclud[ed] 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 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." (*Id.* at p.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 Machine[ry] Co. v. F. M. Ball & Co.* (1953) 118 Cal.App.2d 748." (Slip opinion 34.) The court thus concluded that "[b]ecause the Cipro agreements undisputedly did not restrain competition beyond the exclusionary scope of the [Cipro] patent, ... they do not violate the Cartwright Act." (*Id.* at pp.3–4.)

STANDARD OF REVIEW

This court reviews a grant of summary judgment de novo. (*Aguilar v. Atlantic Ritchfield Co.* (2001) 25 Cal.4th 826, 850 (*Aguilar*).) To obtain summary judgment, defendants need only show "that 'one or more elements of' the 'cause of action' in question 'cannot be established' or that 'there is a complete defense'" to that cause of action. (*Ibid.*, quoting Code Civ. Proc., § 437c, subd. (o)(2).) A defendant may also make the requisite showing by establishing that a plaintiff does not possess the

evidence necessary to prevail on an element of its claim. (*Aguilar*, at pp.854–855.) Under California law, summary judgment is decidedly available to defendants in antitrust cases, as subjecting defendants "to undue costs in the judicial sphere" would "effectively chill procompetitive conduct in the world at large, the very thing that [antitrust law] is designed to protect." (*Id.* at p.852.)

ARGUMENT

I. The Lower Courts—Consistent With California And Federal Law—Correctly Applied The Rule Of Reason In Holding That The Cipro Settlement Does Not Violate The Cartwright Act.

The lower courts properly applied the well-established Rule of Reason test in holding that the Cipro settlement does not violate the Cartwright Act. Contrary to plaintiffs' claim that the lower courts "refused to apply California's traditional antitrust analysis" (POB 3), both courts followed well-established California law in holding that plaintiffs could not establish the first step of the Rule of Reason—showing an actual adverse effect on competition—because the settlement restrained no more competition than the exclusionary potential of the Cipro patent itself. (Slip opinion 33–34; see also 11 AA 2691.) This analysis is

entirely consistent with established precedent—including three other decisions upholding the exact same settlement agreement at issue in this case.

A. The Lower Courts Correctly Held The Cipro Settlement Does Not Violate The Cartwright Act Because It Does Not Exceed The Scope Of The Cipro Patent.

As the superior court recognized, "[t]he Cartwright Act and the federal antitrust laws are interpreted to permit restraints of trade as long as those restraints are reasonable under the circumstances." (11 AA 2672; accord *Chavez v. Whirlpool Corp.* (2001) 93 Cal.App.4th 363, 375; *Marin County Bd. of Realtors, Inc. v. Palsson* (1976) 16 Cal.3d 920, 930, citing *Standard Oil Co. of New Jersey v. United States* (1911) 221 U.S. 1; *Morrison v. Viacom, Inc.* (1998) 66 Cal.App.4th 534, 540.) The Rule of Reason requires that (1) an alleged restraint on trade has anticompetitive effects, and (2) the anticompetitive effects outweigh any pro-competitive benefits. (11 AA 2690; accord *Bert G. Gianelli Distributing Co. v. Beck & Co.* (1985) 172 Cal.App.3d 1020, 1048, disapproved on other grounds in *Dore v. Arnold Worldwide, Inc.* (2006) 39 Cal.4th 384, 394, fn.2; *Marin County*, at pp.934–35.) The first element of this analysis requires a

plaintiff to show that the challenged agreement had a "substantially adverse effect on competition in the relevant market." (*Exxon Corp. v. Superior Court* (1997) 51 Cal.App.4th 1672, 1681; see also *Bert G. Gianelli*, at p.1048; *Marin County*, at p.937; *Marsh v. Anesthesia Services Medical Group* (2011) 200 Cal.App.4th 480, 494.)

Applying well-established California law, the lower courts correctly held that plaintiffs could not demonstrate this actual adverse effect on competition because the Cipro settlement limited no more competition than the patent already limited. (Slip opinion 33–34; 11 AA 2684.) In other words, because the only restraints on competition were those "inherent in the patent" itself, plaintiffs' claims could not proceed as a matter of law under the first step of the Rule of Reason. (Slip opinion 33; 11 AA 2691.)

Under these circumstances, the grant of summary judgment was entirely appropriate—especially when plaintiffs' opening brief does not challenge the Court of Appeal's observation that "the Cipro Agreements *undisputedly* did not restrain competition beyond the scope of the [Cipro] patent." (Slip opinion 3, emphasis added; POB 36 [acknowledging "[t]hat

[defendants'] agreement was limited to the patent parameters" before challenging the legal significance of that fact].) Although plaintiffs assert that the question of reasonableness "in the context of the Cartwright Act is a question of fact to be determined at trial" (POB 42, quoting *Corwin v. Los Angeles Newspaper Service Bureau, Inc.* (1971) 4 Cal.3d 842, 855), the lower courts correctly concluded that, because there were no material facts in dispute and no showing of anticompetitive effects beyond the scope of the patent, plaintiffs could not demonstrate an antitrust violation as a matter of law. (Slip opinion 33; 11 AA 2688 ["The 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."].) Summary judgment was therefore warranted. (See *Aguilar*, *supra*, 25 Cal.4th at p.852 [affirming summary judgment in a Rule of Reason case].)[3]

---

[3] The Generic Defendants and Watson adopt by reference the argument by defendant Bayer that plaintiffs have waived review

(Continued...)

B. California Courts Have Long Held That No Antitrust Liability Attaches For Conduct Within The Scope Of The Patent.

Plaintiffs devote the balance of their brief to criticizing the scope of the patent test. Contrary to what plaintiffs contend, however, this test is consistent with both California and federal antitrust law—as well as sound policy.

1. California Courts Have Long Embraced The Scope Of The Patent Test.

California courts have long recognized the right of patent

---

of their claims under the Unfair Competition Law (UCL) (Bus. and Prof. Code, § 16720, et seq.) and for common law monopolization by failing to provide any developed argument in support of those claims in their opening brief. (See *Rusheen v. Cohen* (2006) 37 Cal.4th 1048, 1055, fn.2; Cal. Rules of Court, rule 8.516(b)(1).) In any event, as the lower courts held, any such claims fail for the same reason as the Cartwright Act claims. (Slip opinion 50–51; see also 11 AA 2687–2688; *Chavez v. Whirlpool Corp., supra*, 93 Cal.App.4th at p.375 [holding that when "the same conduct is alleged to be both an antitrust violation and an 'unfair' business act or practice for the same reason ... the determination that the conduct is not an unreasonable restraint of trade necessarily implies that the conduct is not 'unfair' towards consumers"]; *Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.* (1999) 20 Cal.4th 163, 185 [emphasizing that the contrary approach could "even lead to the enjoining of pro competitive conduct and thereby undermine consumer protection"].)

holders to exclude competition within the scope of a patent, because "[t]he grant of a patent is the grant of a statutory monopoly and is an express exception to laws prohibiting monopolies." (*Aetna Casualty and Surety Co. v. Superior Court* (1993) 19 Cal.App.4th 320, 328, citing *Sears, Roebuck & Co. v. Stiffel Co.* (1964) 376 U.S. 225, 229.) After all, "[t]he very purpose of the patent law is to encourage inventive effort by according the inventor and his assigns control over the invention and protection in the exercise of the rights accorded him as patentee." (*Fruit Machinery, supra,* 118 Cal.App.2d at p.762.)

