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

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Court of Appeal
of the
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CERTIFICATE OF INTERESTED ENTITIES OR PERSONS

Court of Appeal Case No.: D056361

Case Name: In Re Cipro Cases I and II: Karyn McGaughey, et al. v. Bayer Corporation, et al.

☑ There are no interested entities or parties to list in this Certificate per California Rules of Court, Rule 8.208(e)(3).

☐ Interested entities or parties are listed below:

Name of Interested Entity or Person	**Nature of Interest**
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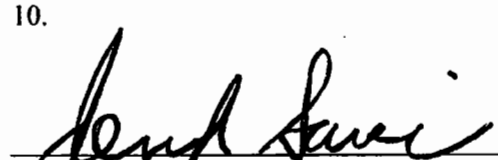

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STATEMENT OF THE NATURE OF THE ACTION AND RELIEF SOUGHT IN SUPERIOR COURT

The operative complaint asserts claims for violations of the Cartwright Act, Business and Professions Code section 16700 *et seq.*, the Unfair Competition Law ("UCL"), Business and Professions Code section 17200 *et seq.*, and the common law doctrine prohibiting monopolistic acts. Respondents filed motions for summary judgment and to dismiss in the San Diego Superior Court. (Appellants' Appendix ("A.A.") 1, 4, 69, 72, 117, 119.) Appellants opposed the motions. (A.A. 137.)

STATEMENT OF ORDER APPEALED FROM AND APPEALABILITY

The Superior Court granted the motions for summary judgment and denied the motions to dismiss as moot on August 21, 2009, and entered final judgment on September 24, 2009. (A.A. 2665, 2678.) Appellants objected to the evidence submitted by Respondents. (A.A. 233.) The Superior Court summarily overruled the objections. Appellants have an appeal as of right. Code of Civil Procedure section 904.1.

INTRODUCTION

This appeal presents the question of whether a jury can find that a patent holder has violated the California antitrust laws by agreeing to pay its generic competitors hundreds of millions of dollars not to compete. Can the sole maker of a product pay its competitors part of its monopoly profits every quarter in exchange for their agreement not to make the product? Obviously not. It would be hard to design a more anticompetitive, more unlawful, or more harmful restraint of trade than paying a potential competitor to stay out of the market. But, in this case, that is what the Defendants-Respondents did.

Respondents Bayer AG and Bayer Corp. ("Bayer") held the patent to the blockbuster anti-infection drug ciprofloxacin hydrochloride ("Cipro"). In late 1996, Bayer stood at a crossroads. Its internal financial projections showed it would earn at least $1.614 billion in monopoly profits through December 2003. However, after five years of prosecuting a patent infringement action against a generic competitor, Respondent Barr Laboratories, Inc. ("Barr"), Bayer faced trial on Barr's counterclaims that the Cipro patent was invalid and unenforceable. In discovery in that case, Bayer's former patent attorneys testified that the company had deliberately concealed prior art from the U.S. Patent and Trademark Office ("Patent Office"), rendering the Cipro patent void, unenforceable, and incapable of infringement. Against this testimony and other evidence of bad faith, Bayer argued that these attorneys suffered from crippling mental infirmities. Confronting the inevitable result of losing the case, Bayer projected that nearly a billion dollars in profit was at risk.

Faced with this calculus, Bayer decided to adopt a simple strategy. It paid Barr and its financial backers $398.1 million to terminate their efforts to compete with Bayer and drop the patent litigation. This was an offer Barr could not refuse: it was more than double the $148 million to

$177 million Barr predicted it would earn selling generic ciprofloxacin in a competitive market through 2003. After obtaining Barr's and other generic drug manufacturers'[1] agreement to this enormous payment to preserve its ill-gotten monopoly, and after dismissal of the litigation, Bayer promptly raised the price of Cipro by 16 percent.

Plaintiffs-Appellants represent a certified class of "hundreds of thousands" of California consumers and third-party payor insurers who purchased Cipro during the class period. *In re Cipro Cases I and II* (Fourth Dist. 2004) 121 Cal. App. 4th 402, 408 (affirming order certifying class and establishing class period from January 9, 1997, until the effects of Respondents' illegal conduct ceased). Appellants assert claims under the Cartwright Act and the Unfair Competition Law, and for common law monopolization. They stand on the same side as the California Attorney General, certain federal courts, the U.S. Department of Justice ("DOJ"), and the Federal Trade Commission ("FTC"), among many others, all of whom agree that reverse exclusionary payment settlements like the one at issue here violate state and federal laws prohibiting anticompetitive behavior.

However, instead of applying conventional antitrust analysis under California law, the Superior Court adopted the rule of *In re Tamoxifen Citrate Antitrust Litigation* (2d Cir. 2006) 466 F.3d 187—one of the cases interpreting the federal Sherman Act in a similar factual context—to limit the reach of the Cartwright Act, the Unfair Competition Law, and the California common law tort of monopolization. Relying on *Tamoxifen*, the Superior Court held that a reverse exclusionary payment settlement of an infringement suit does not violate the Cartwright Act unless (1) the patent

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[1] Hoechst Marion Roussel, Inc. ("HMR") and The Rugby Group, Inc. ("Rugby") are Respondents in this action and, together with Barr, entered into the anticompetitive agreements at issue. Watson Pharmaceuticals, Inc., ("Watson"), which subsequently purchased HMR and Rugby, is also a Respondent in this action.

was fraudulently procured; (2) the patent infringement suit was frivolous; or (3) the terms of the settlement agreement go outside the "exclusionary zone" of the patent. Order at 1-2 (A.A. 2682-83.). The Superior Court performed no independent analysis of the federal rule. Instead, it found that federal case law is "not only instructive in this regard, it is *dispositive*." Order at 3-4 (A.A. 2684-2685.) (emphasis added). Yet, the Second Circuit itself recently recommended reconsideration of *Tamoxifen en banc*, in another case arising out of the Cipro settlement. *Arkansas Carpenters Health & Welfare Fund v. Bayer AG* (2d Cir. 2010) 604 F.3d 98.

The Superior Court erred and should be reversed. As explained in Part One of the Argument, the court first erred by finding that the supposedly novel nature of the Cipro settlements justifies discarding not only the *per se* rule against payments not to compete, but even the flexible rule of reason analysis that California courts have applied for decades. To the contrary, while Hatch-Waxman[2] exclusionary payment settlements may be a relatively new phenomenon, antitrust analysis reviews an agreement between competitors based on its economic substance, not its form. When properly viewed this way, the anticompetitive and unlawful nature of the Cipro Agreements is manifest. Indeed, it is undisputed that, but for the adoption of the *Tamoxifen* standard, a triable issue of fact exists under the *per se* rule or the rule of reason.

Part Two analyzes the decisions of the federal courts and regulatory authorities in this area and their varying rationales. Contrary to the conclusion of the Superior Court, no clear rule has emerged from the federal cases. The *Tamoxifen* standard applied by the court below and by the Federal Circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* (Fed. Cir. 2008) 544 F.3d 1323, has come under sustained attack

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[2] The Hatch-Waxman Act of 1984, 21 U.S.C. § 355, established an abbreviated process for the approval of generic prescription drugs.

by the California Attorney General, President Obama, prominent members of Congress including both Senator Hatch and Congressman Waxman,[3] the Department of Justice, the Federal Trade Commission, state governments, public interest groups, scholars, and medical professionals. The Second Circuit itself recently urged *en banc* reconsideration of the *Tamoxifen* standard, declining to apply it to the same massive payment not to compete at issue here. *Arkansas Carpenters*, 604 F.3d at 110. If this Court chooses to look to federal authorities, it should not adopt *Tamoxifen*. Instead, the Court should look to the DOJ's recommendation that reverse exclusionary payment settlements of litigation under the Hatch-Waxman Act be considered presumptively illegal, subject to a showing of the settlement's pro-competitive benefits.

Assuming, as the Superior Court did, that *Tamoxifen* should be adopted to limit—and as a practical matter prevent—application of the Cartwright Act, the court still erred, because Appellants demonstrated a triable issue of fact, even under the *Tamoxifen* standard. *Tamoxifen* itself recognizes that reverse exclusionary agreements give rise to a claim where the patent holder's infringement action is objectively baseless. As explained in Part Three, Bayer knew its lawsuit was meritless and that it would lose any suit that alleged its bad faith conduct in procuring the Cipro patent because the undisputed facts show that it actively concealed prior art from the Patent Office, rendering its patent unenforceable once and for all.[4] This explains why Bayer's astronomical payments to the generic companies

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[3] As discussed below, Congress passed the Hatch-Waxman Act, among other reasons, to address the high cost of prescription drugs and to promote competition—and the lower prices that competition produces—from generic drug companies. *See* Facts Section 1, *infra*.

[4] Prior art refers to any relevant knowledge, acts, descriptions, or patents existing prior to the application for a patent which pertain to the invention in question.

far exceeded what those companies ever would have earned by invalidating the Cipro patent. The payments were justified to Bayer's Board as preventing the "destruction" of the patent that Bayer concluded would ineluctably result from the litigation.

Rather than consider any of this evidence, the Superior Court wrongly found that the results of Bayer's subsequent patent litigations against other generic manufacturers established that its suit against Barr was not objectively baseless. However, this ignores the record evidence that Bayer fought (or rather bought) off one of those lawsuits with yet another reverse payment settlement, whereas the others never raised the defense of inequitable conduct. The Superior Court wrongly ignored this evidence on the grounds that (1) plaintiffs did not plead the "objectively baseless" standard and (2) if they had, analyzing the evidence would deprive the court of subject matter jurisdiction. As further explained in Part Three, these rulings were contrary to law. Appellants were not required to recite the magic words "objectively baseless" from *Tamoxifen*—decided in 2006—in their complaint in 2002, especially when (1) other federal courts have phrased the standard differently or reached a different result altogether, and (2) the record contains ample evidence of Bayer's bad faith conduct.

As for jurisdiction, discussed in Part Four of the Argument, adjudication of Appellants' claims does not depend on the resolution of a substantial question of patent law, as the U.S. District Court for the Eastern District of New York already found when it remanded this case to the Superior Court. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.* (E.D.N.Y. 2001) 166 F. Supp. 2d 740, 748 (stating that "the original Bayer Barr agreement" may have been "unlawful under state law," and noting that patent law "smacks of a defense more than that of a failure of plaintiffs to state a viable cause of action under state law."). Likewise, the Second

Circuit recognized that antitrust challenges to the Cipro Agreements do not turn on patent law when it declined to transfer the *Arkansas Carpenters* action to the Federal Circuit, the designated federal court for patent appeals.

The Superior Court further erred, as discussed in Part Five of the Argument, by finding that Watson independently escaped liability because the settlement agreements at issue did not name it as a party. Watson is liable by virtue of its joining and benefiting from the conspiracy: it received $124 million to ensure that its corporate affiliates, Rugby and HMR, abided by the terms of the collusive payment.

Finally, as discussed in Part Six of the Argument, the Superior Court erred by overruling Appellants' evidentiary objections in a one-line summary statement, in contravention of settled law.

FACTS

Appellants submitted the following facts in opposition to Respondents' motions for summary judgment.[5]

1. The Hatch-Waxman Act

The Hatch-Waxman Act of 1984, 21 U.S.C. § 355, established an abbreviated process for the approval of generic prescription drugs designed to "get generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs., Inc.* (D.C. Cir. 1991) 930 F.2d 72, 76. *See Eli Lilly & Co. v. Medtronic, Inc.* (1990) 496 U.S. 661, 676. *See also Mylan Pharms., Inc. v. Shalala* (D.D.C. 2000) 81 F. Supp. 2d 30, 32 (the purpose of Hatch-Waxman is to "make available more low cost generic drugs").

The process starts when a generic drug manufacturer files an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") that incorporates by reference the safety and effectiveness data previously submitted by the developer of the so-called "pioneer" drug. With regard to any patents relating to the drug, the generic company must certify "(I) that such patent information has not been filed, (II) that such patent has expired, (III) . . . the date on which such patent will expire, or *(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.*" 21 U.S.C. § 355(j)(2)(A)(vii) (emphasis added).

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[5] Respondents did not object to or in any way dispute the evidence Appellants submitted in opposition to Respondents' motions for summary judgment, save to contend that the *Tamoxifen* standard makes this evidence immaterial. *See* All Defendants' Joint (1) Response to Plaintiffs' Objections to Defendants' Evidence, (2) Response to Plaintiffs' Evidence, and (3) Response to Plaintiffs' Separate Statement of Additional Material Facts, dated June 30, 2009, at 4 ("The only point of significance for the pending motion is that none of the additional facts alleged by plaintiffs are material to the legal issues before the Court."). (A.A. 2511.)

