In the

Court of Appeal

of the

State of California

FOURTH APPELLATE DISTRICT
DIVISION ONE

D056361

IN RE CIPRO CASES I AND II

KARYN McGAUGHEY, et al.,

Plaintiffs-Appellants,

v.

BAYER CORPORATION, et al.,

Defendants-Respondents.

APPEAL FROM THE SUPERIOR COURT OF SAN DIEGO COUNTY
HON. RICHARD E. L. STRAUSS · CASE NOS. JCCP 4154 AND JCCP 4220
SERVICE ON ATTORNEY GENERAL AND DISTRICT ATTORNEY REQUIRED UNDER BUSINESS AND PROFESSIONS CODE § 17209 AND CRC 8.29

BRIEF AMICI CURIAE OF 78 INTELLECTUAL PROPERTY LAW, ANTITRUST LAW, ECONOMICS, AND BUSINESS PROFESSORS IN SUPPORT OF APPELLANT

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Brief Amici Curiae of 78 Intellectual Property Law, Antitrust Law, Economics, and Business Professors in Support of Appellant

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QUESTION PRESENTED

Whether an agreement by a patent owner to pay a potential competitor not to enter the market is legal *per se* despite its obvious anticompetitive effects?

INTEREST OF THE AMICI CURIAE

The Academic Amici are professors who have collectively written extensively on innovation, intellectual property, health law, competition and antitrust. We come from a variety of fields, including law, economics, business, and public policy. Amici have no stake in the outcome of this case.[1] (A list of signatories is in Appendix A). Our sole interest in this case is that patent and antitrust law develop in a way that serves the public interest and public health by promoting both innovation and competition.

[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief.

ARGUMENT

I. The Trial Court Erred in Following a Misguided View That Has Been Rejected By Other Federal Courts

The trial court, applying what it understood to be federal antitrust law, granted summary judgment to Bayer immunizing its anticompetitive market division scheme from scrutiny under the Cartwright Act. The district court relied heavily on the resolution of cases involving the same facts by the United States Second and Federal Circuits. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1332-36 (Fed. Cir. 2008) (following *In re Tamoxifen Citrate Antitrust Litig.,* 466 F.3d 187, 212 (2d Cir. 2006)). Minute Order at 4. It stated as a matter of law that "there is no antitrust violation under California law . . . 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." Minute Order at 5. And in that analysis, the court held, "[p]atent validity is not relevant in the determination of whether the settlement agreements violate antitrust laws." Minute Order at 6.

The precedent that the trial court believed compelled the outcome in this case contains fundamental errors of economic reasoning and would shield many anti-competitive agreements from the reach of antitrust law, causing great harm to competition, to consumers, and (by unjustifiably raising the costs of needed medicines) to public health. Under the trial court's decision in an agreement between a patent holder and an alleged

infringer to settle their patent litigation cannot violate the antitrust laws so long as the patent litigation was not a sham or otherwise baseless and the settlement agreement does not impose restrictions on the alleged infringer that extend beyond the scope of the patent. Such settlements would be immune from antitrust scrutiny even if, as here, the patent holder makes a substantial payment to the alleged infringer in exchange for the latter's promise not to sell the patented product independently during the patent's lifetime, and even if the patent in question is invalid Minute Order at 6. In so holding, the trial court adopted a rule of near per se *legality* for a naked market division scheme, a horizontal agreement that seems anticompetitive on its face.

The trial court's rule, moreover, is based on the mistaken premise that (absent fraudulent procurement) a patent grants full immunity from antitrust scrutiny for any and all anticompetitive effects within the exclusionary power of the patent. Even if the trial court's understanding of the scope of antitrust immunity attaching to an unquestionably *valid* patent were correct, the patent grant itself provides only a presumption of validity. The trial court has effectively converted that rebuttable (and oft-rebutted) presumption into an irrebuttable one. And it has done so in this case in the face of evidence – a $398.1 million payment by the patentee to the defendant to drop its validity challenge – that suggests there was good reason for

the parties to think at the time they settled the case that this particular patent was invalid.[2]