Just as the Cartwright Act "'has not been interpreted to penalize natural monopolies.... [Citation]'" (*Freeman v. San Diego Assn. of Realtors* (1999) 77 Cal.App.4th 171, 200), the statutory monopoly conferred by a patent similarly entitles the owner to exclude others from producing the patented invention, and to settle patent litigation on flexible terms. (See Areeda & Hovenkamp, Antitrust Law (3d ed. 2008) ¶ 658a, p.172 [equating natural monopolies and patent monopolies—and emphasizing "[t]o hold such monopolies unlawful would either be futile or would undermine other principles that our society regards as more important."].) As the U.S. Supreme Court explained in

Standard Oil Co., Inc. v. United States (1931) 283 U.S. 163, 171, "[w]here there are legitimately conflicting claims or threatened interferences [with a patent], a settlement by agreement, rather than litigation, is not precluded by the [antitrust laws]." All of this underscores why the Cipro settlement had no actual adverse effect on competition, as the Federal Circuit observed in upholding this very 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. [Citation.]

(*Cipro III, supra*, 544 F.3d at p.1337.)

California law is entirely consistent with this analytical approach. 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 Machine[ry] Co. v. F.M. Ball & Co.* (1953) 118 Cal.App.2d 748." (Slip opinion 34; see also *Schering-Plough Cartwright Act Cases* (Ala.Cty.Super.Ct. Dec. 17, 2009) JCCP No. 4559 [adopting the scope of the patent

framework].) 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*, at p.762; see also slip opinion 34.)

Plaintiffs seize on the final clause of this quotation and argue that the Court of Appeal "misconstru[ed]" *Fruit Machinery* by not recognizing that "abuse" of a patent can give rise to antitrust liability. (POB 34.) What plaintiffs ignore, however, is that the *Fruit Machinery* decision made clear that any such violation of the antitrust laws would occur because the arrangement would be "*beyond the scope of the patent rights.*" (*Fruit Machinery*, *supra*, 118 Cal.App.2d at p.762, emphasis added.) As the court stated in summarizing other cases in which antitrust liability was found, "it appeared that the patentee or his assignee [in the cited 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." (*Id.* at p.763, citing, e.g., *Standard Sanitary Manufacturing Co. v.*

United States (1912) 226 U.S. 20 [market allocation and price fixing]; *Ethyl Gasoline Corp. v. United States* (1940) 309 U.S. 436 [resale price maintenance].) It is thus clear that the question in *Fruit Machinery* was whether the arrangement exceeded the scope of the patent. Because the patentee in *Fruit Machinery* did not exceed the scope of the patent, there was no antitrust violation, and the lower courts correctly applied the same analysis here.

Plaintiffs have been unable to find any case—in California or elsewhere—that contradicts the scope of the patent framework. While plaintiffs claim that the lower courts "ignore[d]" *Vulcan Powder Co. v. Hercules Powder Co.* (1892) 96 Cal. 510 (POB 32–34), the superior court expressly observed that *Vulcan* provides no support to plaintiffs. (11 AA 2672.) To the contrary, *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*, at p.513; see also POB 32–33 [acknowledging this fact].) "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." (11 AA 2672.) Plaintiffs themselves concede that "[t]he [*Vulcan*] Court's ... analysis focused on whether the patent holder was receiving consideration for some right it had obtained through the patent," i.e., whether the agreement was within the scope of the patent. (POB 33.)

Although plaintiffs argue that the scope of the patent inquiry was only an "aggravating factor in the antitrust analysis" (POB 33), they cite nothing in the text of *Vulcan* itself that supports this assertion. As the superior court recognized, the price-fixing 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. (11 AA 2672.)

2. Importation Of Patent Misuse Into California Law Is Inappropriate.

Having found no California authority supporting their argument, plaintiffs next try to import the doctrine of patent

misuse into California antitrust jurisprudence. Plaintiffs contend that antitrust liability may attach for exclusionary conduct that does not exceed the bounds of the patent grant because a patentee "'may commit patent misuse in improper exploitation of the patent by violating the antitrust laws ....'" (POB 31, quoting *Transitron Electric Corp. v. Hughes Aircraft Co.* (D.Mass 1980) 487 F.Supp. 885, 893 (*Transitron*).) According to plaintiffs, the Court of Appeal's "reasoning [on the scope of the patent test] mistakenly treats what is normally a *sufficient* condition for antitrust liability (restraints beyond the patent's claims) as a *necessary* condition." (POB 31.) This argument fails for at least two reasons.

First, the doctrine of patent misuse is wholly inapplicable to an antitrust analysis. 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. Internat. Trade Com.* (Fed.Cir. 2005) 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

in this case. And even if the doctrine of patent misuse could apply in the antitrust context, it is fully consistent with the scope of the patent rule. (*Princo Corp. v. Internat. 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."].)

Second, the cases that plaintiffs cite actually applied the scope of the patent test—thus confirming that there can be no antitrust liability for restrictions within the exclusionary potential of a patent. In *Transitron*, for example, the court distinguished the equitable defense of patent misuse, which is available to *licensees*, from a Sherman Act violation, noting that "courts ... erect barriers which prevent the frustration of patent law by antitrust law and its highly punitive treble damage provisions," but also provide the doctrine of patent misuse "to relieve a licensee from paying royalties under a patent which is unlawfully obtained or enforced." (*Transitron*, *supra*, 487 F.Supp. at p.892–893, citations omitted.) The *Transitron* court's actual antitrust analysis supports the notion that, absent fraud on the PTO or sham litigation, a patentee's exclusionary conduct within the scope of the patent is free from antitrust liability. (See

id. at pp.891–892 [discussing antitrust theories of fraud on the PTO and "attempt to enforce a patent known to be invalid"].)

Nor can plaintiffs draw any support from *United States v. Masonite Corp.* (1942) 316 U.S. 265 (*Masonite*), or *United States v. Singer Manufacturing Co.* (1963) 374 U.S. 174 (*Singer*). (POB 31, 35.) In *Masonite*, the U.S. Supreme Court held that, although a patent holder can set the price at which it sells its patented product to purchasers, it cannot dictate the prices at which downstream purchasers subsequently re-sell the product to others. (*Masonite*, 316 U.S. at pp.277–78 ["[W]hen the patented product passes to the hands of the purchaser, it is no longer within the limits of the monopoly."].) Because Masonite's agreements did just that, they extended beyond the scope of the patent. (*Id.* at p.277 ["A patent affords no immunity for a monopoly not fairly or plainly within the grant."].)

In *Singer*, the U.S. Supreme Court held that a series of cross-license agreements between Singer and Italian and Swiss sewing-machine manufacturers had the express purpose of eliminating competition from rival Japanese manufacturers, going "far beyond its claimed purpose of merely protecting its own ... machine." (*Singer, supra*, 374 U.S. at p.194.) Plaintiffs

seek to avoid this holding by citing Justice White's concurring opinion, in which he noted that Singer and the Swiss manufacturer "'agreed to settle an interference, at least in part, to prevent an open fight over validity.'" (POB 35, citing *Singer*, at p.199 (conc. opn. of White, J.).) This statement similarly has no bearing on this case. To begin with, the described scenario formed only part of the concerted action that the Supreme Court found to be unlawful after considering the "entire course of dealings between the parties." (*Singer*, at p.190, fn.7.) Moreover, if the antitrust laws made it illegal to resolve patent cases in order "to prevent an open fight over validity," then parties could never settle patent litigation at all. (See *Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc.* (N.D.Ill. 2003) 289 F.Supp.2d 986, 993 (Posner, J., sitting by designation) (*Asahi Glass*) ["It is not 'bad faith' to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights."].)

Plaintiffs are thus unable to cite even *one* case—from any jurisdiction—that imposes antitrust liability for conduct *within* the scope of a patent. The reason for this is simple: courts in and out of California have long recognized that because a patent is

the statutory grant of a lawful monopoly, the antitrust laws do not impose liability on an agreement that goes no further than the scope of what the patent already protects.