A company that files a Paragraph IV certification then gives notice of the filing to the brand name company that holds the allegedly invalid or non-infringed patent. 21 U.S.C. § 355(j)(2)(B). If the brand name company files a patent infringement action against the ANDA applicant within 45 days, the FDA halts its approval process and allows the patent to be litigated. 21 U.S.C. § 355(j)(5)(B)(iii). If no action is filed, the FDA's process for approving the generic drug continues without delay.

The Hatch-Waxman Act provides an incentive for generic manufacturers to challenge patents through a Paragraph IV certification. It rewards the first such filer with a 180-day period of market exclusivity. During this time, the generic manufacturer can sell its version of the drug free from competition from other generic manufacturers, in competition only with the brand name company, thus providing an opportunity and incentive for substantial financial gain. 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day exclusivity period does not start until the first marketing of the generic manufacturer's drug or a court decision of patent invalidity or non-infringement, whichever comes first. *Id.* Conversely, the 180-day exclusivity awarded to the first filer discourages other companies from filing Paragraph IV certifications. Essentially, once a Paragraph IV certification has been filed, the first-filer and the brand name manufacturer litigate the patent until settlement, final judgment, or expiration.

2. The Patent Litigation Over Cipro

On October 22, 1991, Barr filed an ANDA for a generic, bioequivalent version of Cipro.[6] Barr submitted a Paragraph IV certification to the FDA. On December 6, 1991, Barr's attorneys notified Bayer of its ANDA filing and its Paragraph IV certification that Bayer's

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[6] *See* Barr's submission to the FDA regarding ciprofloxacin hydrochloride tablets. (A.A. 1682.)

Cipro patent[7] was invalid and unenforceable.[8] On January 16, 1992, Bayer AG filed a patent infringement action against Barr in the U.S. District Court for the Southern District of New York captioned *Bayer AG v. Barr Laboratories, Inc.*, No. 92 Civ. 0381.[9]

Consistent with its Paragraph IV certification, Barr counterclaimed for a judgment that Bayer's patent be declared both "invalid" and "unenforceable."[10] Barr alleged that Bayer had engaged in inequitable conduct by intentionally failing to disclose two prior art[11] German patent applications ('070 and '850) to the Patent Office.[12] The German applications identified the same co-inventors of the '444 patent and described compounds that were indistinguishable from those Bayer claimed in the '444 patent. Therefore, according to Barr, the German applications

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[7] U.S. Patent No. 4,670,444 of Grohe, *et al.* granted June 2, 1987 ("Cipro patent" or "'444 patent"). (A.A. 2339.)

[8] Letter dated May 6, 1991, from counsel for Barr to counsel for Bayer and Miles Inc., at BLI 011592. (A.A. 335.)

[9] Complaint filed by Bayer in *Bayer AG v. Barr Laboratories, Inc.* (A.A. 345.)

[10] Answer and Counterclaim filed by Barr in *Bayer AG v. Barr Laboratories, Inc.* (A.A. 351.); First Amended Answer and Counterclaim filed by Barr in *Bayer AG v. Barr Laboratories, Inc.* (A.A. 359.). Barr also argued that the '444 patent was void because it failed to describe the scientific process for making ciprofloxacin (or one of its antecedent compounds), but instead described a different process—the Roger-Bellon Method, which did not actually produce ciprofloxacin. "[T]he specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* (Fed. Cir. 1993) 27 U.S.P.Q. 2d 1510, 1513 (citations omitted).

[11] A patent is void if "prior art discloses the method of making an article having the characteristics of the patented product, though all the advantageous properties of the product had not been fully appreciated." *Gen. Elec. Co. v. Jewel Incandescent Lamp Co.* (1945) 326 U.S. 242, 248.

[12] *See, e.g.*, Expert Report of Dr. Ivor R. Elrifi ("Elrifi Report"), at ¶¶ 30-41. (A.A. 1804-08.)

contained prior art that rendered the '444 claims unpatentable,[13] and Bayer's decision not to disclose the applications constituted inequitable conduct that rendered the '444 patent void. "A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution." *Digital Control Inc. v. Charles Mach. Works* (Fed. Cir. 2006) 437 F.3d 1309, 1313. As Barr's counsel explained in a 1994 court filing:

> The public is paying a premium price—over $600 million dollars each year—for the antibiotic ciprofloxacin. . . . Bayer is able to command a premium for the drug due to its monopoly in the market; a monopoly created by the patent that Barr contends is invalid and was inequitably obtained. Every day that this case is delayed is another day that Barr is unable to compete in the marketplace and reduce the price of ciprofloxacin for consumers.[14]

Had the trial not been short-circuited and Barr prevailed, the entire Cipro patent would have been rendered unenforceable. *Baxter Int'l, Inc. v. McGaw, Inc.* (Fed. Cir. 1998) 149 F.3d 1321, 1332. This could not have been changed by subsequent proceedings before the Patent Office.[15]

Bayer's Board knew that Bayer's loss of the trial to Barr would result in the "destruction" of Bayer's Cipro patent and the monopoly profits

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[13] Specifically, the German '070 patent application described a cycloaracylation process for forming a derivative of quinolones, napthyridines, and pyrido-pyrimidines that replaced the ethyl N-substituent normally present with a cyclopropyl N-substituent. This was precisely the same category of compounds claimed by Bayer in its U.S. patent application for Cipro. Elrifi Report, at ¶ 31. (A.A. 1804-05.)

[14] Letter dated Sept. 1, 1994 from Counsel for Barr to the Honorable Kathleen A. Roberts, U.S. Magistrate Judge. (A.A. 371.)

[15] Excerpts from the Nov. 5, 2004 Deposition of Michael Jester ("Jester Dep."), at 201:9-11 ("Q: Inequitable conduct cannot be cured on reexam, correct? A: Yes. Correct."). (A.A. 1847.)

flowing from it.[16] Bayer readily concluded that such a result would be catastrophic to Bayer's pharmaceutical business. A presentation by a Bayer Board committee estimated that Bayer would lose $3.336 *billion* in future sales if Barr succeeded.[17]

3. Bayer's Bad Faith

Barr's evidence of inequitable conduct was persuasive. Michael Jester, a patent attorney of 30 years' experience retained as an expert in this case, testified he had no doubt that Barr's evidence would have satisfied the clear and convincing standard required by patent law.[18] Dr. Simon, Bayer's German patent agent, *admitted* that the German '850 patent application constituted prior art and the company knew about it.[19] However, despite the examiner's questions about prior art, the record reveals that Bayer deceived the Patent Office by failing to disclose the German applications in over six years of prosecuting its claim to Cipro.[20]

Bayer's response to this evidence is telling. It essentially mounted an insanity defense, contending that its agent Dr. Simon suffered from "[d]epression serious enough to require treatment with tricyclic antidepressants" which affected his ability to perform his job as a lawyer in

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[16] Bayer Board presentation dated Jan. 7, 1997, at BCP4610055. (A.A. 691.)

[17] Bayer Board presentation dated Oct. 25, 1996, at BCP 4630023. (A.A. 1440.) *See also* Bayer Board presentation, at BCP-P-1572-009 ("Whilst a settlement may have a significant negative impact for our image, a loss would be much worse."). (A.A. 1434.)

[18] Jester Dep., at 193:15-194:16. (A.A. 1845-46.)

[19] Exh. 4 to the Jester Dep., ¶ 5, at 2-4. (A.A. 1852-54.)

[20] Jester Dep., at 135:10-12, 14-16 ("But the deception is compounded during six years of prosecution there's numerous opportunities to disclose '070 and '850. . . . But at the very end of this whole prosecution, the deception is compounded by telling the examiner, in effect, you have the closest prior art when he doesn't"). (A.A. 1844.)

Bayer's patent department.[21] The anti-depressant medication or some kind of "confused thinking," Bayer stated, might explain the failure of Bayer's patent department to disclose the prior art.[22] Or perhaps the problem was Dr. Simon's mental competency to testify. Before the Patent Office, Bayer set aside the insanity theory, arguing instead that

> Dr. Simon was 72 years old and had been retired for almost 10 years with health problems when he testified in deposition about events 14 years earlier. Dr. Simon had a cerebral hemorrhage after he retired which affected his memory and overall health.[23]

As for the other employees who should have insisted on disclosing the prior art, Bayer claimed that they too suffered from incapacitating mental problems. Another of Bayer's patent lawyers, for example, suffered "from Parkinson's or a related degenerative disease involving extreme mental degeneration."[24]

Mr. Jester testified that these contentions were "incredible and unbelievable. . . . No person could perform such meticulous and complex legal work involving sophisticated pharmaceutical chemistry over such an extended period of time without comprehending the consequences of his intended actions."[25]

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[21] Bayer's Response to Barr's Eighth Set of Interrogatories, dated Jan. 26, 1996, at BCP1010326. (A.A. 1479.)

[22] *Id.*

[23] Attachment 5 to Request for Reexamination of U.S. Patent No. 4,670,444, Summary of Barr's 112/102(d) Invalidity Defense and Bayer's Response Thereto, at 13, BCP0010155. (A.A. 1917.)

[24] Bayer's Response to Barr's Eighth Set of Interrogatories, at BCP1010326. (A.A. 1479.)

[25] Exh. 4 to the Jester Dep., ¶ 14, at 6. (A.A. 1856.)

4. The Events of 1995 and 1996

On January 4, 1995, the FDA granted tentative approval to Barr's ANDA, authorizing Barr to sell its generic version of Cipro at lower, competitive prices, but for Bayer's infringement suit.[26]

On March 29, 1996, Barr, Rugby, and Rugby's subsidiary HMR entered into an agreement to jointly manufacture, sell, and distribute generic ciprofloxacin.[27] Under the agreement, HMR and Rugby agreed to help Barr pay for the *Bayer v. Barr* litigation. In exchange, Barr agreed to provide Rugby and HMR with half of the profits from its sale of generic ciprofloxacin or half of any settlement payment from Bayer. HMR and Rugby concluded that Bayer would lose the litigation and that Barr would secure a judgment invalidating Bayer's patent.[28]

Bayer's motion for partial summary adjudication addressed only the invalidity defense. Bayer did not move for summary judgment against the defense of inequitable conduct. On June 5, 1996, the court denied Bayer's

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[26] Letter dated Jan. 4, 1995 from the U.S. Department of Health and Human Services to Barr, at BLI 003412-14. (A.A. 381-83.)

[27] Agreement By and Between Rugby Laboratories, Inc. and Barr Laboratories, Inc. (A.A. 384.)

[28] Excerpts from the Feb. 27, 2003 Deposition of William K. Hoskins, at 96:7-10, 97:25-98:2, 98:12-16. (A.A. 528-30.) On December 20, 1996, the generic companies amended their agreement, substituting HMR for Rugby as the party that would receive a share of Bayer's cash payments to Barr. Rugby retained the right to share in any profits from HMR's eventual sale or distribution of Cipro. In August 1997, HMR transferred those rights to Respondent Watson as part of its sale of Rugby to Watson. *See* Amendment to Agreement By and Between Rugby Laboratories, Inc. and Barr Laboratories, Inc., dated Mar. 29, 1996 (A.A. 647.); Feb. 27, 1998 Side Letter Agreement Regarding Ciprofloxacin, dated Feb. 27, 1998 ("Side Letter Agreement") (A.A. 651.); Letter Agreement between Aventis Pharmaceuticals and Watson, dated June 5, 2003 (A.A. 662.).

partial motion.[29] On September 5, 1996, the court denied Bayer's motion to reargue the motion, and set the case for trial for early 1997.[30]

5. The Board Meetings

In July 1996, shortly after the court denied summary judgment, Bayer's Board of Directors decided to try to settle the case.[31] At the first settlement meeting in August 1996, HMR's general counsel told Bayer's representative that Barr would prevail in invalidating Bayer's Cipro patent.[32] HMR then proposed that Bayer license Cipro to Barr and HMR/Rugby to settle the litigation.[33] During subsequent meetings in autumn 1996, Barr again proposed a settlement based on an immediate license.[34] Bayer refused that offer, proposing instead that Barr accept a cash payment of approximately $50 million.[35]

Negotiations continued through December 1996. By then, Bayer had convinced Barr and HMR to accept large cash payments as the main

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[29] June 5, 1996 Memorandum and Order, at BLI-004074. (A.A. 557.)

[30] Sept. 5, 1996 Memorandum and Order, at BCP 0010740-41. (A.A. 563-64.)

[31] Excerpts from the Sept. 25, 2003 Deposition of Walter Wenninger ("Wenninger Dep."), at 126:11-22 (A.A. 573.); memorandum recording excerpts from a Bayer Board of Directors meeting held on July 2, 1996, at BCP 4550001E (A.A. 577.).

[32] Presentation to Bayer by HMR's general counsel. (A.A. 578.)

[33] *Id.* at BCP3640031. (A.A. 599.)

[34] Excerpts from the Sept. 16, 2003 Deposition of Bruce L. Downey ("Downey Dep."), at 163:14-164:13. (A.A. 607-08.)