The Second Circuit rule endorsed by the trial court is far outside the mainstream of judicial and academic analysis of exclusionary settlements. The United States Court of Appeals for the Sixth Circuit considers such agreements per se *illegal*, *see In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), and the Federal Trade Commission considers them presumptively anticompetitive, *see In re Schering Plough Corp.*, No. 9297 (F.T.C. Dec. 18, 2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005), while the United States Court of Appeals for the Eleventh Circuit applies its own modified version of the rule of reason that inquires into the underlying validity of the patent before characterizing the conduct, *see Valley Drug Co. v. Geneva Pharmaceuticals, Inc.,* 344 F.3d 1294 (11th Cir. 2003). Even the Second Circuit panel in this very case has questioned the Second Circuit rule, in an opinion decided after the trial court issued its order. *Arkansas Carpenters' Health and Welfare Fund v. Bayer AG*, 604 F.3d 98, 108 (2d Cir. 2010) (identifying "several reasons why this case might be appropriate for reexamination," including the opposition of the United States, the pernicious effects of the rule, and errors in the *Tamoxifen* opinion). Only the United States Court of Appeals for the Federal Circuit has adopted the Second Circuit approach, and it did so in a case in which Second

[2] In evaluating the anticompetitive effect of a settlement, the relevant question is what the parties believed about the validity of the patent at the time they entered into the settlement.

Circuit law applied. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008).

Similarly, although academic commentators are divided on the treatment to be accorded such settlements, they uniformly agree they should not be considered per se *legal*. Some, including some of the undersigned, have written that settlements involving a large payment from the patent holder to the challenger should be presumptively anti-competitive.[3] Others have argued for applying the rule of reason[4] or for per se illegality.[5] Other courts

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[3] *See, e.g.,* 1 *Herbert Hovenkamp et al., IP and Antitrust* §15.3a1(C) (2d ed. 2010); *Robin Cooper Feldman, The Role of Science in Law* 167 (Oxford 2009); Jeremy Bulow, "The Gaming of Pharmaceutical Patents," in 4 *Innovation Policy and the Economy*, (Adam B. Jaffe et al. eds. 2004); Michael A. Carrier, "Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality," 108 *Mich. L. Rev.* 37 (2009); Joseph Farrell & Carl Shapiro, "How Strong Are Weak Patents?" 98 *Am. Econ. Rev.* (2008); C. Scott Hemphill, "Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem," 81 *NYU L. Rev.* 1553 (2006); Herbert Hovenkamp et al., "Anticompetitive Settlement of Intellectual Property Disputes," 87 *Minn. L. Rev.* 1719 (2003); Mark A. Lemley & Carl Shapiro, "Probabilistic Patents," 19 *J. Econ. Perspectives* 75 (2005); Rudolph J.R. Peritz, Three Statutory Regimes at Impasse: "Reverse Payments" in "Pay-for-Delay" Settlement Agreements between Brand-Name and Generic Drug Companies, in MORE COMMON GROUND FOR INTERNATIONAL COMPETITION LAW?, Josef Drexl, Warren Grimes, Rudolph J.R. Peritz, Edward Swaine, eds. (Aldershot, U.K.: Edw. Elgar Pub., 2010); Carl Shapiro, "Antitrust Limits to Patent Settlements," 34 *Rand J. Econ.* 391 (2003).

[4] Daniel A. Crane, "Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications," 54 *Fla. L. Rev.* 747, 779-96 (2002); Roger D. Blair

and commentators note that the antitrust analysis is more complex for settlements that generate offsetting benefits to consumers, e.g., those involving negotiated entry dates or patent licenses.[6] But none take the position adopted by the trial court here – that the court need not consider the validity of the patent at all in the antitrust analysis of whether that patent could have excluded a generic competitor from the market, but can instead conclusively presume that validity.

The undersigned amici differ in their views on precisely what standard should be applied to judge the legality of exclusionary settlements. We need not resolve those differences in this case because we all agree that exclusionary settlements of patent lawsuits can sometimes violate the antitrust laws. The court below took the remarkable step of concluding that

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& Thomas F. Cotter, "Are Settlements of Patent Disputes Illegal Per Se?", 47 *Antitrust Bull.* 491, 534-38 (2002); David W. Opderbeck, "Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation," 98 *Geo. L.J.* ___ (forthcoming 2010).

[5] Maureen A. O'Rourke & Joseph F. Brodley, "An Incentives Approach to Patent Settlements," 87 *Minn. L. Rev.* 1767, 1781-82 (2003); Catherine J.K. Sandoval, "Pharmaceutical Reverse Payment Settlements: Presumptions, Procedural Burdens, and Covenants Not to Sue Generic Drug Manufacturers," 26 *Santa Clara Comp. & High Tech. L.J.* 141 (2009); Joshua P. Davis, Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal, 41 *Rutgers L. J.* __ (forthcoming 2010).