C. Federal Courts Have Uniformly Applied The Scope Of The Patent Test—Including Three Courts That Have Upheld This Very Settlement.

The scope of the patent test also has been adopted by every federal appellate court to have considered the issue under the Sherman Act, including two appellate courts (and one federal district court) that reviewed—and upheld—the very same settlement agreement at issue here. Those cases include:

- *Cipro IV*, *supra*, 604 F.3d 98 [2d Cir.];
- *Cipro III*, *supra*, 544 F.3d 1323 [Fed. Cir.];
- *Cipro II*, *supra*, 363 F.Supp.2d 514 [E.D.N.Y.];
- *Federal Trade Com. v. Watson Pharmaceuticals, Inc.* (11th Cir. Apr. 25, 2012, No. 10-12729) 2012 WL 1427789 (*Watson*);
- *Tamoxifen*, *supra*, 466 F.3d 187 [2d Cir.];
- *Schering-Plough*, *supra*, 402 F.3d 1056 [11th Cir.];
- *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.* (11th Cir. 2003) 344 F.3d 1294 (*Valley Drug*);
- *Asahi Glass*, *supra*, 289 F.Supp.2d 986 [Posner, J.];
- *King Drug Co. of Florence, Inc. v. Cephalon, Inc.* (E.D.Pa. 2010) 702 F.Supp.2d 514.

Federal appellate courts have uniformly concluded that so long as a patent litigation settlement goes no further than the exclusionary scope of the patent itself, a plaintiff cannot establish an antitrust violation under the Rule of Reason as a matter of law. (E.g., *Cipro III*, *supra*, 544 F.3d at p.1336 ["The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent."]; *Tamoxifen*, *supra*, 466 F.3d at p.213 n.27 ["[T]he question is whether the exclusionary effects of the agreement exceed the scope of the patent's protection[]" (internal quotation marks omitted); *Schering-Plough*, *supra*, 402 F.3d at p.1066 ["[T]he proper analysis of antitrust liability requires an examination of ... the extent to which the [settlement] agreements exceed th[e] scope ... of the exclusionary potential of the patent ...."].)

Plaintiffs' assertion that "the federal authorities are not monolithic" and that the federal courts have adopted varying standards is demonstrably incorrect. (POB 37.) *First*, plaintiffs argue, as they did below, that the courts in *Andrx Pharmaceuticals, Inc. v. Biovail Corp. Internat.* (D.C. Cir. 2001) 256 F.3d 799, and *In re Cardizem CD Antitrust Litigation* (6th Cir. 2003) 332 F.3d 896, applied a per se standard to a Hatch-

Waxman patent settlement. As the Court of Appeal correctly noted, however, the agreement that triggered both of those cases was distinguishable because "the reverse payment in *Cardizem* restrained competition *beyond* the exclusionary zone of the subject patent." (Slip opinion 37, emphasis added [also noting that, 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"]; see also 11 AA 2673 [distinguishing *Cardizem* on this ground].) Plaintiffs' argument that the court's holding "did not depend on the fact that the agreement also restrained trade beyond the patent's scope" (POB 39) finds no support in the opinion itself, which is why other courts and the U.S. Department of Justice have concluded that the crux of *Cardizem*'s holding is that the agreement exceeded the scope of the patent. (See, e.g., *Cipro III*, *supra*, 544 F.3d at p.1335 [distinguishing *Cardizem* on this ground]; Br. for the United States as *Amicus Curiae, Andrx Pharmaceuticals, Inc. v. Kroger Co.* (U.S. filed July 9, 2004) No. 03-779, 2004 WL 1562075, at *13 [the restraints in *Cardizem* "extended beyond the legitimate scope of the patent claims by reaching non-infringing products

and conduct by petitioner that the patent conferred no right to exclude or demand"].) Plaintiffs' argument that the *Cardizem* "court rejected a defense based on the challenged patent's presumed exclusionary effects" (POB 40), is thus beside the point, as the court found the agreement there (unlike the settlement here) *exceeded* the scope of the patent.

Second, plaintiffs' claim that the Eleventh Circuit applies a different test is also incorrect. (POB 43–45.) As an initial matter, plaintiffs observe that "[t]he Eleventh Circuit [a]pplies the Rule of Reason." (POB 43.) That is exactly what the lower courts did here, consistent with California law. (Slip opinion 33 ["We further conclude that the Cipro agreements do not violate the Cartwright Act under rule-of-reason analysis ...."].) Plaintiffs go on to argue that the Eleventh Circuit's examination of the "'scope of the exclusionary potential of the patent'" "incorporates an analysis of the patent's likely ability to exclude infringing use, *i.e.*, its strength as tested through patent litigation." (POB 43.) As the Eleventh Circuit confirmed just last month, however, plaintiffs' characterization is incorrect. (*Watson*, *supra*, 2012 WL 1427789 at *10, fn.8.) In rejecting a similar assertion by the FTC, the Eleventh Circuit has explained that "[w]hen read in the

context of the facts and reasoning of *Schering-Plough*, the phrase 'strength of the patent' refers to the potential exclusionary scope of the patent—that is, the exclusionary rights appearing on the patent's face and not the underlying merits of the infringement claim." (*Ibid.*) The *Watson* decision thus reaffirmed that "so long as [a reverse payment settlement's] anticompetitive effects fall within the scope of the exclusionary potential of the patent," there is no antitrust violation. (*Id.* at *11.)

The lower courts therefore correctly recognized that "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 the antitrust law." (Slip opinion 37–38.) Nor is it surprising that the lower courts considered these cases persuasive, especially when they include decisions upholding the exact same settlement challenged in this case. After all, California courts have long recognized the value of examining Sherman Act jurisprudence when analyzing Cartwright Act claims. (*Marin County*, *supra*, 16 Cal.3d at p.925.) As the Court of Appeal noted, "[s]ince the Cartwright Act and the federal Sherman Act share similar language and

objectives, California courts often look to federal precedents under the Sherman Act for guidance." (Slip opinion 16, quoting *Fisherman's Wharf Bay Cruise Corp. v. Superior Court* (2003) 114 Cal.App.4th 309, 334.)

Although California courts have observed that the Cartwright Act may differ from the Sherman Act in certain respects (see *State of California ex rel. Van de Kamp v. Texaco, Inc.* (1988) 46 Cal.3d 1147, 1164), plaintiffs offer no authority to suggest that the Cartwright Act differs from federal antitrust law in evaluating the rights granted to a patent holder under the federal Patent Act. (See POB 37.) To the contrary, as the Court of Appeal recognized (slip opinion 34), California case law—as reflected in *Fruit Machinery* and *Vulcan*—has consistently mirrored federal law in recognizing the rights of patentees to engage in exclusionary conduct within the scope their patent grant. (See *Vulcan, supra,* 96 Cal. at pp.515–516; *Fruit Machinery, supra,* 118 Cal.App.2d at p.763.)

This does not mean, as plaintiffs wrongly contend, that the lower courts found federal authority "dispositive" (POB 16) without performing their own analysis of the scope of the patent test and simply "adopt[ed] this standard as the law of California"

(POB 5). To the contrary, the lower courts expressly recognized that "federal decisional law is not binding on this Court" (11 AA 2690), and instead found the "*reasoning*" of the analogous federal cases to be "sound and applicable" (slip opinion 32–33, emphasis added.) The opinions below demonstrate that both courts engaged in a detailed analysis of plaintiffs' allegations before holding that the Cipro settlement does not violate the Cartwright Act under well-established California law. (Slip opinion 15–38; 11 AA 2672–2676.)