[35] Excerpts from the May 13, 2003 Deposition of Christopher Seaton ("Seaton Dep."), at 76:14-24, 77:3-11 (A.A. 612-13); Nov. 14, 1996 notes by counsel for Bayer memorializing settlement discussions with Barr (A.A. 624); Bayer's responses to a civil investigative demand made by the Texas Attorney General, at BLI-012495-97 (A.A. 602-04.)

settlement consideration.[36] With the trial date fast approaching, Bayer paid Barr $3 million solely for an agreement to delay the trial.[37]

Bayer convened a "working group" of executives in late 1996 to analyze Bayer's prospects of losing the trial and consider how the "destruction" of its Cipro monopoly would affect the company.[38] Bayer estimated that generics would capture approximately 90 percent of the ciprofloxacin market within one year.[39] Christopher Seaton, Bayer's then-vice president of planning and business administration, described Bayer's incentive to buy off generic entry:

> The first point to make is that nothing will be able to offset the loss of margin that would occur if Cipro were to go generic quickly. . . . The loss from Cipro genericisation [sic] could be expected to grow in year two (1999). . . .

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[36] Seaton Dep., at 93:13-24, 94:1-8. (A.A. 614-15.)

[37] Bayer memorandum entitled "Barr Settlement Discussions," at BCP 4630084 (A.A. 636); Bayer memorandum entitled "Barr Laboratories Payment," at BCP 2010007-008 (A.A. 641-42).

[38] Excerpts from the Sept. 29, 2003 Deposition of Richard Pott, at 22:14-23:12 (A.A. 670-71.); Wenninger Dep., at 60:14-61:15 (A.A. 569-70.)

[39] Carol D'Eugenio, Bayer's deputy director of marketing research, testified: "I am assuming that within 12 months post generic entrance, whether it be one or multiple, that by month 12 the generic form has eroded 90 percent of the total compound; they captured 90 percent share." Excerpts from the Feb. 4, 2003 Deposition of Carol D'Eugenio, at 90:3-11. (A.A. 1255.) Paula Centurelli, a Bayer consultant hired to assess the impact of generic competition for Cipro, testified that similar antibiotics lost as much as 90 percent of sales and revenues within six months of generic entry. Excerpts from the June 5, 2003 Deposition of Paula L. Centurelli, at 110-11, 232-33, 315-16. (A.A. 1271-72, 1274-77.) Leslie Noble, Bayer's director of strategic contracting, operations, and trade relations, testified that Bayer expected the erosion of Cipro sales after Barr's entry would be "very quick and very steep." Excerpts from the Feb. 13, 2003 Deposition of Leslie Noble, at 10-11, 277:19. (A.A. 1259-61.) Jennifer Stahl, Bayer's director of the Cipro brand, stated that generic penetration would be "fast and furious." Memorandum of Jan. 14, 2003 entitled "Re: Cipro Patent Loss," at CEN 0030113. (A.A. 1265.)

> Again, there is no credible cost reduction strategy that would overcome such a massive hemorrhage.[40]

Mr. Seaton sent this memoranda to David Ebsworth, then-president of the pharmaceutical division at Bayer's U.S. subsidiary.[41] Mr. Ebsworth agreed with Mr. Seaton's analysis. He testified that the introduction of generic ciprofloxacin in 1997 would have placed the viability of Bayer's U.S. pharmaceutical business in serious doubt; Cipro was Bayer's most profitable product by far.[42]

Just as Bayer had a strong incentive to offer $398.1 million to protect its monopoly, so Barr had a strong incentive to accept it. Barr could reasonably expect to earn $148 million to $177 million selling generic ciprofloxacin in a competitive market through 2003, because generic cipro would, of course, be sold at a much lower price.[43] In fact, the total profits Barr gained from the agreement were 3.3 to 4 times larger than the profits Barr reasonably expected to gain through competition.[44]

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[40] May 12, 1997 e-mail from Christopher Seaton to David Ebsworth and Kevin Kuehm, at BCP 2030057 (A.A. 1280); May 12, 1997 e-mail from Christopher Seaton to David Ebsworth and Kevin Kuehm, at BCP 2030165 (A.A. 1283.)

[41] Excerpts from the July 2, 2003 Deposition of David Ebsworth, at 16:13-16. (A.A. 1289.)

[42] *Id.* at 73:10-23, 74-76. (A.A. 1292-95.) *See also* Excerpts from the Oct. 4, 2003 Deposition of Manfred Schneider, at 13-15 (of all Bayer AG's products, Cipro brought in the most revenue worldwide and was critical to Bayer's economic health). (A.A. 1305-07.) Similarly, as explained in HMR's settlement proposal to Bayer: "Focus on the size of the pie is key—focus on the share of a smaller pie is a mistake." BCP 3640028. (A.A. 596.)

[43] Exhs. 3 & 4 to the May 28, 2003 Deposition of Timothy Catlett ("Catlett Dep.") (A.A. 2352, 2376); Declaration of Raymond S. Hartman, "Analysis of the Anti-Competitive Nature of the Cipro Supply and Settlement Agreements" ("Hartman Liability Report"), at 35 (A.A. 1203.)

[44] Hartman Liability Report, at 36. (A.A. 1204.)

6. The Cipro Agreements

Bayer, Barr, and the other generic Defendants settled their patent case on January 8, 1997.[45] Barr, HMR, Rugby, Apotex, and Bernard Sherman[46] agreed to abandon any and all challenges to the validity or enforceability of Bayer's '444 patent for Cipro. In exchange, Bayer agreed

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[45] Seaton Dep., at 133:18-24 (A.A. 616); excerpts from the minutes of the Jan. 10, 1997 Bayer Board of Directors meeting, at BCP 4610013-4610014 (A.A. 699-700). The Cipro Agreements consisted of four separate documents:

- Settlement Agreement and Mutual Release among Bayer AG, Bayer US and Barr Laboratories (the "Barr Settlement Agreement");
- Settlement Agreement and Mutual Release among Bayer AG, Bayer US, HMR and Rugby (the "HMR/Rugby Settlement Agreement");
- Settlement Agreement and Mutual Release among Bayer AG, Bayer US, Bernard Sherman and Apotex, Inc. (the "Apotex Settlement Agreement"); and
- Supply Agreement among Bayer AG, Bayer US, Barr and HMR (the "Supply Agreement").

(A.A. 701, 734, 749, 761.) The Supply Agreement was amended on August 28, 2003, to extend the parties' arrangement until the end of 2005. *See* Amended and Restated Supply Agreement, at BCP 4660016. (A.A. 830.)

[46] HMR, Rugby, Apotex, and Mr. Sherman were not parties to the *Bayer v. Barr* litigation; none had filed an ANDA for ciprofloxacin; and the protective order in the *Bayer v. Barr* litigation denied them access to the discovery in that action. Responses and Objections of Hoechst Marion Roussel, Inc. to Plaintiffs' First Requests for Admission to Defendants, Response to Request for Admission No. 20, dated Dec. 2, 2003 (A.A. 859); Downey Dep., at 136:12-18, 411:22-412:8 (A.A. 538, 554-55.) HMR, Rugby, and Apotex were well-established companies that manufactured generic drugs. They were each capable of obtaining FDA approval to bring a generic version of Cipro to market and to sell it at lower, competitive prices. Mr. Sherman was the majority controlling shareholder of Barr and the CEO and controlling shareholder of the Canadian generic drug company Apotex, Inc. As such, he was privy to the details of the *Bayer v. Barr* litigation that Bayer sought to cloak in secrecy.

to make total payments of $398.1 million to Barr, including an initial payment of $49.1 million and quarterly cash payments until December 2003.[47] Bayer retained the option to stop making cash payments to Barr, and instead to license ciprofloxacin to Barr for resale.[48] If another litigant subsequently obtained a judgment of invalidity or unenforceability against the '444 patent, Bayer agreed that it would stop making payments to Barr.[49] Bayer never exercised the "resale" option, but paid the entire amount.[50] Barr shared the money equally with HMR.[51]

Bayer and Barr authorized their counsel to submit a two-page "Consent Judgment" to the district court ending their patent litigation.[52] The Consent Judgment disclosed no details of the Cipro Agreements, and the parties never provided them to the court presiding over the *Bayer v. Barr* litigation.

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[47] Barr Settlement Agreement, at BCPO 100223 (requiring initial payment of $49.1 million) (A.A. 703); Supply Agreement, § 4.01, at BCP3920175 (obligation to disburse quarterly payments) (A.A. 788.)

[48] Supply Agreement § 4.02, at BCP3920177. (A.A. 790.)

[49] Supply Agreement §§ 1.01, 4.01, at BCP3920155, BCP3920175-76. (A.A. 768, 788-89).

[50] Bayer's Amended Responses to MDL Plaintiffs' First Request for Admissions, Response to Request for Admission No. 2, dated Feb. 18, 2004. (A.A. 845).

[51] On January 9, 1997, Barr and HMR executed an Escrow Agreement that established the Barr Escrow Account. (A.A. 889). The agreement provided that Barr and HMR would each receive one-half of all funds that Bayer paid into the escrow account. Bank records from the escrow account confirm that Bayer made regular payments to Barr and HMR pursuant to the terms of their settlement agreements through at least January 2003. (A.A. 901). *See also* Barr Laboratories Inc.'s Responses and Objections to Plaintiffs' First Set of Requests for Admissions to Defendants, Responses to Requests for Admission Nos. 1, 2, 4, 6, 7, dated Dec. 1, 2003. (A.A. 977-80).

[52] Barr Settlement Agreement, at BCPO 100224-100226. (A.A. 704-06).

7. Bayer and Barr Impede Future Challengers

As a further condition of settlement, Barr's counsel agreed to switch sides and be retained by Bayer. To avoid potential ethical conflicts, Barr had to waive applicable privileges that might have impeded such an unusual arrangement.[53] This deal prohibited Barr's attorneys from representing other potential competitors or disclosing what they had uncovered (and were set to prove at trial) concerning the prior art in the '444 patent and the inequitable conduct in its prosecution.

After entering into the Cipro Agreements, Barr switched its Paragraph IV certification to a Paragraph III certification, requesting approval to market generic ciprofloxacin upon the expiration of Bayer's patent. Barr also stated it was reserving its right to switch back to a Paragraph IV certification, so any subsequent challenger to the Cipro patent would have to anticipate litigation not just against Bayer, but also against Barr.[54]

8. The Patent Office Narrows Bayer's Patent

Bayer then amended the '444 patent by filing an *ex parte* re-examination application to the Patent Office. By petitioning for re-examination, Bayer conceded that its '444 patent was defective. *See In re Etter* (Fed. Cir. 1985) 756 F.2d 852, 857, 858 (en banc) (petitions for re-examination focus "on curing defects" of "patents thought 'doubtful.'") (quoting H.R. No. 66-1307, 96th Cong., 2d Sess. (1980), at 3). In its application, Bayer voluntarily cancelled certain claims, narrowed other claims, added new claims, and belatedly disclosed the prior art German

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[53] Excerpts from the June 30, 2003 Deposition of Dr. Roland Hartwig ("Hartwig Dep."), at 173:5-14, 173:24-174:22. (A.A. 1467-68).

[54] Hartman Liability Report, at 5. (A.A. 1173).

'070 and '850 applications it had previously failed to disclose.[55] The re-examination effectively neutralized any future challenges to the '444 patent other than those based on Bayer's inequitable conduct.[56]

9. Bayer Passes the Cost of the Settlement to Purchasers

Bayer recouped the payments due under the Cipro Agreements, and much more, by passing on the cost to purchasers in California and throughout the United States. Beginning in 1997, Bayer raised prices for Cipro at rates that were among the highest in the pharmaceutical industry. The price of Cipro increased 16 percent from the beginning of 1997 to the end of 1998.[57] Between 1997 and 2003, Bayer gained revenues of approximately $5.717 billion and profits of approximately $4.859 billion from sales of Cipro tablets alone.[58] Under the Supply Agreement, Barr began re-selling Bayer-manufactured Cipro in June 2003, six months before the '444 patent expired.[59] The agreement required Barr to buy the Cipro from Bayer at 85 percent of its current price; Barr therefore did not undercut Bayer's price on the Cipro that it re-sold.[60] Between June 2003

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[55] Request for Reexamination of U.S. Patent No. 4,670,444. (A.A. 1481.)

[56] "Bayer was able to revise and strengthen the original '444 patent so that the IP vulnerabilities identified by Barr in its original litigation were cured by Bayer. Bayer then disclaimed patent coverage for certain of the original '444 claims, narrowed the remaining claims of the '444 patent and submitted the revised patent to the US PTO for ex parte reexamination. . . . [T]he exploitation of information shared during settlement negotiations allowed Bayer to alter and increase the scope and strength of the '444 patent in order to . . . effectively blockade and foreclose future generic entry." Hartman Liability Report, at 1, 5, 37-42. (A.A. 1169, 1173, 1205-10).