[6] *Schering Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (finding that a cross-license agreement did not violate the antitrust laws); 1 *Hovenkamp et al., supra* note 2, at §7.4e3 (discussing delayed entry settlements).

exclusionary settlements can never be illegal *as a matter of law* unless the underlying lawsuit was a sham. As a result, unless the opinion is reversed, the law will never develop to distinguish pro- and anti-competitive settlements. At a minimum, whether the settlement here is anticompetitive presents an issue of fact for trial.

II. Exclusion Payments Are Generally Anticompetitive

A. The Settling Parties Have an Incentive to Preserve Monopoly Profits in Ways That Harm Consumers, Competition, and Public Health.

A monopolist and any uniquely strong or early-arriving potential entrant have a strong incentive to enter into an exclusionary settlement. The settlement preserves the monopoly and thus keeps prices and profits high. Recognizing this, antitrust law has long condemned horizontal market division schemes as illegal per se. *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990). In the Hatch-Waxman setting, where the first drug manufacturer to file a successful Abbreviated New Drug Application (ANDA) to produce a generic version of a patent pharmaceutical is entitled to a period of statutory exclusivity, the patent owner's incentive to settle with that first generic entrant is particularly great. And because the Food and Drug Administration regulates entry into the pharmaceutical market, if a generic ANDA filer agrees to leave the market it may be years before another challenger can legally arise.

The fact that the parties to the settlement can maximize their profits through a horizontal market division agreement does

not mean that such a settlement is in the public interest. The extra profit the parties share comes from somewhere. In the case of an exclusionary settlement under the Hatch-Waxman Act, it comes from the pockets of consumers: users of medicines who would be able to purchase lower cost medications if the generic manufacturer's legal arguments were successful. Absent the settlement, the patent litigation might reveal that the patent was invalid or not infringed, leading to more competition and lower prices. With an exclusion payment, the pharmaceutical patentee buys assurance that its patent will not be invalidated—something the patent law alone does not give and that the Hatch Waxman Act did not contemplate. It uses some of this extra monopoly profit, obtained by avoiding what might have been a successful legal challenge, to pay off the potential competitor.

Such a settlement denies consumers the benefits of enhanced competition that Congress intended to result if the patent were found invalid or not infringed. Those benefits are not merely a windfall from abrogation of a legitimate patent. On the contrary, they result from the right to invalidate patents the government should never have issued. The United States Supreme Court has repeatedly emphasized the importance of encouraging challenges to weak patents. *See, e.g., United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57 (1973); *Blonder-Tongue Labs. v. Univ. of Illinois Found.*, 402 U.S. 313 (1971); *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969); *see also Aronson v. Quick Point Pencil Co.,* 440 U.S. 257, 264 (1979). Discovering the truth about the patent's validity or scope is integral to the operation of a

patent system fundamentally bound up with the public interest. The interests of consumers are given no weight at all in the trial court's calculus. Nor is the public interest in testing weak patents given any weight at all.

Under the trial court's rule, a patent owner and potential entrant are permitted to enter into an exclusionary settlement that denies these benefits to consumers *regardless* of contemporaneous evidence about the likelihood that the patent will be found invalid or not infringed. In this case that evidence takes the form of a large exclusionary payment from the patent holder to the potential rival, likely an indication that the patent holder considered its patent to be weak. Indeed, that payment was so large ($398.1 million) that it dwarfed the profits the generic manufacturer would expect to receive from successful entry. Put another way, even if it was *absolutely certain that the patent was invalid*, the patent owner could have paid Barr $398.1 million not to invalidate the patent, and Barr would have been better off taking the money and allowing the patent to remain in force than invalidating the patent. The presence of such a payment may or may not be conclusive evidence that the patent was invalid, but it is certainly evidence that could have led a jury to find that at the time they entered into the settlement, the parties believed the patent was likely invalid.