D. There Is No Basis For Applying A Per Se Rule.

Plaintiffs' contention that the Cipro settlement should be found per se illegal (POB 17–48) would therefore be unprecedented. No court has ever adopted such a rule for a settlement within the scope of a patent, and even plaintiffs' amici and commentators cannot agree on what standard should apply.

Under the Cartwright Act, "[c]ertain restraints which lack redeeming virtue are conclusively presumed to be unreasonable and illegal." (*Morrison v. Viacom, Inc.*, *supra*, 66 Cal.App.4th at p.540; accord *Marin County*, *supra*, 16 Cal.3d at pp.930–931.) But this category of restraints on trade is limited to activities found to have a "pernicious effect on competition" and lack "any

redeeming virtue," such as price-fixing, division of markets, group boycotts and tying arrangements. (*Marin County*, at pp.930–931, citing *Northern Pacific Ry. v. United States* (1958) 356 U.S. 1, 5.)

As the lower courts held, Hatch-Waxman settlements generally, and the Cipro settlement specifically, do not come close to falling within the narrow and exceptional per se category. Far from giving Hatch-Waxman settlements a "special privilege" (POB 5), the lower courts simply applied the presumptive Rule of Reason standard under the antitrust laws. As in the superior court, "[plaintiffs] have cited no California case, nor is there one, supporting that a per se illegal analysis is applicable to the specific agreement at issue here, a reverse payment settlement agreement under the Hatch Waxman Act concerning a patent." (11 AA 2689.)

This makes sense. There is nothing even remotely anticompetitive about settling a Hatch-Waxman patent case. Plaintiffs' argument that the Cipro settlement was nothing more than "a naked payoff ... from one horizontal competitor to other horizontal competitors to suppress competition" (POB 17), completely ignores the presence of the patent. It is 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.

Plaintiffs take issue with the Court of Appeal's discussion of the statutory presumption of validity, arguing that a patent "requires a court-approved injunction to be enforced." (POB 26.) But numerous courts, including the federal court that hears all patent appeals, have recognized that patent litigation settlements are themselves a viable and permissible form of enforcement between the competing parties. As the Federal Circuit stated in *Cipro,* "[s]ettlements in patent cases ... frequently provide that the alleged infringer will not challenge the validity of the patent[]" and "the mere fact that the Agreements insulated Bayer from patent validity challenges by the generic defendants was not in itself an antitrust violation." (*Cipro III, supra,* 544 F.3d 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.1338.) California courts agree: where, as here, a patent holder could lawfully "restrain" competition through the enforcement of its patent, any conduct that imposes a similar or lesser restraint is presumptively lawful. (See *Fruit Machinery, supra*, 118 Cal.App.2d at p.763 [holding that when "the exercise of patent rights was involved," only an arrangement "beyond that which was necessary or incidental to the scope of [the] patent" falls "within the proscription of the antitrust laws"].)

Plaintiffs' proposed rule would in fact create a presumption of patent *invalidity*—requiring that a patent must first be upheld in court to have any exclusionary effect at all. But such a rule, which would impact *all* patents, not just pharmaceutical patents, has no basis in the law. (See 35 U.S.C. § 154(a)(1) ["Every patent shall ... grant to the patentee ... the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States."].) Such a rule also would run afoul of the longstanding antitrust framework holding that—absent fraud on the PTO or objectively baseless sham litigation—the good-faith exercise of patent rights is protected from antitrust liability within the exclusionary scope of the patent. (See *Walker*

Process Equipment, Inc. v. Food Machine & Chemical Corp. (1965) 382 U.S. 172, 177 [a patentee's "good faith would furnish a complete defense"]; *Tamoxifen*, *supra*, 466 F.3d at p.213, quoting *Cipro II*, 363 F.Supp.2d at p.535 ["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."].)

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. (E.g., *Tamoxifen*, *supra*, 466 F.3d at p.206 [holding that Hatch-Waxman settlements with reverse payments are not per se illegal]; *Valley Drug*, *supra*, 344 F.3d at pp.1309–1311 [same].) That includes the courts that have upheld this very settlement. (E.g., *Cipro III*, *supra*, 544 F.3d at p.1332; *Cipro I*, *supra*, 261 F.Supp.2d at p.252.) It would be anomalous indeed to find that the Cipro settlement was a per se antitrust violation after five other courts (two California courts and three federal courts) not only rejected the per se argument, but also found the settlement

lawful.

Given this, it is no surprise that plaintiffs can find no support for their proposed per se rule. Even the commentators and agencies that plaintiffs cite with approval are on record as disagreeing with the per se standard. Neither the Department of Justice, nor the Federal Trade Commission, nor the academic commentators that plaintiffs cite (such as Professor Hovenkamp) argue for a per se standard. (See POB 40–42 [describing the DOJ-FTC-Hovenkamp proposal].)[4] As the current General Counsel of the FTC has stated, "[T]he notion that it is per se unlawful ... for a patent owner to pay cash or other value to an alleged infringer ... ignores the first principle that enforcing valid patents makes a major contribution to consumer welfare." (Bernard & Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles* (2006) 15 Fed.Cir.B.J. 617, 617–618.)

---

[4] Plaintiffs claim that the California Attorney General advocated a per se standard in its rule 8.500(g) letter, but they cite to a general proposition of law noted in the Attorney General's letter, not to the Attorney General's proposed analysis of Hatch-Waxman settlements. (POB 23.)

Perhaps recognizing the novelty of a per se approach, plaintiffs also mention in passing the "presumptive illegality" standard advocated by certain agencies and commentators. (POB 40–43.) But this standard similarly has no basis in antitrust law, which is why it has been rejected by every court to consider it. Although plaintiffs attempt to argue that the presumptive illegality standard would be a "modified Rule of Reason" (POB 42), they concede that this standard is "only slightly less stringent than the *per se* rule" (POB 37) because it would *eliminate* the first step of the Rule of Reason, *assume* that every Hatch-Waxman settlement has actual adverse effects on competition, and *shift the burden* to defendants to demonstrate that a settlement had pro-competitive benefits. (POB 42; 11 AA 2581–2582.) Such a burden-shifting rule would create an entirely new approach to antitrust claims arising from patent litigation settlements, and create serious due process problems by impermissibly shifting the burden of proof. (Compare POB 42 ["Defendants bear the initial burden."] with *Aguilar*, *supra*, 25 Cal.4th at p.861 [holding that a Cartwright Act plaintiff has the burden of proof].) Plaintiffs do not and cannot cite any legal authority that would support this new framework. (See *Watson*,

supra, 2012 WL 1427789, at *2, *11; *Schering-Plough*, *supra*, 402 F.3d at pp.1075–1076.)

As the Eleventh Circuit observed in rejecting that approach or a per se approach, "[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; see also *Watson*, *supra*, 2012 WL 1427789, at *12.) The parties to a patent case are free to settle disputed claims, and a settlement that extends no further than what the patent already protects has no actual adverse effect on competition under the antitrust law.

II. The Scope Of The Patent Test Is Consistent With Sound California Policy.

Public policy fully supports the scope of the patent test—especially given the policies in favor of the settlement of litigation. As a threshold matter, plaintiffs' approach ignores the fact that consumers benefit from innovation, which the law promotes by recognizing that patent holders should enjoy a statutory monopoly within the scope of the patent grant. Moreover, the undisputed record demonstrates that, far from

hurting competition, permitting Hatch-Waxman patent settlements can actually increase the number of patent challenges, and thus encourage the amount of overall competition in the pharmaceutical industry.