[57] E-mail from Daniel McIntyre to PMC, dated June 29, 1999. (A.A. 1166).

[58] Hartman Liability Report, at 34. (A.A. 1202).

[59] Supply Agreement § 3.06, at BCP3920167. (A.A. 780).

[60] *Id.* § 3.06(a), at BCP3920166-167. (A.A. 779-80).

and December 2003, Barr sold Bayer-manufactured Cipro at prices that equaled or exceeded the prices Bayer charged for Cipro.[61]

10. Bayer Avoids Determinations of Its Inequitable Conduct and Signs Another Reverse Payment Settlement

Four other potential generic competitors—Ranbaxy, Schein, Mylan, and Carlsbad—challenged the validity of the re-examined '444 patent in lawsuits filed after the Cipro Agreements resolved the *Bayer v. Barr* litigation. The issue of Bayer's inequitable conduct was not adjudicated in any of these actions. Bayer paid Ranbaxy over $60 million to abandon its Hatch-Waxman challenge before any issue was litigated to conclusion.[62] Mylan withdrew its inequitable conduct defense because the company lacked sufficient time to litigate it before the '444 patent expired.[63] Neither Schein nor Carlsbad raised the defense or counterclaim of inequitable conduct.[64]

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[61] Catlett Dep., at 117:4-17, 118:24-119:16, 197:2-8. (A.A. 996-99). *See also* Argument Section I.B, *infra*; Declaration of Raymond S. Hartman, "Calculation of Damages to the Class of End Payors" ("Hartman Damages Report"), at 10, III.A.8.c (A.A. 1037).

[62] Commercialization and License Agreement Between Bayer AG and Ranbaxy Laboratories Limited, dated June 16, 1999, at BCP 0100055-60; 0100072-88 (Articles 2, 8) (A.A. 1505-10, 1522-38); letter dated Oct. 4, 1999 from counsel for Ranbaxy to counsel for Bayer (A.A. 1585); Stipulation of Dismissal filed in *Bayer AG v. Ranbaxy Pharmaceuticals, Inc.*, No. 98 Civ. 4464 (D.N.J.), at BCP 0960352 (A.A. 1590).

[63] Letter dated Nov. 16, 2000 from counsel for Mylan Pharmaceuticals, Inc., to the Honorable Garrett Brown, U.S. Magistrate Judge, in *Bayer AG v. Mylan Pharmaceuticals, Inc.*, No. 99 Civ. 4659 (D.N.J.), at BCP 1941110 (A.A. 1399); excerpts from the Dec. 12, 2003 Deposition of Brian Roman, at 134:11-25, 136:9-24 (A.A. 1368-69).

[64] Stipulation and Final Judgment entered in *Bayer AG v. Schein Pharmaceutical, Inc.*, No. 99 Civ. 2181 (D.N.J.), at BCP 1941185 (A.A. 1596); excerpts from the Oct. 28, 2003 Deposition of Bruce R. Genderson, at 36:6-12 (A.A. 1459); Pre-trial Order dated Apr. 8, 2002 and filed in

PROCEDURAL HISTORY OF THIS CASE

Appellants filed their consolidated amended complaint on August 5, 2002, alleging violations of the Cartwright Act, the UCL, and the common law doctrine prohibiting monopolistic acts. Following removal, the Eastern District of New York remanded the case to the Superior Court. 166 F. Supp. 2d 270.

The Superior Court overruled Respondents' demurrer as to all claims on November 26, 2002. Discovery commenced in January 2003. On November 25, 2003, the Superior Court certified a class of the "hundreds of thousands" of California consumers and third-party payors who purchased Cipro during the class period, which began on January 9, 1997, and ended when the effects of Respondents' illegal conduct ceased. *See Cipro Cases I and II*, 121 Cal. App. 4th at 408. This Court affirmed the class certification order on July 21, 2004. *Id.*

On August 20, 2009, the Superior Court issued a tentative ruling granting summary judgment. On August 21, 2009, the Superior Court heard oral argument. At the end of the argument, the court stated that "maybe Congress will make a different game plan sometime down the road, but I think that's up to Congress and not up to me." Tr. of Aug. 21, 2009 Hearing, Reporter's Transcript, at 288:28–289:2. In an order dated that same day ("Order"), the court granted the motions, stating that

> the agreement does not violate the Cartwright Act. The undisputed evidence establishes that no triable issue of material fact exists that the agreement did not fall outside the exclusionary zone 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.

Bayer AG v. Carlsbad Technology, Inc., No. 01 Civ. 8678 (S.D. Cal.), at BCP 2380657 (A.A. 1602).

Order at 1-2 (A.A. 2682-83).[65] The court found federal authority "dispositive." Order at 4 (A.A. 2685). The court summarily overruled all of Appellants' evidentiary objections. Order at 7 (A.A. 2688). Appellants timely filed their notice of appeal on November 19, 2009. (A.A. 2715.)

STANDARDS OF REVIEW

This Court reviews a grant of summary judgment *de novo*. *Aguilar v. Atl. Richfield Co.* (2001) 25 Cal. 4th 826, 860. Summary judgment may be granted only if the evidence shows "that there is no triable issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Code of Civil Procedure section 437c, subdivision (c). Summary judgment cannot be granted unless Respondents have demonstrated "that one or more elements of the cause of action in question cannot be established, or that there is a complete defense thereto." *Aguilar*, 25 Cal. 4th at 850 (quoting Code Civ. Pro. § 437c, subd. (o) (internal quotation marks omitted). The Court resolves all inferences against Respondents and views the evidence in the light most favorable to Appellants. *Martinez v. Chippewa Enterprises, Inc.* (Second Dist. 2004) 121 Cal. App. 4th 1179, 1184.

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[65] Three groups of Respondents filed motions: (1) Bayer, (2) the generic manufacturers (Barr, Rugby and HMR) and (3) Watson. The court granted all three motions separately in the same order, but largely re-stated its analysis of the Bayer motion in granting the motions of the other Respondents. Where this has occurred, Appellants will, for the sake of clarity, cite only to the Superior Court's first statement of its analysis.

ARGUMENT

I. Conventional Antitrust Analysis Condemns the Cipro Agreements

A. The Cipro Agreements Violate the Law *Per Se*

To begin with, neither Respondents nor the Superior Court dispute that, but for *Tamoxifen*, the Cipro Agreements violate California law.

The Cartwright Act guarantees a competitive marketplace free from illegal trusts. The Act prohibits all trusts, which include groups of companies that enter into horizontal agreements in restraint of trade.[66] Business and Professions Code section 16720, subdivision c. The Act rests "on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress[.]" *Marin County Bd. of Realtors, Inc. v. Palsson* (1976) 16 Cal. 3d 920, 935 (citation omitted).

Some categories of anticompetitive conduct are "conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use." *B.W.I. Custom Kitchen v. Owens-Illinois, Inc.* (First Dist. 1987) 191 Cal. App. 3d 1341, 1348. California law condemns as *per se* illegal conduct that has a "pernicious effect on competition and lack of any redeeming virtue," and where a case involves such conduct the jury need not weigh its anti-competitive effects against any pro-competitive justifications. *Id. See also Marin County*, 16 Cal. 3d at 935.

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[66] The Cartwright Act requires proof of "a combination" to restrain trade. Respondents do not dispute that the Cipro Agreements constitute a "combination" under the Cartwright Act. Combinations to monopolize or divide up markets violate the Cartwright Act. *Dimidowich v. Bell & Howell* (9th Cir. 1986) 803 F.2d 1473, 1478.

It is hard to imagine a more blatantly illegal or pernicious arrangement than a monopolist's payment to a competitor to stay out of its market. "The offense of monopoly involves the willful acquisition of the power to control prices or exclude competition from commerce in a particular geographic area with respect to a specific product." *Lowell v. Mother's Cake & Cookie Co.* (First Dist. 1978) 79 Cal. App. 3d 13, 23. The California courts have always nullified payments made to divide up markets or to block the entry of competing firms. A classic case, *Wright v. Ryder* (1868) 36 Cal. 342, involved a contract nullified as anticompetitive under which the California Steam Navigation Company sold a steamer to the Oregon Steam Navigation Company on the condition that the Oregon company would not operate the boat or compete in California waters for 10 years. *See id.* at 344, 351. Such covenants not to compete have long been declared *per se* illegal under the Cartwright Act. *Mother's Cake & Cookie*, 79 Cal. App. 3d at 23 ("Though not specifically listed [in the Cartwright Act], monopoly is a prohibited restraint of trade."). *See Burdell v. Grandi* (1907) 152 Cal. 376, 383.[67] Similarly, agreements or payments between horizontal competitors to allocate markets also violate the Cartwright Act *per se*. *Guild Wineries & Distilleries v. J. Sosnick & Son* (First Dist. 1980) 102 Cal. App. 3d 627, 633 ("It is settled that distributors cannot lawfully agree to divide territories or customers.").

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[67] The Cartwright Act's companion statute, Business and Professions Code section 16600—enacted in 1872 as Civil Code section 1673—reinforces the illegality of covenants not to compete: "Except as provided in this chapter, every contract by which anyone is restrained from engaging in a lawful profession, trade, or business of any kind is to that extent void." Business and Professions Code section 16660. Section 16660 unequivocally forbids covenants not to compete like the one at issue here. *See Hunter v. Super. Ct. of Riverside County* (Fourth Dist. 1939) 36 Cal. App. 2d 100, 113 ("If the judgment comes within the inhibition of that section, then it is to that extent void. There is nothing which the parties to the action could do which would in any way add to its validity.").

There is no dispute in the record that Respondents—horizontal competitors—entered into the Cipro Agreements for the purpose of suppressing competition with a reward funded by the monopoly profits that Bayer stood to lose. Under settled California law, the reverse payment from Bayer to Barr violates the Cartwright Act *per se* because it secured an agreement not to compete and allocated the market to Bayer in exchange for monopoly profits.

The Superior Court, however, declined to apply the *per se* rule. Relying on *Marin County*, 16 Cal. 3d 920, the court reasoned that the well-established principle of *per se* illegality could not be applied because no *other* case has applied the *per se* rule "to the specific agreement at issue here, a reverse-payment settlement under the Hatch Waxman Act concerning a patent." Order at 2 (A.A. 2683). To the contrary, the substance, purpose, and effect of the Cipro Agreements demonstrate that they violate the antitrust laws *per se*, a conclusion reached by the U.S. Court of Appeals for the Sixth Circuit.

No court has ever held that the *per se* rule cannot be applied until some other court has applied it first to an identical or substantially similar agreement. This circular reasoning, if upheld, would make the *per se* rule a dead letter. In fact, the *per se* rule exists in order for the courts to make categorical judgments. It does not condemn specific agreements based on their particular language or details; it condemns entire classes of agreements based on their terms and economic effects. Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* (2d ed. 2003), vol. 7, ¶ 1509a, at 396 ("But sometimes the reasonableness judgment can be generalized for a class of behavior or for a class of claimed defenses"). Economic analysis, not *stare decisis* alone, drives the inquiry. *Id.* ¶ 1509b, at 403 (*per se* rule applies where "serious pernicious effects are likely to result from most of its concrete

manifestations, and social benefits are likely to be absent or small or readily achievable in other ways").

Thus, in 1972, no court had held simple market division to be *per se* illegal under the Sherman Act—a proposition we now take for granted. Eleanor M. Fox & Lawrence A. Sullivan, *Cases and Materials on Antitrust* (1989), at 344 ("Before 1972, although commentators often asserted that agreements by competitors to divide markets were, without more, *per se* unlawful, there was as yet no case explicitly so holding"). That did not stop the Supreme Court from finding such a division to be *per se* unlawful in *United States v. Topco Associates, Inc.* (1972) 405 U.S. 596, even in the context of a then-novel joint venture between supermarkets to create a generic brand. Similarly, novelty and the absence of prior authority did not stop the Court from summarily reversing and granting summary judgment to the plaintiffs in *Palmer v. BRG of Georgia* (1990) 498 U.S. 46 (per curiam), despite the fact that the agreement to end competition occurred in the context of a licensing agreement.

> The revenue-sharing formula in the 1980 agreement between BRG and HBJ, coupled with the price increase that took place immediately after the parties agreed to stop competing with each other in 1980, indicates that this agreement was "formed for the purpose and with the effect of raising" the price of the bar review course.

Id. at 49.

Furthermore, several cases have in fact applied the *per se* rule to agreements not to compete dressed up as patent settlements. In *Vulcan Powder Company v. Hercules Powder Company* (1892) 96 Cal. 510, the California Supreme Court invalidated a horizontal market allocation contract between competitors who claimed they were merely exchanging their patent rights to dynamite. The court first made it clear that simply holding a patent does not give a company free rein to enter into

anticompetitive contracts, including market allocation contracts, with competitors. *Id.* at 515-16 ("In some text-books and decisions, it has been stated, generally, that the rule about contracts in restraint of trade being void does not apply to patent rights; but as applied in the adjudicated cases, it means only that a trader may sell a patent right, or a secret in his trade or art, and restrain himself generally from the use of it, or from other acts which would lessen the value of the patent sold.").