B. The Trial Court Wrongly Assumed That Every Patent Holder Has an Absolute Right to Prevent Competition

By claiming to focus on the "exclusionary zone" of the patent, but ignoring the question of whether the patent was valid

in the first place, the trial court falls back on the *assumption* that the patent holder, by virtue of the patent grant, has an absolute right to enter into a settlement that excludes competitors from the market, simply because of the presumption of validity afforded to patents. But that assumption is false. A patent does not confer a certain legal right. While it is presumed valid, that presumption is merely a way for courts considering validity to weigh evidence, not a substantive conclusion that patents are valid. *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985). Rather, the grant of a patent reflects an initial judgment by the Patent and Trademark Office that the invention is patentable. That judgment is made after only limited scrutiny. When a patent is asserted in litigation, accused infringers are entitled to demonstrate that the patent should not have issued. As the Court put it in *Lear, Inc. v. Adkins,* 395 U.S. 653 (1969):

> A patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office. Moreover, the legal conclusion is predicated on factors as to which reasonable men can differ widely. Yet the Patent Office is often obliged to reach its decision in an ex parte proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity. Consequently, it does not seem to us to be unfair to require a patentee to defend the Patent Office's judgment when his licensee places the question in issue . . .

Id. at 670. Virtually every accused infringer asserts invalidity, and nearly half of all litigated patents are ultimately found

invalid.[7] The number is even higher in pharmaceutical cases – an FTC study of all pharmaceutical patent litigation between 1992 and 2000 found that the patent owner lost in 73% of the cases. http://ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf (page 10).

Further, in cases such as this one, the fact that the patent owner must pay the accused infringer a large sum of money to stay out of the market and not to challenge the patent is strong evidence that the parties to the litigation – those with the most knowledge of the facts – see the patent as likely to be held invalid or not infringed. The patent holder in such situations rationally understands that to protect the value of a monopoly to which it was never in fact entitled, it must share some of the ill-gotten revenue with those who would otherwise invalidate it. The defendants, in turn, have every incentive to settle in exchange for a share of the monopoly profits rather than to litigate. Because the generic competitor can charge only a competitive price, it is possible for a settlement to provide a share of the monopoly price profits that convey to the generic competitor even greater profits than would be achieved by a successful lawsuit. Indeed, that appears to be precisely what happened here.

The *per se* legality rule does not merely protect established rights of patent holders. Rather, by letting patent owners buy

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[7] John R. Allison & Mark A. Lemley, "Empirical Evidence on the Validity of Litigated Patents," 28 *Am. Intell. Prop. L. Ass'n. Q.J.* 185 (1998) (studying all patent validity litigation over an 8-year period and finding that 46% of all patents litigated to judgment were held invalid).

immunity from competition even with "fatally weak" patents, it has greatly expanded patent holders' rights, turning a rebuttable (and often-rebutted) presumption into an irrebuttable one. A presumption of validity does not entitle a patentee to evade the test of patent litigation, any more than a criminal defendant's presumption of innocence entitles him to avoid trial.

Allowing holders of weak patents thus to boost their profits is a poor way to encourage innovation, because by definition a weak patent often reflects no true innovation. And allowing them to do so by buying insulation from the very challenge that would invalidate the weak patent is perverse. The United States Supreme Court has recognized "the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." *Lear*, 395 U.S. at 670. That interest would be ill-served by allowing patentees to avoid any scrutiny of the validity or scope of application of their patents simply by agreeing to split their unwarranted profits with those who would challenge their right to those profits.

C. Permitting Exclusion Payments Is Not Necessary To Encourage Settlements in the Public Interest

The Second Circuit in *Tamoxifen* recognized that the rule the trial court adopted shields troubling settlements from the antitrust laws, but concluded that the policy favoring settlement is so strong that it must extend even to "fatally weak" patents, "even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved." *Tamoxifen Citrate*, 466 F.3d at 211.

We agree that there is a general policy in favor of settlement. We strongly disagree, however, with the view that patent settlements must *always* be encouraged. That view confuses a general policy in favor of settlements that are in the public interest with an endorsement of a particular kind of settlement. The general preference for settlement over litigation must be tempered when settlements have important adverse effects on third parties; in the language of economics, there is no good reason to encourage settlements that impose significant negative externalities. Patent litigation serves the crucial role of testing weak patents and protecting the public from monopolies based on invalid patents. That benefit is particularly important in the context of the Hatch-Waxman Act, which exhibits a Congressional desire to encourage generic drug manufacturers to challenge pharmaceutical patents.

A successful patent challenge provides valuable (and in the case of medicines necessary) benefits to third parties, including anyone who seeks to practice the patented technology and consumers via enhanced competition.[8] *Per se* legality undermines the important role of patent litigation in protecting the public from undeserved monopolies based on patents that may well prove to be invalid.