A. The Scope Of The Patent Test Furthers The Long-Standing Policy Favoring Settlement Of Litigation.

California courts have long recognized the benefits to both the parties and the courts of settling litigation. (See *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].) As this court has stated: "The need for settlements is greater than ever before. 'Without them our system of civil adjudication would quickly break down.' [Citation]." (*Neary v. Regents of the University of California* (1992) 3 Cal.4th 273, 277.) This policy applies with equal effect to settlements of patent litigation: "it is well settled that the law favors settlements and this would extend to patent infringement suits as well." (11 AA 2689; see also *Standard Oil, supra*, 283 U.S. at p.171 ["[w]here there are legitimately conflicting claims or threatened interferences [with a patent], a settlement by

agreement, rather than litigation, is not precluded by the [antitrust laws]."]; *Cipro III*, *supra*, 544 F.3d at p.1333 ["[T]here is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation."].)

Hatch-Waxman settlements are no different from any other patent settlement on this score. Plaintiffs argue that Hatch-Waxman settlements are distinct because monetary consideration flows to the alleged infringer rather than to the patent holder. (POB 2.) As numerous courts have explained, however, there is nothing inherently unusual about a settlement that provides consideration from the patent holder to the alleged infringer as part of the resolution of a lawsuit. (E.g., *Valley Drug*, *supra*, 344 F.3d at p.1309 ["We cannot conclude that the exclusionary effect of the Agreements not to enter the market were necessarily greater than the exclusionary effects of the [] patent merely because [the patent holder] paid [the generic challengers] in return for their respective agreements."].)

After all, in every patent settlement (even outside the Hatch-Waxman context), the alleged infringer typically receives consideration from 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. (*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 Glass*, *supra*, 289 F.Supp.2d at p.994; accord *Cipro I*, *supra*, 261 F.Supp.2d at p.252 ["[E]ven in the traditional context, implicit consideration flows from the patent holder to the alleged infringer."]; Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy* (2004) 71 Antitrust L.J. 1033, 1033 ["[C]onsideration is moving from the patent holder to the alleged infringer in most settlements of patent disputes."].)

A settlement payment from a patent holder to a generic challenger is even more logical in the Hatch-Waxman context.

Litigation under the Hatch-Waxman Act reverses the traditional risks associated with patent litigation. A generic manufacturer can challenge the patent on a branded drug by filing an ANDA IV without actually entering the market and risking infringement damages. (*Tamoxifen*, *supra*, 466 F.3d at pp.206–207.) 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. By contrast, a loss for the branded manufacturer would invalidate its patent, quickly costing it potentially billions of dollars in sales. (*Id.* at p.210 [describing the generic challenger as having "the whip hand"].)

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. (*Cipro I*, *supra*, 261 F.Supp.2d at pp.250–251; see also *Redwood Theatres, Inc. v. Festival Enterprises, Inc.* (1988) 200 Cal.App.3d 687, 705–

706 [noting the importance of considering the unique aspects of a particular industry in analyzing a Cartwright Act claim].)

Nor does the *amount* of monetary consideration alter the analysis. Although plaintiffs make much of the size of the payment from Bayer to Barr (a number which in any event was only a single-digit percentage of Bayer's Cipro revenue during that time period), courts have uniformly held that the size of the payment is irrelevant to the antitrust analysis. (E.g., *Schering-Plough, supra,* 402 F.3d at p.1075 ["[T]he size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy."].) The reason for this, as courts have explained, is that no matter the consideration given, "[i]n a reverse-payment case, the settlement leaves the competitive situation unchanged from before the defendant tried to enter the market." (*Asahi Glass, supra,* 289 F.Supp.2d at p.994.)

Plaintiffs also grossly mischaracterize why litigants settle as a general matter, as reflected in their statement that "[r]espondents ... do not dispute that they entered into the Cipro

agreements for the purpose of eliminating competition." (POB 20.)[5] Defendants most certainly *do* dispute this, because—as numerous courts have recognized—the primary purpose of settling litigation, including Hatch-Waxman patent litigation, is to eliminate the risk and uncertainty of litigation. Parties cannot know in advance if they will prevail—"[n]o one can be *certain* that he will prevail in a patent suit." (*Asahi Glass*, *supra*, 289 F.Supp.2d 986 at p.993.) Indeed, even plaintiffs' own expert has recognized that there is "inherent uncertainty" in the outcome of a patent case. (POB 6.) Given this uncertainty, it is only natural that parties settle litigation some of the time, and the mere existence of a settlement does not violate the antitrust laws. (*Watson*, *supra*, 2012 WL 1427789, at *12.)

---

[5] Plaintiffs incorrectly assert that defendants' Joint Response to Plaintiffs' Evidence in the superior court (11 AA 2507–2513) did "not dispute the evidence Petitioners submitted, save to contend that the law makes it immaterial." (POB 8.) What the Joint Response actually stated, however, is that while plaintiffs' "evidence" consisted of points of argument rather than statements of fact—with citations to the record that did not even support many of those assertions—none of this created a genuine dispute sufficient to defeat summary judgment, because none of plaintiffs' points were material to the legal issues before the superior court. (11 AA 2511–2512.)

Plaintiffs' argument that such settlements improperly "halt adversarial testing" is also baseless. (POB 25.) As an initial matter, settling a patent case involving one generic company does not prevent other generic companies from bringing their own challenges. That is exactly what happened here. Three subsequent companies challenged the Cipro patent in court, and in each case the patent was upheld. (See *Cipro II*, *supra*, 363 F.Supp.2d at p.547 ["Bayer's success in its litigations against Schein, Mylan and Carlsbad forecloses any argument that its lawsuits were shams."].) And, in any event, a party has no obligation to continue litigation for someone else's benefit. (*Id.* at p.532 ["Requiring parties to a lawsuit either to litigate or negotiate a settlement in the public interest, at the risk of treble damages is, as a practical matter, tantamount to establishing a rule requiring litigants ... 'to act as unwilling private attorneys general and to bear the various costs and risks of litigation.'"].) Parties, including parties in Hatch-Waxman cases, settle for any number of reasons despite strong confidence in the strength of their case. As the Eleventh Circuit recently noted:

> Rational parties settle to cap the cost of litigation and to avoid the chance of losing. Those motives exist not

> only for the side that is likely to lose but also for the side that is likely, but only likely, to win. A party likely to win might not want to play the odds for the same reason that one likely to survive a game of Russian roulette might not want to take a turn. With four chambers of a seven-chamber revolver unloaded, a party pulling the trigger is likely (57% to 43%) to survive, but the undertaking is still one that can lead to undertaking.

(*Watson*, 2012 WL 1427789, at *12.) There is no basis to preclude such settlements.

B. The Undisputed Record Evidence Shows That Settlements Like The Cipro Settlement Increase Competition And Benefit Consumers.

Although plaintiffs' policy arguments about settlements do not raise a material issue of fact because they do not bear on the relevant question—whether the settlement was within the scope of Bayer's patent—the undisputed record also demonstrates that Hatch-Waxman patent settlements, including settlements with monetary consideration, *increase* competition and benefit consumers.

As an initial matter, monetary consideration is often needed for a patent holder and an alleged infringer to reach a settlement. Plaintiffs make the conclusory argument that there is no need for monetary consideration in Hatch-Waxman patent

settlements because "patent settlements can be negotiated for early entry alone." (POB 29; see also *id.* at pp.6–7.) But while *some* settlements might occur in this manner, plaintiffs have no support for the proposition that most or all pharmaceutical patent suits would settle without some form of payment.

To the contrary, 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. (E.g., Schildkraut, *supra*, 71 Antitrust L.J. at p.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. (2 RA 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. (*Ibid.*) Independent economic analysis confirms this conclusion: "[W]ithout a payment from the

branded manufacturer to the generic manufacturer, the parties may be unable to reach agreement on a settlement—even if a settlement would lower prescription drug costs by bringing a generic version to market sooner than would occur if the case were resolved by a court decision." (B. Dickey, J. Orszag & R. Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse Payment" Settlements* (August 10, 2010), p.4.)