The *Vulcan* court found it significant that the plaintiff and another party to the contract did not own a dynamite patent. The money these parties received did not result from a sale or exchange of patent rights; instead, they received it in exchange for their agreement not to compete. *Id.* at 515 ("[I]t is obvious that the consideration moving from them was their covenant to refrain from competition in the dynamite business, and that they had no patent rights to 'interchange.'"). The court then found the agreement void under California law, for "no case has been cited in which it has been held that several persons or companies can legally enter into a business combination to control the manufacture, or sale, or price of a staple of commerce merely because some of the contracting parties have letters patent for certain grades of that staple." *Id.* at 516. While the court also noted that the restraints in question exceeded the technological scope of the patent, the court's analysis did not depend on this fact. *Id.* Instead, the court focused on whether the patent holder was receiving consideration for some right it had obtained through the patent. *Id.* at 515-16.

The Cipro Agreements, like the agreement in *Vulcan*, did not license patented rights. Bayer did not *receive* money in exchange for a license. To the contrary, it *paid* money to entities that had no patent right, in exchange for their agreement not to compete with the patented product. Patent licenses and other reciprocal business arrangements such as patent pools can have pro-competitive effects by expanding consumer choice. But a

generic drug company's agreement to stay out of the market, like the agreement at issue here, and like the market allocation agreement struck down in *Vulcan*, has *no* pro-competitive effects. Partly for this reason, such agreements between patent holders and non-patent holders are historically rare, and have cropped up only recently in the area of pharmaceutical patents, as drug companies sought ways to avoid the consequences of the Hatch-Waxman Act.[68] Under California law, a naked payment from a patent holder to a non-patent holder to abandon its challenge to the patent's validity and stay out of the market for the patented product—thus ensuring supra-competitive prices—must be scrutinized under the rule that agreements not to compete are *per se* illegal. *See* Areeda & Hovenkamp, vol. 12, ¶ 2046, at 321 ("Potentially anticompetitive IP settlements are entitled to deference when they involve the creation of IP licenses whose scope must be assessed against competitive risks. But when no license is created, no such deference is needed.").

The supposed novelty of a settlement of patent litigation also did not deter the Supreme Court from declaring such a settlement unlawful in *United States v. Singer Manufacturing Company* (1963) 374 U.S. 174. In *Singer*, American, Italian, and Swiss sewing machine companies unlawfully agreed to "settle" their various patent disputes, *id.* at 180, 185, making a truce to avoid litigation and collude against Japanese manufacturers. Concurring, Justice White stated that the "patent laws do not authorize, and the Sherman Act does not permit," arrangements "between business rivals to encroach upon the public domain and usurp it to themselves." *Id.* at 200. In *Singer*, the defendants

> agreed to settle an interference, at least in part, to prevent an open fight over validity. There is a public

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[68] *See* Jester Dep., at 60:18-19 (it is "unusual in the patent universe to settle a patent infringement case in that fashion.") (A.A. 1842).

> interest here, which the parties have subordinated to their private ends—the public interest in granting patent monopolies only when the progress of the useful arts and of science will be furthered because as the consideration for its grant the public is given a novel and useful invention.

Id. at 199. Rather than advancing any policy in favor of patent settlements, the Court in *Singer* expressly vindicated a "public policy favor[ing] the exposure of invalid patent monopolies before the courts in order to free the public from their effects." *Id.* at 200 n.1. *See also United States v. Line Material Co.* (1948) 333 U.S. 287, 319 (stating that courts should not condone patent-based arrangements which create "a powerful inducement for the abandonment of competition, for the cessation of litigation concerning the validity of patents, for the acceptance of patents no matter how dubious, for the abandonment of research in the development of competing patents.").

Consistent with *Singer* and the basic principles of antitrust analysis, courts have not hesitated to find that exclusionary reverse payment settlements like the Cipro Agreements violate the antitrust laws *per se*. In *Andrx Pharmaceuticals, Inc. v. Biovail Corporation International* (D.C. Cir. 2001) 256 F.3d 799, the D.C. Circuit considered allegations that the brand name company "HMRI paid Andrx 10 million dollars per quarter effectively not to enter the market" to settle Hatch-Waxman litigation over the patent to a hypertension drug. *Id.* at 809. "One can fairly infer from these facts, which were alleged in the counterclaim, that but for the Agreement, Andrx would have entered the market." *Id.* As a result, Andrx "acted unlawfully when it agreed with a competitor to settle the dispute, suppress information and exclude others from the market." *Id.* at 813 n.15 (citing *Singer*, 374 U.S. 174). The court remanded the claim to allow the plaintiffs to replead it.

In *In re Cardizem CD Antitrust Litigation* (6th Cir. 2003) 332 F.3d 896, the Sixth Circuit found the same $89.83 million reverse payment settlement to be *per se* illegal on a more complete record. *Id.* at 907. The deal raised serious concerns because "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." *Id.* at 908. Consumers paid "higher prices" for "drugs as a result of the contractually mandated absence of competition." *Id.* at 904. The reverse payment thus constituted "a horizontal agreement to eliminate competition in the market . . . a classic example of a *per se* illegal restraint of trade." *Id.* at 908.

In this case, Bayer paid its generic competitors an even steeper price—$398.1 million—to "stay out of the market." *Id.* at 908. *See* Facts Section 6, *supra*. Bayer then did it again, settling a later infringement suit brought by Ranbaxy for payments totaling $60 million. *See* Facts Section 10, *supra*. These agreements between competitors give rise to a "serious pernicious effect"—the total foreclosure of competition—and have no social value. Areeda & Hovencamp, vol. 7, ¶ 1509b, at 403. Indeed, Bayer sharply increased the price of Cipro and earned increased monopoly profits during the remainder of the patent term. *See* Facts Section 9, *supra*. The rule of *per se* illegality therefore applies to the Cipro Agreements.

B. Even if the *Per Se* Rule Does Not Apply, a Triable Question Exists Under the Rule of Reason

Even if the Cipro Agreements were so "novel" that they should not be condemned *per se*, the alternative is not presumptive legality: the court must apply the rule of reason.

Under California law, the rule of reason requires the plaintiffs to bear the initial burden of showing that the "restrictive trade practices have

substantial or serious anticompetitive effects within the relevant market." *Feldman v. Sacramento Bd. of Realtors, Inc.* (Third Dist. 1981) 119 Cal. App. 3d 739, 747 (reversing grant of summary judgment to defendants). Once the plaintiffs satisfy this burden, the burden then shifts to the defendants to show countervailing pro-competitive justifications for the practices under scrutiny, which the trier of fact weighs against the anticompetitive effects. *Id. See also Bert G. Gianelli Distrib. Co. v. Beck & Co.* (First Dist. 1985) 172 Cal. App. 3d 1020, 1048 (reversing grant of summary judgment to defendants), *overturned on other grounds by Dore v. Arnold Worldwide, Inc.* (2006) 39 Cal. 4th 384. "Whether a restraint of trade is reasonable in the context of the Cartwright Act is a question of fact to be determined at trial." *Corwin v. Los Angeles Newspaper Serv. Bureau, Inc.* (1971) 4 Cal. 3d 842, 855.

As with the *per se* analysis, Respondents below never questioned that triable issues of fact exist under the rule of reason, which would, at a minimum, preclude summary judgment but for the application of *Tamoxifen*. How could they? The undisputed facts show that the Cipro Agreements restrained competition in California to an unreasonable degree:

1) Bayer more than doubled the annual rate of increase in the price of Cipro after the agreements.[69] Bayer increased the price of Cipro by 16 percent from January 1997 to December 1998 alone.[70]

2) Following generic entry in 2004, the price of ciprofloxacin immediately dropped and in the months

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[69] *See* Hartman Liability Report, at 40. (A.A. 1208).

[70] *See* e-mail from Daniel McIntyre to PMC, dated June 29, 1999, referencing a *Wall Street Journal* article (A.A. 1166). *See also* Hartman Liability Report, at 40 ("Bayer increased the prices for the three major [Cipro] dosages 4.56%, 4.85% and 4.33% annually in the five years prior to the settlement agreements and 10.53%, 11.66% and 74.83% respectively for the seven years after the settlement agreements.") (A.A. 1208).

> thereafter continued to decline. This shows that Bayer was able to, and did, charge monopoly prices in California for over seven years. It also shows that, had generic companies entered the market in 1997, consumers would have paid much less for ciprofloxacin throughout the class period.[71]

At least two other factual disputes relate to the question, properly left for the jury to decide, of whether Bayer's payment had anticompetitive effects:

1) Whether the settlement provided Barr with more or less money than it would have earned had its patent challenge succeeded.[72]

2) Whether the limited license granted to Barr in 2003 had anti-competitive or pro-competitive effects.[73]

As for Respondents' anticompetitive intent, it is evident on the face of the Cipro Agreements.[74] The nearly $400 million payment not to compete made the generic manufacturers stakeholders in the Cipro patent. Ordinarily, monetary consideration moves from a licensee or infringer *to* a patent holder, reflecting the fact that a valid patent has been violated, or would be violated, by another's use of the technology. Here, in contrast,

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[71] *See* Hartman Liability Report, at 29-44 (A.A. 1197-1212); Hartman Damages Report, at 22-29 (A.A. 1049-56). *See also* Declaration of Raymond S. Hartman, "Analysis of the Anti-Competitive Nature of the Cipro Supply and Settlement Agreements and Definition of the Antitrust Market Relevant to Those Agreements: Rebuttal Declaration" (A.A. 1859).

[72] The total profits Barr gained from the Cipro Agreements were up to four times larger than the profits Barr reasonably expected to achieve through competition with Bayer. *See* Hartman Liability Report, at 36. (A.A. 1204).

[73] Respondents claim a pro-competitive effect from Barr's sale of Cipro at a price almost identical to that of Cipro sold by Bayer. As Dr. Hartman has testified, this is downright "laughable." Hartman Liability Report, at 39-40 n.89 (A.A. 1207-08). *See* Hartman Damages Report, at 10 (A.A. 1037).

[74] The result would therefore be the same whether the Court applies the traditional rule of reason analysis or the standard of presumptive illegality advocated by the Department of Justice. *See* Argument Section II.B.1, *infra*.

consideration moved in the other direction (hence the term "reverse" payment) *from* the patent holder to generic companies holding no relevant license or patent. The generic companies had nothing to offer in return except their agreement to drop their counterclaims and not to compete. *Cf. Vulcan*, 96 Cal. at 515 ("[I]t is obvious that the consideration moving from them was their covenant to refrain from competition . . . that they had no patent rights to 'interchange.'").

II. The Court Adopted a Flawed and Highly Criticized Line of Federal Authority

Instead of applying the *per se* rule or the rule of reason under California law, the Superior Court adopted a rule unprecedented in California jurisprudence: the analysis of the Second Circuit Court of Appeals in *Tamoxifen*. Not only has this standard been criticized by the United States Department of Justice, the Federal Trade Commission, the majority of state antitrust enforcement agencies including the California Attorney General, numerous professors of law, business and economics, major consumer organizations, and the American Medical Association, but, after the Superior Court adopted this standard, the Second Circuit itself questioned whether *Tamoxifen* should be reversed rather than applied to protect the Cipro Agreements. *Arkansas Carpenters*, 604 F.3d at 110 ("[W]e believe there are compelling reasons to revisit *Tamoxifen* with the benefit of the full Court's consideration of the difficult questions at issue and the important interests at stake. We therefore invite the plaintiffs-appellants to petition for rehearing in banc."). The Superior Court erred by adopting this standard and should be reversed.

A. The *Tamoxifen* Standard: Presumptive Legality

The doctrine adopted by the Superior Court originated in two Eleventh Circuit cases, *Valley Drug Company v. Geneva Pharmaceuticals, Inc.* (11th Cir. 2003) 344 F.3d 1294, and *Schering-Plough Corporation v.*

F.T.C. (11th Cir. 2005) 402 F.3d 1056. In *Valley Drug*, the Eleventh Circuit considered Abbott's settlement payments of between $3 and $4.5 million per quarter in exchange for delayed generic sales of a drug used to treat hypertension and enlarged prostate. 344 F.3d at 1298. The court rejected *per se* illegality based on the fact or size of the reverse payments. *Id.* at 1309. Instead, the court focused on the "scope of the exclusionary potential of the patent," and approved the payments on the grounds that a jury could not reasonably conclude that "the exclusionary effect of the Agreements were bolstered by the exit payments to a degree that exceeds the potential exclusionary power of the patent." *Valley Drug*, 344 F.3d at 1311. In *Schering-Plough*, the Eleventh Circuit approved a $15 million patent settlement payment by a brand name drug company in exchange for delayed generic sales of a drug used to treat high blood pressure. 402 F.3d at 1058, 1061 n.8. Following *Valley Drug*, the court explained that "[w]hat we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection." *Id.* at 1076.