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[8] *See, e.g.,* Joseph Farrell and Robert Merges, "Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help," 19 *Berkeley Tech L.J.* 943 (2004); Joseph Scott Miller, "Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents," 19 *Berkeley Tech. L.J.* 667 (2004).

Reversing the trial court's rule insulating cartels involving weak patents from scrutiny would by no means subject every patent settlement to an antitrust challenge. As noted above, some (including some of the undersigned) have suggested that a large exclusionary payment could be a suitable red flag, providing a limiting principle on such challenges; experience over time might suggest other approaches, but no such evolution can occur if *per se* legality is the law.

Nor is immunizing exclusion payments necessary to encourage the many settlements that are in the public interest. Both generally and in the pharmaceutical context, patent owners and generic firms can and do settle patent cases without exclusion payments, by agreeing to let the generic company enter in exchange for a license fee, by agreeing to delay entry without a payment, or in other ways that do not involve paying the generic company to forego competition. Indeed, the Federal Trade Commission, to which pharmaceutical patent settlements must now be reported, found 14 agreements settling patent litigation during 2003 and 2004, with none involving an exclusion payment. *See* http://www.ftc.gov/opa/2005/01/drugsettlement.htm. The fact that pharmaceutical companies can and do settle litigation without exclusion payments shows that there is no need to allow anticompetitive settlements in order to get the social benefits that most settlements provide.

III. The Costs of Allowing Anticompetitive Settlements Are Enormous

Decisions on the validity of patents implicate important public interests. *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.,* 324 U.S. 806, 816 (1945) ("'A patent by its very nature is affected with a public interest."); *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177 (1965); *Pope Manufacturing Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly."). Nowhere is that more true than in the area of pharmaceuticals. Consumers pay literally tens of billions of dollars more for patented drugs than they would for the same drugs if unpatented. Numerous studies have shown that higher drug prices result in consumers having to forego needed medicines. One study found that among people 65 and older, "a one-dollar increase in the out-of-pocket per tablet cost resulted in the purchase of 114 fewer tablets per year."[9]

Where those patents are validly granted, the monopoly price arguably reflects a needed incentive to innovation. But

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[9] Jan Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, 19 Health Aff. 219, 228 (2000); *see also* Kaiser Family Foundation et al., *National Survey on Prescription Drugs* 4 (Sept. 2000) (reporting that 9% of U.S. citizens 65 and older have had to cut down on food or other basic necessities to pay for prescription drugs), *available at* http://www.pbs.org/newshour/health/prescriptions/summaryandchartpack.pdf.

where a patent owner insulates a "fatally weak" patent from judicial scrutiny by entering into an anticompetitive agreement to avoid invalidation, it is the public that bears the cost of an *improperly* obtained monopoly on needed medicines. Anticompetitive settlements of this sort are all too common, and violate the legislative purpose behind the Hatch-Waxman Act, which was in part to encourage generic manufacturers to challenge weak patents. A recent study estimated that, across 20 drugs involved in pay-for-delay settlements, each one-year delay in generic entry costs consumers and the government roughly $12 billion." C. Scott Hemphill, "An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition," 109 *Colum. L. Rev.* 629, 650 (2009). And the American Medical Association has identified pay-for-delay settlements as a significant driver of higher drug costs. Statement of the American Medical Association before the Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce, United States House of Representatives, April 13, 2009. Those anticompetitive agreements will continue to proliferate unless and until the courts recognize the potential for anticompetitive harm and apply the antitrust laws accordingly.

Conclusion

We urge the Court to reverse the grant of summary judgment.

DATED: November 29, 2010

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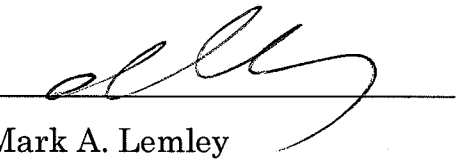
CERTIFICATE OF COMPLIANCE

Counsel of Record hereby certifies that pursuant to Rule 8.204(c)(1) or 8.504(d)(1) of the California Rules of Court, the enclosed brief of Amici Curiae is produced using 13-point or greater Roman type, including footnotes, and contains 3,943 words, which is less than the total words permitted by the rules of court. Counsel relies on the word count of the computer program used to prepare this brief.

DATED: November 29, 2010

By: 

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