The very statistics that plaintiffs cite in their brief prove the point. Plaintiffs claim that "[d]uring the period when reverse payments were considered to be illegal, drug companies ... continued to settle patent disputes at approximately the same rate." (POB 6–7.) But plaintiffs' statistics show that the number of Hatch-Waxman settlements has increased from 14 in 2007 to 28 in 2011. (POB 29–30) Equally important, the number of patent *challenges* has increased dramatically during the same time period, "with a record 65 new first-to-file lawsuits in 2009, up from 51 in the prior year and more than double the number just three years ago." (RBC Capital Markets, *Pharmaceuticals: Analyzing Litigation Success Rates* (January 15, 2010) at p.1.)

This demonstrable increase in patent challenges shows that

Hatch-Waxman patent settlements, including those with monetary consideration, can *increase* competition by reducing the potential costs and risks of bringing a patent challenge. As numerous courts have held, it is vital that generic companies bringing Hatch-Waxman challenges have the full range of litigation options—including settlement—available to them, because their incentive to bring such challenges in the first place depends in significant measure upon having the flexibility to decide when, and on what terms, to resolve the litigation rather than fighting "to the death" in every case. (*Valley Drug, supra,* 344 F.3d at pp.1299, 1308; *Asahi Glass, supra,* 289 F.Supp.2d at p.994.) As the judge presiding over the federal Cipro litigation recognized in upholding the Cipro settlement:

> The incentives created by the Hatch-Waxman Amendments have led to generic investment in product development, patent review and product challenges through litigation. Indeed, Barr has admitted that it has over ten ANDA challenges in litigation today and more than twice that number under review. To maximize these incentives, a generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it. Otherwise, the incentives to mount an ANDA IV challenge could be reduced.

(*Cipro I, supra,* 261 F.Supp.2d at p.256.)

As this and other decisions recognize, a generic company like Barr can have multiple patent challenges going at any one time. Those challenges can result in any number of outcomes, ranging from a victory to a loss to settlements involving licenses, payments, or both. (2 RA 344 [declaration of Barr CEO Bruce Downey, ¶14].) A rule overly restricting settlement options, as plaintiffs propose, decreases the likelihood that a generic company will be able to reach a settlement and increases the likelihood that the generic company will have to litigate a patent challenge through trial and all appeals. Given the enormous expense of mounting a successful patent challenge through appeal if settlement is not available, such a rule could discourage generic companies from bringing as many challenges in the first place, even if those challenges could lead to pro-competitive results. (2 RA 350–351 [declaration of Barr CEO Bruce Downey, ¶36]; see also *Schering-Plough*, *supra*, 402 F.3d at p.1075 ["Hatch-Waxman settlements, like[] the ones at issue here ... may benefit the public by introducing a new rival into the market, facilitating competitive production, and encouraging further innovation."]; *Tamoxifen*, *supra*, 466 F.3d at pp.203, 212 [same].) Needless to say, if the number of challenges to drug patents

decreases, there will be fewer opportunities to invalidate such patents and the number of cheaper, generic alternatives on the market will go down.

Moreover, plaintiffs wholly ignore the fact that many settlements that include monetary consideration *also* provide for early generic entry well before the date of patent expiration. That is precisely the situation here. Because of the Cipro settlement, Barr entered the market with a lower-priced competing product in June 2003, six months before the expiration of the Cipro patent and one year before Bayer's exclusivity ended under the FDA regulatory regime. (2 RA 374–376, 378–380; 5 AA 996 [deposition of Barr sales and marketing executive, noting an eight percent discount from Bayer's wholesale acquisition cost].) During that period, Barr achieved significant market penetration, resulting in increased competition and lower drug prices. (2 RA 374–375, 378–380.)

It is no answer for plaintiffs to complain that the settlement was not "good enough"—for example, by arguing that the license should have been longer or that the price of the license should have been lower. As the U.S. Supreme Court has made clear, an agreement does not violate the antitrust laws

simply because plaintiffs can imagine a more competitive settlement; after all, the antitrust laws do not require "that a monopolist alter its way of doing business whenever some other approach might yield greater competition." (*Verizon Communications Inc. v. Law Offices of Curtis v. Trinko, LLP* (2004) 540 U.S. 398, 415–416 (*Trinko*); accord *Buffalo Broadcasting Co., Inc. v. American Society of Composers, Authors and Publishers* (2d Cir. 1984) 744 F.2d 917, 933 ["[T]he antitrust laws do not permit courts to ban all practices that some economists consider undesirable."].)

Patent law supports this reasoning as well, because it has long been established that a patentee has the right to grant or refuse a license, and to decide the license terms. (*TransCore, LP v. Electric Transaction Consultants Corp.* (Fed.Cir. 2009) 563 F.3d 1271, 1275–1276, quoting *Spindelfabrik Suessen-Schurr, Stahlecker & Grill GmbH v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft* (Fed.Cir. 1987) 829 F.2d 1075, 1081 ["[A] patent license agreement is in essence nothing more than a promise by the licensor not to sue the licensee ... [and] patent license agreements can be written to convey different scopes of promises not to sue."]; *Brulotte v. Thys Co.* (1964) 379 U.S. 29, 33

["A patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly."].)

For these reasons, abandoning the traditional Rule of Reason approach in favor of plaintiffs' per se standard would restrict the parties' ability to settle Hatch-Waxman litigation and dramatically increase its costs, which in turn could lead to *fewer* Hatch-Waxman challenges, *fewer* settlements, and *fewer* early-entry licenses, all in direct contravention of the public policies in favor of settlement, reward for patent innovation, and increased Hatch-Waxman challenges.[6] Plaintiffs' proposed standard, then, would undermine not only the policy in favor of settlement, but

---

[6] Although irrelevant to the question of whether this settlement exceeded the scope of the Cipro patent, plaintiffs' claim that Hatch-Waxman settlements cost consumers $3.5 billion is based on an FTC study that has been criticized, including by a former economic advisor to President Clinton, as "unreliable." (B. Dickey, J. Orszag & R. Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse Payment" Settlements* (August 10, 2010), at p.3; see also Davis et al., *FTC Call for Settlement Ban Is ... Full of Sound and Fury, Signifying Nothing* (Jan. 14, 2010), at pp.1–5 [concluding that the FTC study on which this statistic was based was "exceedingly flawed" because it "presume[d] patent invalidity across the board" and assumed that settlement is achievable without monetary payments].)

also the goals of the Hatch-Waxman Act itself. (See *Asahi Glass, supra*, 289 F.Supp.2d at p.994 ["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."].)

Given the sound legal basis for the lower courts' holdings, plaintiffs' policy arguments reflect an improper effort to achieve judicial legislation. Although plaintiffs claim that such settlements "have been almost universally condemned by prosecutors, legislators, and leading policy makers" (POB 2), the U.S. Congress has considered multiple bills, including a bill currently pending, that would alter the legal treatment of Hatch-Waxman patent settlements and outlaw Hatch-Waxman settlements that include monetary consideration, but has yet to pass any one of them. (E.g., S. 27, 112th Cong. (2011); S. 3677 (amend.), 111th Cong. (2010); S. 369, 111th Cong. (2009); H.R. 1706, 111th Cong. (2009).)

III. Assessing Liability For Conduct Within The Scope Of A Patent, As Plaintiffs Advocate, Would Create A Conflict With Federal Patent Law And Would Be Preeempted.