In a 2-1 split decision, the Second Circuit extended the Eleventh Circuit's analysis to uphold a $21 million reverse payment by the drug company Astra Zeneca to settle patent litigation surrounding the breast cancer drug Tamoxifen. *See In re Tamoxifen Citrate Antitrust Litig.* (2d Cir. 2006) 466 F.3d 187. The court asserted a new rule amounting to presumptive *legality*, immunizing patent settlements from antitrust scrutiny unless they: (1) involve a patent that was procured by fraud; (2) arise from a patent suit intentionally filed for improper purposes; or (3) contain contractual provisions exceeding the patent's scope. *Id.* at 208-09 & n.22. But, even as it required antitrust plaintiffs challenging exit payments to make at least one of these three showings, the majority admitted to misgivings.

> There is something on the face of it that does seem "suspicious" about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn by winning the lawsuit and entering the newly competitive market in competition with the patent holder.

Id. at 208.[75] The Federal Circuit, the first appellate court to consider the legality of the Cipro Agreements, agreed with the majority in *Tamoxifen*. The court affirmed the dismissal of the indirect purchasers' federal claims arising from the Cipro Agreements.[76] *See In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Fed. Cir. 2008) 544 F.3d 1323.

B. The Second Circuit Questioned Its Own *Tamoxifen* Standard

The Superior Court here adopted *Tamoxifen* and the Federal Circuit's *Cipro* decision following it "as persuasive authority," finding that there was not "any basis to support that the agreement is *per se* illegal under federal law." Order at 3 (A.A. 2684). In so doing, the Superior Court failed to acknowledge that federal law remains unsettled and that there is a split of authority among the circuits on the issue of Hatch-

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[75] Dissenting, Judge Pooler pointed out that "consumers have no ability to affect the settlement, which, in some cases, may benefit both parties beyond any expectation they could have from the litigation itself while harming the consumer. There is a panglossian aspect to the majority's tacit assumption that the settling parties will not act to injure the consumer or competition." *Tamoxifen*, 466 F.3d at 228 n.5.

[76] After the district court granted summary judgment to the defendants in the federal multi-district Cipro litigation, the indirect purchaser plaintiffs' appeal was transferred for resolution to the Federal Circuit because those plaintiffs, unlike the direct purchaser plaintiffs (and unlike Appellants here), asserted a claim for fraud on the Patent Office under *Walker Process Equipment, Inc. v. Food Machinery and Chemical Corporation* (1965) 382 U.S. 172. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, Second Circuit Case No. 05-2863, Docket Entry of Nov. 7, 2007.

Waxman exclusionary payment settlements. While the court distinguished *Cardizem* on its facts, *id.* ("the agreement at issue in that case exceeded the exclusionary scope of the patent involved"), the Superior Court never addressed *Singer* or the strong language in *Cardizem* condemning exclusionary reverse payment settlements regardless of whether they restrict competition beyond the "scope" of the patent. Contrary to the court's conclusion that *Tamoxifen* has been universally accepted, the "Sixth Circuit's *per se* treatment . . . appears to conflict with the Second and Eleventh Circuits' approach. . . . This apparent conflict in the circuits has not been resolved by the Supreme Court."[77] ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS, at 1137 (6th ed. 2007). Even the Federal Circuit grudgingly acknowledged the circuit split: "To the extent that the Sixth Circuit may have found a *per se* antitrust violation based solely on the reverse payments, we respectfully disagree." *Cipro*, 544 F.3d at 1335.

The Second Circuit in *Arkansas Carpenters* identified four reasons to call into question the *Tamoxifen* standard: (1) the United States has taken the position that *Tamoxifen* adopted an "improper standard" which should be repudiated; (2) the *Tamoxifen* decision has opened the floodgates to reverse payment settlements; (3) the drafters of the Hatch-Waxman Act, and other authorities, have criticized the *Tamoxifen* standard as having turned the statute on its head; and (4) the *Tamoxifen* court based its decision

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[77] The Federal Trade Commission has also observed that the Circuits are split. *See* FTC Statement Before the House Subcommittee on Commerce, Trade, and Consumer Protection, "How Pay-For-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs" ("Rosch Statement"), at 4-7 (Mar. 31, 2009) (explaining circuit split as to illegality of pay-for-delay settlements); *available at* http://www.ftc.gov/os/2009/03/P859910payfordelay.pdf. (A.A. 2011-14).

"in no small part" on an "erroneous" interpretation and application of the Hatch-Waxman Act. *Arkansas Carpenters*, 604 F.3d at 108-10.

1. The Department of Justice

As Appellants pointed out to the court below, in contrast to *Tamoxifen*'s conclusion that these agreements are *per se* legal, the United States has concluded that reverse exclusionary payment agreements are "presumptively unlawful" under the Sherman Act, which supports the position that they are "unlawful under the Cartwright Act as well." Tr. of Aug. 21, 2009 Hearing, Reporter's Transcript, at 273:26-27. While the Superior Court failed to acknowledge the significance of this position, the Second Circuit recognized its import. At the invitation of the Second Circuit, the United States submitted a brief which "urged" the court "to repudiate *Tamoxifen*, arguing that *Tamoxifen* adopted an improper standard that fails to subject reverse exclusionary payment settlements to appropriate antitrust scrutiny." *Arkansas Carpenters*, 604 F.3d at 108. According to the Justice Department, the *Tamoxifen* standard

> inappropriately permits patent holders to contract their way out of the statutorily imposed risk that patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract. Except in instances of knowing fraud or objectively baseless patent claims, the *Tamoxifen* standard treats a private settlement agreement excluding competition as the equivalent of a litigated judgment affirming the validity of the patent. In most cases, this standard effectively bars considering whether the agreement might violate the antitrust laws, and so offers no protection to the public interest in eliminating undeserved patents.

DOJ Br. at 14-15 (A.A. 2568-2569). The fact is, "[a]llowing the patent holder to claim antitrust immunity for its contracts as if they were litigated injunctions, while evading the risk of patent invalidation, deprives

consumers of significant benefits from price competition in the pharmaceutical industry." *Id.* at 17 (A.A. 2571). With regard to the rebuttable presumption of patent validity:

> There is no basis for a standard that treats the presumption of validity as virtually conclusive and allows it to serve as a substantive basis to limit the application of the Sherman Act—particularly since many litigated patents, notably in the Hatch-Waxman Act context, are held invalid. The result is to treat all but the most obviously invalid patents as equally potent bulwarks against competition from generic drugs. This result seems particularly unacceptable when a substantial payment for an agreement to withdraw a patent validity challenge strongly implies that the payor recognized a significant risk of patent invalidation through litigation.

Id. at 18-19 (A.A. 2572-2573).

The Department of Justice recommends instead a modified rule of reason, under which "excessive reverse payment settlements [are] deemed presumptively unlawful unless a patent-holder can show that settlement payments do not greatly exceed anticipated litigation costs." *Arkansas Carpenters*, 604 F.3d at 109. In the case of a payment like the $398.1 million provided for in the Cipro Agreements, "[t]he exchange of money for continued market exclusivity is starkly apparent." DOJ Br. at 24 (A.A. 2578). "Absent another explanation for it, such a payment is naturally viewed as consideration for the generic's agreement to delay entry beyond the point that would otherwise reflect the parties' shared view of the likelihood that the patentee would ultimately prevail in the litigation. A payment in exchange for such additional exclusion is presumptively violative. . . ." *Id.* at 22 (A.A. 2576).

2. *Tamoxifen* Produced a Wave of Reverse Payment Settlements

In adopting *Tamoxifen*, the Superior Court also wrongly aligned California law with a rule that has unleashed a wave of anticompetitive agreements, as the Second Circuit explained in *Arkansas Carpenters*. 604 F.3d at 109 ("[T]here is evidence that the practice of entering into reverse exclusionary payment settlements has increased since we decided *Tamoxifen*. Prior to our *Tamoxifen* decision, there were fourteen settlements of Hatch-Waxman lawsuits, none of which involved reverse payments to a generic manufacturer.").

Prior to *Tamoxifen*, the successful enforcement efforts of the Federal Trade Commission limited the number of reverse payment settlements. But this did not prevent Hatch-Waxman litigations from settling. Between 2000 and 2004, "there were at least as many settlements as there were in the seven years in which pharmaceutical companies were settling litigation with payments and restrictions on generic entry. Parties simply found different ways to resolve their disputes, presumably on the basis of the relative strength of their cases."[78] Thus, the *Tamoxifen* court had no basis to assume that applying antitrust principles to reverse exclusionary payment settlements "would place a huge damper on such settlements contrary to the law . . . that settlements are not only permitted, they are to be encouraged." *Tamoxifen*, 466 F.3d at 212 n.26. Instead, *Tamoxifen* itself ushered in a new era of reverse exclusionary settlements. As the Second Circuit noted, after *Tamoxifen* "twenty of twenty-seven Hatch-Waxman settlements have involved reverse payments." *Arkansas Carpenters*, 604 F.3d at 109.

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[78] Rosch Statement, at 19. (A.A. 2026).

3. *Tamoxifen* Has Been Roundly Criticized

The Superior Court further erred by failing to consider that the drafters of the Hatch-Waxman Act, the Federal Trade Commission, and prominent legal scholars have condemned reverse exclusionary payments and court decisions allowing them as wrongly decided. *See Arkansas Carpenters*, 604 F.3d at 109. In 2000, Representative Waxman declared that "[t]he law has been turned on its head. . . . We were trying to encourage more generics and through different business arrangements, the reverse has happened."[79] In 2002, Senator Hatch described reverse payment deals as "appalling."[80] A Senate Judiciary Committee report that year condemned "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market. Agreeing with smaller rivals to delay or inhibit competition is *an abuse*[.]"[81]

The Federal Trade Commission agrees that reverse payments harm consumers and violate the law by driving up the prices of prescription drugs. According to FTC Commissioner Thomas Rosch, the "threat" that "anticompetitive 'pay-for-delay' deals" pose "is a matter of pressing national concern."[82] "These anticompetitive patent settlements present one of the *greatest threats* American consumers face today," the FTC

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[79] Cheryl Gay Stolberg, *et al.*, "Keeping Down the Competition: How Companies Stall Generics and Keep Themselves Healthy," *The New York Times* (July 23, 2000). (A.A. 2224).

[80] Cong. Rec. S7566 (daily ed. July 30, 2002), 148 Cong. Rec. S7565-66 (July 30, 2002). (A.A. 2234).

[81] Report entitled "The Drug Competition Act of 2001," S. Rep. No. 107-167 (2002), at 4 (emphasis added). (A.A. 2239).

[82] Rosch Statement, at 1. (A.A. 2008).

Chairwoman told members of Congress in 2007.[83] The current FTC Chairman, Jon Leibowitz, declared that "when drug companies agree not to compete, consumers lose,"[84] and that "[e]liminating these pay-for-delay settlements is one of the most important objectives for antitrust enforcement in America today."[85] An FTC study released in January 2010, entitled "Pay-for-Delay: How Drug Company Pay-offs Cost Consumers Billions," found that reverse payments "are 'win-win' for the companies: brand-name pharmaceutical prices stay high, and the brand and the generic share the benefits of the brand's monopoly profits. Consumers, lose, however: they miss out on generic prices that can be as much as 90 percent less than brand prices."[86]

The FTC has repeatedly denounced the rule accepted by the Superior Court. The rule "misapplie[s] the antitrust law" and "disrupt[s] the carefully balanced patent system by overprotecting weak and narrow patents; allowing patent holders to buy protection that their patents cannot provide; and ignoring consumers' interests in competition safeguarded by the antitrust laws."[87]

Nowhere were the troubling dynamics of reverse exclusionary payments expressed more clearly than in a brief to the U.S. Supreme Court in April 2009 by a group of prominent scholars and economists seeking review of *Tamoxifen*. As the group pointed out, the rule the Superior Court

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[83] Prepared Statement of the Federal Trade Commission Before the Antitrust Task Force of the House Committee on the Judiciary (Sept. 25, 2007) (emphasis added). (A.A. 2182).

[84] *See* http://www.ftc.gov/opa/2010/01/payfordelay.shtm.

[85] Concurring Statement of Commissioner Jon Leibowitz, *Federal Trade Commission v. Watson Pharmaceutical, et al.* (Feb. 2, 2009). (A.A. 2175).