Aside from having no support in law or policy, plaintiffs' proposed per se approach also would create an impermissible conflict with federal law, and thus be preempted. By assessing antitrust liability for conduct within the scope of a patent, plaintiffs' approach would upset the policy balance struck by Congress through the federal patent laws, by undermining what it means to have a patent under the Patent Act. By contrast, the scope of the patent test reflects the balance that Congress that struck between the patent laws, on one hand, and the antitrust laws, on the other. As the Federal Circuit recognized in upholding the validity of the Cipro settlement, "the outcome is the same" whether the analysis starts with the Sherman Act or starts with the Patent Act, because the two meet in the middle. (*Cipro III, supra,* 544 F.3d at p.1336.)

It is well established that "state law must yield to congressional enactments if it 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" (*Biotechnology Industry Organization v. District of*

Columbia (Fed.Cir. 2007) 496 F.3d 1362, 1372 (*Biotechnology Industry*), quoting *Hines v. Davidowitz* (1941) 312 U.S. 52, 67.) This is particularly true in the context of federal patent rights: "state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws." (*Bonito Boats, Inc. v. Thunder Craft Boats, Inc.* (1989) 489 U.S. 141, 152 (*Bonito Boats*).) Federal patent law determines the scope and duration of a patent, granting patentees "'the right to exclude others from making, using, or selling the invention throughout the United States,' for a [set] period." (*Id.* at p.150, quoting 35 U.S.C. § 154; see also *Biotechnology Industry*, *supra*, 496 F.3d at p.1372 ["This court has repeatedly recognized as important the pecuniary rewards stemming from the patent right."]; *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 patents laws cannot trigger any liability under the antitrust laws."].) "The federal patent system thus embodies a *carefully crafted bargain* for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years." (*Bonito Boats*, at

pp.150–151, emphasis added.) This congressional bargain is no different for pharmaceutical patents challenged under the Hatch-Waxman Act.

The ability to settle patent litigation is a critical element of a patentee's exclusionary rights. (*Cipro III*, *supra*, 544 F.3d at p.1338 ["there is no legal basis for restricting the right of a patentee to choose its preferred means of enforcement and no support for the notion that the Hatch-Waxman Act was intended to thwart settlements."].) Rather than be forced to litigate "to the death," a patentee may therefore choose to seek peace with a patent challenger and protect its patent in exchange for consideration. As numerous courts have recognized, so long as the patent was not procured by fraud and the enforcement litigation was not an objectively baseless sham, settling such litigation amounts to no more than the permissible exercise of the patent right. (*Watson*, *supra*, 2012 WL 1427789, at *8 ["Our decision [gives] full effect to the patent's terms ...."]; *Tamoxifen*, *supra*, 466 F.3d at p.213; *Cipro II*, *supra*, 363 F.Supp.2d at p.535.)

Plaintiffs' proposed standard would impermissibly alter the balance struck by Congress by curbing a patentee's federal right

to settle patent litigation, even if the resulting settlement restrains no more competition than the patent itself. (See *Valley Drug*, *supra*, 344 F.3d at p.1309 [a per se rule against "any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally."].) As the Federal Circuit—the court with exclusive jurisdiction over patent appeals—has emphasized in upholding the validity of *this very settlement*:

> We conclude that in cases such as this, wherein all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent.

(*Cipro III*, *supra*, 544 F.3d at p.1336.) Plaintiffs are thus incorrect in stating that the Federal Circuit did not consider the Patent Act in its decision (POB 52, fn.29)—the Federal Circuit expressly recognized that the scope of the patent test reflects where the rights granted by the Patent Act end and the

obligations imposed by the Sherman Act begin. If California were to impose liability in these circumstances, then having a patent would mean something different in this State than in any other—and California law will have undermined the federal right to exclude granted to a patent holder under the Patent Act. All of this underscores why plaintiffs' expansive interpretation of the Cartwright Act is ultimately self-defeating, because it would be preempted by federal law. (See *Biotechnology Industry*, *supra*, 496 F.3d at p.1373.)

IV. The Superior Court Properly Granted Summary Judgment.

Plaintiffs finally resort to arguing that fact disputes preclude the entry of summary judgment even under the scope of the patent test. Although plaintiffs make a number of misleading factual assertions, none of those assertions creates a genuine issue of *material* fact because none of them rebuts the threshold point that the Cipro settlement did not exceed the scope of a patent that already foreclosed all generic competition. And, in any event, appellants' arguments find no support in the undisputed factual record or the law.

First, plaintiffs contend that factual issues existed in the

underlying patent case between Bayer and Barr. (POB 57–59.) The problem for plaintiffs, however, is that they cannot argue that the underlying patent case was a "sham" (POB 57) because they failed to make such an allegation in the trial court. (Slip opinion 38–41; 11 AA 2692; *Government Employees Insurance Co. v. Superior Court* (2000) 79 Cal.App.4th 95, 98, fn.4 [noting that a "plaintiff cannot bring up new, unpleaded issues in his or her opposing papers" to defeat summary judgment].) Indeed, plaintiffs stated in their reply brief in the Court of Appeal that they "do not contend that Bayer is liable for its conduct in procuring or enforcing the Cipro patent." (Reply Br. of Appellants, *In re Cipro Cases I & II* (Nov. 15, 2010) 2010 WL 5079934, at *35.)

Moreover, plaintiffs' contention that the underlying patent lawsuit was objectively baseless is wrong as a matter of law. (POB 57.) The Federal Circuit's decision upholding the lawfulness of the Cipro Settlement held that "no fraud occurred" in Bayer's procurement of the Cipro patent (544 F.3d at p.1341)—and Federal Circuit law governs on questions of federal patent law, including whether there was fraud on the PTO. (See *Lockwood v. Shephard, Mullin, Richter & Hampton* (2009) 173

Cal.App.4th 675, 684 [noting that the Federal Circuit has exclusive final jurisdiction over patent cases, citing 28 U.S.C. § 1295(a)(1)].) In any event, the record conclusively shows that Bayer's underlying patent claims—which were meritorious enough to survive Barr's motion for summary judgment in the patent case—were not a "sham." That is especially true where, as here, the patent holder defeated subsequent challenges to its patent: far from constituting "post-hoc rationalizations" (POB 60), Bayer's subsequent victories constitute an objective fact that contradicts the notion that its patent case against Barr was objectively baseless. (*Cipro II*, *supra*, 363 F.Supp.2d at p.547 ["Bayer's success in its litigations against Schein, Mylan and Carlsbad forecloses any argument that its lawsuits were shams."]; *see also Blank v. Coffin* (1942) 20 Cal.2d 457, 463 ["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."].)

Nor can plaintiffs avoid summary judgment by arguing that Barr "would have won" the underlying litigation and invalidated the Cipro patent. (See, e.g., POB 45, fn.23 [arguing

that "the original Cipro patent would almost certainly have been nullified"].) Again, plaintiffs did not raise this argument in the trial court. As plaintiffs represented to the federal district court when arguing for remand to the California superior court, "their state law antitrust claims ... do not depend upon a finding that Bayer's patent is invalid." (*In re Ciprofloxacin Hydrochloride Litigation* (E.D.N.Y. 2001) 166 F.Supp.2d 740, 749.) As with the sham claim, then, plaintiffs are precluded from arguing this point on appeal to defeat summary judgment.