[86] *See* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

[87] *Id.*; Rosch Statement, at 6 (A.A. 2013).

adopted privileges drug companies' interest in windfall profits over the public interest in affordable prescription drugs:

> The fact that the *parties* to the settlement can maximize their profit through a horizontal market division agreement does not mean that such a settlement is in the *public* interest. The extra profits 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. . . . 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 challenge, to pay off the potential competitor.[88]

Because reverse exclusionary payments maintain artificially high prices for vital prescription drugs, the California Attorney General has consistently denounced them as unlawful. For example, the Attorney General's 2007-08 biennial report condemned reverse payments, finding they cause harmful and "collusive delays." The report noted the Attorney General "filed several lawsuits challenging improper agreements between

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[88] Brief Amici Curiae of 54 Intellectual Property, Antitrust Law, Economics, and Business Professors, the American Antitrust Institute, the Public Patent Foundation and the AARP in Support of Granting the Petition, *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 2009 WL 797579 (Mar. 23, 2009) (No. 08-1194) (emphasis in original). (A.A. 2283). The signatories to a brief to the U.S. Supreme Court in the *Tamoxifen* case that made this same point included Carl Shapiro, the Transamerica Professor of Business Strategy and Professor of Economics at U.C. Berkeley, and Joseph Farrell, also a Professor of Economics at U.C. Berkeley, who are now Deputy Assistant Attorney General for Economics at the Antitrust Division of the DOJ, and Director of the Bureau of Economics of the FTC, respectively. Brief Amici Curiae of 41 Professors of Economics, Business, and Law in Support of Granting the Petition, *Joblove v. Barr Labs., Inc.*, 127 S. Ct. 3001 (2007) (No. 06-830). (A.A. 2320, 2322.)

pharmaceutical manufacturers to delay the launching of generic equivalent drugs."[89]

Likewise, the leading treatise on antitrust law concludes that reverse payments to generic manufacturers disproportionately larger than the cost of litigation "indicate that the parties harbored significant doubt that the patents in question were valid or infringed, which entails a significant possibility that, if pursued to a judicial outcome, generic competition would have entered the market. Such amounts are presumptively unreasonable, with the presumption defeated only by a showing that alternative challengers are able, both legally and physically, to enter the market immediately." Areeda & Hovenkamp, vol. 12, ¶ 2046, at 333.

The Superior Court erred by failing to accord sufficient weight to these authorities. In particular, courts must accord "considerable weight" to the Federal Trade Commission's interpretation of federal statutes in its designated areas of responsibility, which include the antitrust laws and the pharmaceutical industry. *Davis v. United States* (1990) 495 U.S. 472, 484. *See Doyle v. F.T.C.* (5th Cir. 1966) 356 F.2d 381, 383-84; *Arkansas Carpenters*, 604 F.3d at 105.

4. ***Tamoxifen* Misinterpreted Hatch-Waxman**

Finally, the *Tamoxifen* decision relied on an "erroneous characterization" of the Hatch-Waxman Act. *Arkansas Carpenters*, 604 F.3d at 109-10. Specifically,

> *Tamoxifen* was based in no small part on the panel majority's belief that reverse exclusionary settlements

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[89] Excerpts from the California Attorney General's Biennial Report: Major Activities 2007-2008 (Sept. 15, 2008). (A.A. 2337). Doctors agree. In 2008, the American Medical Association passed a resolution declaring the urgent need to "stop 'pay for delay' arrangements by pharmaceutical companies." Excerpts from 2008 American Medical Association Resolutions. (A.A. 2325).

> "open[] the [relevant] patent to immediate challenge by other potential generic manufacturers . . . spurred by the additional incentive . . . of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit . . ." 466 F.3d at 214. If understood as a legal conclusion that the statutory exclusivity period cedes to the first ANDA filer to successfully defend, this remark was erroneous.

Arkansas Carpenters, 604 F.3d at 109.[90] Thus, it was error for the Superior Court to impose this flawed standard on the people of California.

C. The Superior Court Misinterpreted California and U.S. Supreme Court Jurisprudence

The Superior Court also ignored that *Tamoxifen* conflicts with established principles of antitrust jurisprudence. It misinterpreted California cases, wrongly finding that they support the application of *Tamoxifen* here.

1. The Court Ignored the Prohibition Against Patent Abuse

The court erred by concluding, as a matter of law, that "there is only antitrust liability for conduct which goes beyond the exclusionary scope granted by the patent[.]" Order at 6 (A.A. 2687). To the contrary, a long line of cases holds that a patent holder can unlawfully abuse a patent without stepping beyond its bounds. The "primary purpose" of patent law "is not the creation of private fortunes for the owners of patents but is 'to

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[90] The Second Circuit amended this paragraph of its opinion on June 17, 2010. Commenting on the *Arkansas Carpenters* decision, the Chairman of the Federal Trade Commission stated: "This is further evidence that courts are rethinking their approach to pay-for-delay settlements, which cost American consumers $3.5 billion a year in higher prescription drug prices. Hopefully, the courts will put an end to these deals. In the meantime, the FTC will continue to explain, in court and in the halls of Congress, why these sweetheart deals for drug companies are such a bad deal for American consumers and taxpayers." *See* http://www.ftc.gov/opa/2010/04/cipro.shtm.

promote the progress of science and useful arts.'" *Quanta Computer, Inc. v. LG Elecs., Inc.* (2008) 553 U.S. 617, 128 S. Ct. 2109, 2116 (quoting *Motion Picture Patents Co. v. Universal Film Mfg. Co.* (1917) 243 U.S. 502, 511 (quoting U.S. Const., Art. I, § 8, cl. 8)). It follows that "[i]ntellectual property rights do not confer a privilege to violate the antitrust laws." *United States v. Microsoft Corp.* (D.C. Cir. 2001) 253 F.3d 34, 63 (citation omitted). A patent holder "should not be permitted by legal devices to impose an unjust charge upon the public in return for the use of it." *Motion Picture Patents*, 243 U.S. at 513. To protect the public from anticompetitive devices, the patent abuse doctrine forbids a patent holder from misusing its patent to commit antitrust violations. *Andrx*, 256 F.3d at 813 n.15 ("[A] patent-right holder is not immune from antitrust liability.").

The doctrine has deep roots in U.S. Supreme Court jurisprudence. "Whilst the remuneration of genius and useful ingenuity is a duty incumbent upon the public, the rights and welfare of the community must be fairly dealt with and effectually guarded. Considerations of individual emolument can never be permitted to operate to the injury of these." *Kendall v. Winsor* (1858) 62 U.S. 322, 329. "Active and vigorous competition then tend to be impaired not from any preference of the public for the patented product but from the preference of the competitors for a mutual arrangement[.]" *United States v. Masonite Corp.* (1942) 316 U.S. 265, 281. The patent abuse doctrine warns against such collusive dealings, holding that "[p]atents give no protection from the prohibitions of the Sherman Act" when they are deployed in "a plan to restrain commerce." *United States v. New Wrinkle, Inc.* (1952) 342 U.S. 371, 378. *See also Standard Sanitary Mfg. Co. v. United States* (1912) 226 U.S. 20, 49.

The U.S. Supreme Court has held that an agreement involving a patent can violate the antitrust laws even where it creates "no monopoly or restraint other than the monopoly or restraint granted by the patents[.]"

Masonite, 316 U.S. at 276. A patent holder "may commit patent misuse in improper exploitation of the patent *either* by violating the antitrust laws *or* extending the patent beyond its lawful scope." *Transitron Elec. Corp. v. Hughes Aircraft Co.* (D. Mass. 1980) 487 F. Supp. 885, 893 (emphasis added). *See, e.g., Line Material*, 333 U.S. at 315 (invalidating restraints that did not affect any substantive rights other than those granted by a patent, but instead were limited to "things produced under the patent"); *United States v. Univis Lens Co.* (1942) 316 U.S. 241, 248 (invalidating restraints unrelated to any "patent other than the patent which was practiced").

2. California Law Does Not Support Adopting *Tamoxifen*

In addition, the Superior Court misread and misapplied California precedents such as *Fruit Machinery Company v. F. M. Ball & Company* (First Dist. 1953) 118 Cal. App. 2d 748. In *Fruit Machinery*, the court stated that the manipulation for anticompetitive purposes of a contract involving patent rights can violate the Cartwright Act, even if—as was the case in *Fruit Machinery*—the contractual provisions remain fully *within* the patent's scope. The *Fruit Machinery* court upheld an arrangement under which the defendant, a fruit canning company, obtained a sublicense in exchange for its agreement to pay a regular royalty to the plaintiff, a company holding an exclusive license to the patent to a peach-pit-removing machine. The sublicense permitted the defendant to lease and use the machines in its canning operations. The plaintiff sued to collect royalties from the defendant. The defendant argued that the sublicense constituted an unreasonable restraint of trade because other canning companies were paying lower royalty rates to the plaintiff to use the machines. The companies who were paying the lower rates owned shares in the licensee company and had purchased the machines outright. The court found no

antitrust violation, explaining the royalty rate paid by the defendant was not disproportionately higher than the rate paid by the owners: the "differential in royalty rates which plaintiff has maintained between the leased and canner-owned machines bears a reasonable relationship to differences in costs and capital risks between the two types of uses, thus not giving the canner-owners the 'advantage' which defendant asserts but has not proven." *Id.* at 762.

The court noted that the ownership interest granted to the owners in their contracts did not exceed the scientific scope of the patent, but concluded that, if the difference between the rates paid by the defendant and the owners were sufficiently large, and the rate paid by the defendant sufficiently high, the arrangement would violate the antitrust laws even though it did not extend beyond the patented technology.

> As to the possibility of plaintiff's spreading the differential to such an extent as would put the arrangement beyond the scope of the patent rights and within the proscription of the antitrust laws, a sufficient answer is that such has not happened yet, and we read into the license and sublicense agreements no intendment that plaintiff, in fixing rates from time to time, should or could establish such a differential as would *lose to the parties the privileges, the sanctions and the protection accorded by the patent law and subject them to the proscriptions and penalties of the antitrust laws*.

Id. (emphasis added).

The Superior Court purported to quote *Fruit Machinery* as follows:

> In [*Fruit Machinery*], the California Court of Appeal ruled that in cases in which the exercise of patent rights is involved, a patent holder "brings himself within the proscription of the antitrust laws *only* when the patentee or his assignee acts beyond that which was necessary or incidental to the scope of this patent." (Fruit Machinery, (1953) 118 Cal. App. 2d 748.)

Order at 4 (emphasis added). The quoted phrase appears nowhere in the case. *Fruit Machinery* does not hold that a patentee may "only" violate the antitrust laws by acting beyond what is necessary or incidental to the scope of the patent. In fact, as described above and in Appellants' brief to the Superior Court, a full and accurate reading of the case makes the opposite quite clear.[91]

Further, the Superior Court stated that "California cases involving antitrust violations and patents likewise hold that conduct falling within the scope of a patent is not an antitrust violation." Order at 4 (A.A. 2685). In support of this proposition, the court incorrectly relied on *Sears, Roebuck & Company v. Stiffel Company* (1964) 376 U.S. 225. That case did not address California law but the law of Illinois. It held that a firm cannot violate the unfair competition laws if it copies and sells a product which is not covered by a valid patent. *Id.* at 231 ("Sharing in the goodwill of an article unprotected by patent or trade-mark is the exercise of a right possessed by all—and in the free exercise of which the consuming public is deeply interested") (citation omitted). This holding is irrelevant to the facts here. What *is* relevant about *Sears* is the Supreme Court's observation that a patent "cannot be used to secure any monopoly beyond that contained in the patent . . . *and* the patent monopoly may not be used in disregard of the antitrust laws." *Id.* at 230 (citations omitted) (emphasis added). Thus,

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[91] *See* Plaintiffs' Consolidated Opposition to Defendants' Motions for Summary Judgment, at 28-30. (A.A. 176-78.) A "differential" that would "lose to the parties" the privileges of patent law, presented as a hypothetical in *Fruit Machinery*, was found to exist in subsequent cases involving disparate royalties in licenses for shrimp peeling equipment that were struck down as anticompetitive, but which did not grant any rights other than those granted by the patents themselves. *See La Peyre v. F.T.C.* (5th Cir. 1966) 366 F.2d 117; *Peelers Co. v. Wendt* (W.D. Wash. 1966) 260 F. Supp. 193; *Laitram Corp. v. King Crab, Inc.* (D. Alaska 1965) 244 F. Supp. 9, *modified*, 245 F. Supp. 1019.

Sears stands for the exact opposite principle than what it was cited for—in fact, a patent can be misused in violation of the antitrust laws even if there is no attempt to extend the patent's parameters beyond the statutory grant.

The Superior Court also cited *Aetna Casualty and Surety Company v. Superior Court* (Fourth Dist. 1993) 19 Cal. App. 4th 320. That case held only that an insurance policy providing coverage for "advertising injury" does not obligate the insurance company to defend the insured from allegations of patent infringement. *See id.* at 327.