Moreover, as courts have uniformly held, arguments about who "would have won" the patent litigation cannot properly be part of the antitrust analysis, because there is no reliable way for a jury to determine what might have happened if the Bayer-Barr patent litigation had proceeded to trial and through all appeals more than ten years ago. "Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages ...." (*Valley Drug, supra,* 344 F.3d at p.1308.) As a federal appellate court recently held in upholding another Hatch-Waxman patent settlement, "attempt[ing] to decide how some other court in some other case

at some other time was likely to have resolved some other claim if it had been pursued to judgment ... would be deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task." (*Watson*, *supra*, 2012 WL 1427789, at *14.) Moreover, such an approach would "undo much of the benefits of settling patent litigation, and discourage settlements." (*Id.* at *13; accord *Cipro II*, 363 F.Supp.2d at p.530 ["Such an inquiry would undermine any certainty for patent litigants seeking to settle."].) For this reason, courts addressing the antitrust implications of Hatch-Waxman settlements have universally declined to engage in such speculative analysis. (E.g., *Cipro III*, *supra*, 544 F.3d at p.1336; *Tamoxifen*, *supra*, 466 F.3d at p.204; see also *Forbes v. County of San Bernardino* (2002) 101 Cal.App.4th 48, 59 [holding that the outcome of a potential appeal and retrial was a matter of "pure speculation" that cannot be a basis for liability].)

Second, plaintiffs take issue with the lower courts' treatment of their evidentiary objections, contending that the court "failed to hold the trial court to the directive in *Reid v. Google, Inc.*, (2010) 50 Cal.4th 512, that each evidentiary objection must be separately addressed." (POB 60.) Plaintiffs'

argument fails, because it ignores the central holding of *Reid* that is relevant here: "[I]f the trial court fails to rule expressly on specific evidentiary objections, it is presumed that the objections have been overruled, the trial court considered the evidence in ruling on the merits of the summary judgment motion, and the objections are preserved on appeal." (*Reid*, at p.534.) As the Court of Appeal correctly noted, the superior court considered plaintiffs' objections (and defendants' responses) before holding that those objections should be overruled. (Slip opinion 51–52.) And while the "objections were preserved on appeal and [plaintiffs] were free to challenge the trial court's consideration of specific items of objected-to evidence on appeal," plaintiffs waived consideration of any objections by failing to "argue that the admission of any specific evidence constituted prejudicial error." (Slip opinion 51–52.) Plaintiffs' evidentiary objections therefore provide no basis upon which to disturb the lower court's proper grant of summary judgment.

V. Summary Judgment For Defendant Watson Should Be Affirmed For Additional Reasons.

Summary judgment was proper as to Watson for the same reason as for all defendants—because plaintiffs cannot

demonstrate any unreasonable restraint of trade. But as to Watson, there is an additional reason to affirm: Watson was not a party to the Cipro settlement. To state a Cartwright Act claim against Watson, plaintiffs must establish that some agreement or concerted conduct of Watson constituted an unlawful restraint of trade that resulted in "antitrust injury"—"the type of injury the antitrust laws were intended to prevent" and that would not have occurred but for the violation. (*Morrison v. Viacom, Inc.*, *supra*, 66 Cal.App.4th at p.548; *O.K. Sand & Gravel, Inc. v. Martin Marietta Technologies, Inc.* (7th Cir. 1994) 36 F.3d 565, 573.)

It is undisputed that Watson was not a party to the 1996 litigation funding agreement between Rugby and Barr or any of the 1997 settlement agreements with Bayer. (2 AA 248, ¶18.) Thus, no act of Watson caused injury to plaintiffs. As the superior court held, "Watson was not involved in the Cipro settlement agreement and had no relationship to [its alleged affiliates] HMR or Rugby when those agreements were made." (11 AA 2711; *Cipro I*, *supra*, 261 F.Supp.2d at pp.213, 218.) In 1998, Watson purchased Rugby from HMR. (2 AA 273, ¶ 9.) Watson expressed an interest in sharing in the proceeds from the Settlement Agreements, but HMR refused. (3 AA 552; 3 RA 600–

601.) As a result, Watson never did anything that changed the obligations of the parties to the agreements as they existed when Watson acquired Rugby, or that had any impact on when a competing ciprofloxacin product was introduced. It is undisputed that the only funds Watson received were from the sale of Barr's competing ciprofloxacin product, which was undeniably *pro-competitive*. (2 AA 277, ¶ 14; 4 AA 652.)

Any argument that Watson could be liable ignores the requirement of antitrust injury and the undisputed factual record. Both before and after its purchase of Rugby, Watson could not legally sell a generic ciprofloxacin product because it did not have an ANDA or approval by the FDA. (See 21 U.S.C. § 355(j).) It would have taken Watson years to obtain the necessary FDA approval of a ciprofloxacin ANDA (see, e.g., 3 RA 647, 658–659 [more than three years passed before approval of Schein's ANDA]), and Watson may still have lost the patent challenge to Bayer, as did three other companies which challenged Bayer's patent. Nothing Watson did kept generic ciprofloxacin from the market or caused any injury to plaintiffs.

In any event, as plaintiffs' opening brief failed to make any argument about these alternative grounds for affirmance—

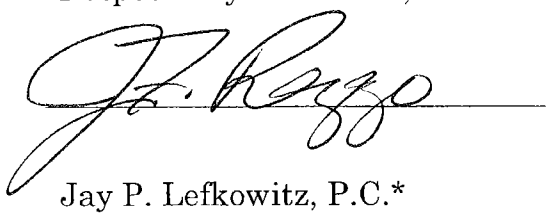
grounds which Watson raised in both the superior court and the Court of Appeal—plaintiffs' argument is waived. (*Rusheen v. Cohen*, *supra*, 37 Cal.4th at p.1055, fn.2; Cal. Rules of Court, rule 8.516(b)(1).) The grant of summary judgment to Watson should be affirmed.

CONCLUSION

For the foregoing reasons, and those in the brief of defendant Bayer, this court should affirm.

May 29, 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 Defendants Barr Laboratories, Inc., Hoechst Marion Roussel, Inc., The Rugby Group, Inc., and Watson Pharmaceuticals, Inc.

Jay P. Lefkowitz, P.C.*
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 Defendant Barr Laboratories, Inc.

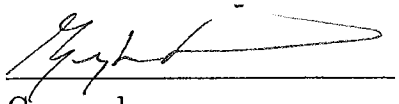
David E. Everson*
Heather S. Woodson*
Victoria Smith*
STINSON MORRISON HECKER LLP
1201 Walnut Street, Suite 2900
Kansas City, MO 64106
(816) 842-8600

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

* Admitted *pro hac vice*

CERTIFICATE OF WORD COUNT

Pursuant to California Rules of Court, rule 8.504(d)(1), the undersigned certifies that the foregoing brief contains 13,996 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

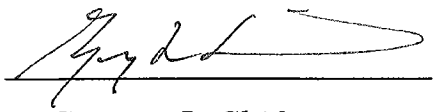
PROOF OF SERVICE

I am over the age of eighteen years and not a party to this action. My business address is 655 15th Street, NW, Washington, DC 20005. On May 29, 2012, I served the following document(s):

ANSWER BRIEF OF RESPONDENTS 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 Kirkland & Ellis LLP, 655 15th Street, NW, Washington, DC 20005 addressed as set forth below. I am familiar with Kirkland & Ellis' 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.

I declare under penalty of perjury under the laws of the United States that the above is true and correct. Dated May 29, 2012.



Gregory L. Skidmore

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: Karyn 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 MCKENNA LONG & ALDRIDGE LLP 600 West Broadway Suite 2600 San Diego, CA 92101	Counsel for Defendant/Respondent Bayer Corporation: **By U.S. Mail**
Administrative Office Of The Courts Attn: Carlotta Tillman 455 Golden Gate Avenue 6th Floor San Francisco, CA 94102	**By U.S. Mail**

SERVICE LIST	
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, Div. One Symphony Towers 750 B Street, Suite 300 San Diego, CA 92101	**By U.S. Mail**