3. The Court Misinterpreted the Policy in Favor of Settlements and the Presumption of Patent Validity

The Superior Court wrongly invoked the general rule that "the law favors settlements, and this would extend to patent infringement suits as well," Order at 2 (A.A. 2683), as well as the statutory presumption of patent validity, Order at 4 (A.A. 2685) ("because patents are presumed valid and provide the patentee with the right to exclude others (infringers) from the market, the challenged anticompetitive effects of the agreement at issue here were directly attributable to the patent").

First, as to the policy favoring settlements, the *Tamoxifen* rule did not lead to more settlements of Hatch-Waxman litigations—just more anticompetitive ones. *See* Argument Section II.B.2, *supra*. Moreover, in the context of Hatch-Waxman litigation, the law does not in fact favor settlements at all costs: it favors early generic entry, either as a result of a license in consideration of settlement, or a judgment against the patent holder.

Second, in relying so heavily on the presumption of validity and the policy in favor of settlement, the Superior Court ignored the crucial role of litigation in policing patent monopolies. The presumption of patent validity—like any other rebuttable presumption—can be overcome. *See* 35 U.S.C. § 282. The Supreme Court has observed that a patent grant

> 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.

Lear, Inc. v. Adkins (1969) 395 U.S. 653, 670. The public stands to gain when vulnerable patents are tested through litigation. *See Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.* (1971) 402 U.S. 313, 344 (patent law "encourage[s] authoritative testing of patent validity").[92] In fact, approximately half of all litigated patents, and three-quarters of litigated pharmaceutical patents, are nullified.[93] Challenges to prescription drug patents are especially important. Pharmaceutical monopolies defended by patents have led to skyrocketing prices, which deter patients from buying their prescribed medicine.[94] In *Blonder-Tongue*—another key case ignored

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[92] *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.* (1945) 324 U.S. 806, 816 ("The far-reaching social and economic consequences of a patent . . . give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.") (citation omitted); *United States v. Glaxo Group Ltd.* (1973) 410 U.S. 52, 58 ("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.").

[93] John R. Allison and Mark A. Lemley, "Empirical Evidence on the Validity of Litigated Patents," 38 Am. Intell. Prop. L. Ass'n Q.J. 185 (1998) (A.A. 2044); Hartman Liability Report, at 9 (A.A. 1177); Prepared Statement of the Federal Trade Commission Before the Senate Special Committee on Aging, "Barriers to Generic Entry" (July 20, 2006) (A.A. 2137).

[94] Scientific studies published in peer-reviewed journals have found that many people, especially people with low incomes, do not buy some or all of their prescribed medicine when it is too expensive. *See* Stephen B. Soumerai, *et al.*, *Cost-Related Medication Nonadherence Among Elderly*

by the Superior Court—the U.S. Supreme Court held that "the opportunities for holders of invalid patents to exact licensing agreements or other settlements from alleged infringers" should be strictly limited. 402 U.S. at 342.

The Superior Court therefore erred by finding that the rebuttable presumption of patent validity renders immaterial the widespread and harmful effects of this reverse payment.[95] To the contrary, a reverse exclusionary payment logically demonstrates "the inherent *uncertainty* of

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and Disabled Medicare Beneficiaries, Archives of Internal Medicine, vol. 166, at 1829 (2006) (finding that "concern about cost was the predominant reason reported (79.4 percent of [elderly and disabled] respondents) for not filling prescriptions," and that "a substantial proportion of [Medicare] enrollees and almost one quarter of the disabled beneficiaries reported cutting back on basic needs to be able to afford their medications") (A.A. 1973, 1976); Dawn Klein, *et al.*, *Elders Who Delay Medication Because of Cost: Health Insurance, Demographic, Health, and Financial Correlates*, The Gerontologist, vol. 44, at 779 (2004) (finding that "because of the high cost of some medications, patients may decide that the medication is too costly and that they do not really 'need' the medication, even if they can afford it. . . . [N]oncompliance for any reason with the use of prescription medication may contribute to emergency room visits, inpatient admissions, and overall health care costs.") (A.A. 1985); Michael A. Steinman, M.D., *et al.*, *Self-Restriction of Medications Due to Cost in Seniors Without Prescription Coverage*, Journal of General Internal Medicine, vol. 16, at 797 (2001) (finding that "[l]ow income and high out-of-pocket drug costs both play an important role in medication restriction, consistent with basic economic principles.") (A.A. 1993); Emily R. Cox, *et al.*, *Medicare Beneficiaries' Management of Capped Prescription Benefits*, Medical Care, vol. 3, at 296 (2001) (finding that 23.3 percent of Medicare beneficiaries who were at risk of reaching their prescription cap took less than the prescribed amount of medication, 16.3 percent stopped using medications, and 14.7 percent went without food, clothing, or shelter) (A.A. 1996).

[95] Because patents restrain competition, California courts *strictly* construe the rights of patent holders to uphold "the patent policy favoring free competition, dissemination of ideas and maximum utilization of intellectual resources." *Sinclair v. Aquarius Elec., Inc.* (First Dist. 1974) 42 Cal. App. 3d 216, 224.

the incumbent's statutorily presumptive patent validity," Dr. Hartman concluded.

> Indeed, the incumbent is willing to pay the generic to stay out of the market precisely because the settlement assures the incumbent of a monopoly rent while ongoing litigation offers only the expectation of a monopoly rent, the expectation being determined by the probabilistic validity of the patent.[96]

D. If Federal Law is Persuasive, the Justice Department's Recommendation Fits with California Law and Policy

The Superior Court erred by forsaking traditional analysis under the *per se* rule against agreements not to compete or, alternatively, the rule of reason, the two modes of analysis established under California law. However, if this Court looks to federal jurisprudence for an alternative standard, the Justice Department model provides one of the best models for the law in California—where a "settled public policy" favors "open competition," health care "has a special moral status and therefore a particular public interest," and the Legislature has enacted numerous laws to facilitate consumer access to generic drugs in recognition that "[a]ffordability is critical in providing access to prescription drugs for California residents, particularly the uninsured and those with inadequate insurance." *Edwards v. Arthur Andersen LLP* (2008) 44 Cal. 4th 937, 945; *Potvin v. Met. Life* (2000) 22 Cal. 4th 1060, 1070; Health & Safety Code § 130500; Stats. 2006, c. 619, s. 1 (A.B. 2911).

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[96] Hartman Liability Report, at 22-23. (A.A. 1190-91). In other words, the incumbent will compare the "probabilistic validity" of the patent—the incumbent's evaluation of the risk that it will be struck down—with the incumbent's actual monopoly profits, to determine the size of the reverse payment it will offer.

III. The Superior Court Failed to Apply *Tamoxifen* Correctly

Even if *Tamoxifen* correctly states the applicable standard under California law, the court still erred because Appellants demonstrated a triable issue of fact with regard to the "objective baselessness" of Bayer's infringement litigation. The Superior Court wrongly ignored this evidence on the theory that Appellants "failed to allege that Bayer's infringement suit was objectively baseless" and their complaint did not allege the specific facts demonstrating Bayer's inequitable conduct before the Patent Office. Order at 5 (A.A. 2686). Then, the court found that "Bayer's success in its litigations against Schein, Mylan and Carlsbad forecloses any argument that its lawsuits were shams." *Id.* (quoting Defendants' statement of Undisputed Material Facts). The Superior Court erred in both respects.

A. Appellants Demonstrated a Triable Issue of Fact Under *Tamoxifen*

The evidence that the court erroneously refused to consider establishes a triable issue of fact under *Tamoxifen*. As set forth above, this evidence includes:

- The frivolous nature of Bayer's patent defenses in the *Bayer v. Barr* litigation over the '444 patent, which depended on the jury reaching the remarkable conclusion that every relevant employee in its patent department suffered from crippling mental health issues;

- The magnitude by which the reverse payment to Barr and its business partners exceeded the profits any of them could hope to earn selling generic cipro in a competitive market free of illegal anticompetitive activity; and

- The other suspicious circumstances of the agreement, including the co-opting of Barr's counsel.

See Facts Sections 2-3, 5-7, *supra*.

The Superior Court erroneously found that "Bayer's success in its litigations against Schein, Mylan and Carlsbad forecloses any argument that its lawsuits were shams." Order at 5 (A.A. 2686). The Superior Court may not weigh the evidence and draw inferences in favor of the moving party on summary judgment. Further, the court ignored the Ranbaxy reverse payment settlement; the fact that these subsequent litigations concerned the patent that was narrowed as part of the scheme to settle the *Bayer v. Barr* litigation; and the fact that none of them raised the issue of Bayer's inequitable conduct because it would have taken too long to litigate and Bayer's patent was nearing expiration. *See* Facts Section 10, *supra*. Moreover, this approach applies the wrong legal standard. Even under Respondents' authorities, the trier of fact must weigh the restraint's effect on active and vigorous competition against the extent to which it "promoted enterprise and productivity *at the time it was adopted*." *Polk Bros., Inc. v. Forest City Enters., Inc.* (7th Cir. 1985) 776 F.2d 185, 189 (emphasis added). *See Valley Drug*, 344 F.3d at 1306 ("We begin with the proposition that the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into."). Therefore, evidence of what happened after the parties entered into the Cipro Agreements is irrelevant to the question of whether Bayer's suit was frivolous.

B. The Court Wrongly Refused to Consider the Evidence of Bayer's Inequitable Conduct

Relying on *Oakland Raiders v. National Football League* (First Dist. 2005) 131 Cal. App. 4th 621, the Superior Court refused to consider whether a triable issue of fact exists under the *Tamoxifen* standard. The court reasoned that the operative complaint does not allege the "objective baselessness" of Bayer's infringement suit or Bayer's "inequitable conduct" before the Patent Office. This approach misstates California pleading

standards, misapplies *Oakland Raiders* and, if it really were the law, would lead to absurd results.

In *Oakland Raiders*, the Oakland Raiders football team (the "Raiders") argued that the NFL breached fiduciary duties owed to them in various ways, such as by requiring it, but not other teams, to participate in the World League of American Football in Europe. 131 Cal. App. 4th at 627. The Superior Court found that neither the NFL nor its Commissioner owed the Raiders a fiduciary duty. *Id.* at 630. In opposing the NFL's motion for summary judgment, the Raiders raised new claims for breach of fiduciary duty they had not asserted in their complaint, claims both the Superior Court and Court of Appeal characterized as "Additional Claims." *Id.* at 646. These "Additional Claims" concerned *different* purported fiduciary duties arising from *different* specific agency relationships relating to the management of *different* special-purpose entities than the Raiders had identified in their complaint. *Id.* at 648-649.[97]

Oakland Raiders is inapposite. Appellants did not invoke any new legal entities, relationships, or duties on summary judgment. They did not submit counter-declarations. They did not assert any new claims for relief. It was not Appellants, but Respondents who raised the question of objective baselessness for the very first time, in the context of an affirmative defense raised on summary judgment. Consequently, they (and the court) can hardly complain when plaintiffs advance facts to contravene the defense.

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[97] "Significantly, the second cause of action contains approximately three pages of text alleging specific actions by defendants that the Raiders claims [sic] constitute breaches of fiduciary duty. Nowhere in that cause of action, however, do we find any reference to an alleged breach of fiduciary duty associated with the LTIP [an executive compensation program], or to an alleged breach of an agency relationship involving [NFL Commissioner] Tagliabue and the Raiders connected with the formation and operation of the NFLE [NFL Enterprises]." *Oakland Raiders*, 131 Cal. App. 4th at 648-49.

Indeed, precluding plaintiffs' evidence on the basis of *Oakland Raiders* would be doubly absurd here because (a) plaintiffs do not agree that the "objectively baseless" standard applies and (b) the "objectively baseless" standard was not recognized until the *Tamoxifen* court announced it in 2006. Appellants did not spring a trap on the Respondents. The depositions, documents, and expert reports in *this* litigation have always included the facts of the *Bayer v. Barr* litigation, insofar as they show the anticompetitive purpose and effect of the enormous, illegal payment by Bayer to foreclose competition in California and throughout the United States.

Furthermore, the Superior Court's interpretation of *Oakland Raiders* would improperly limit a summary judgment opposition to the facts pleaded in the complaint, drafted before any discovery. This would turn summary judgment on its head, because "a plaintiff resisting a motion for summary judgment bears no burden to establish any element of his or her case unless and until the defendant presents evidence either affirmatively *negating* that element (proving its absence in fact), or affirmatively showing that the plaintiff does not possess and cannot acquire evidence to prove its existence." *Reeves v. Safeway Stores, Inc.* (Sixth Dist. 2004) 121 Cal. App. 4th 95, 107 (emphasis in original) (citing *Aguilar*, 25 Cal. 4th at 854-55). Trial courts deciding summary judgment, and Courts of Appeal reviewing a summary judgment order, must evaluate the entire record. They must

> liberally construe *the evidence* in support of the party opposing summary judgment (*Wiener v. Southcoast Childcare Centers, Inc.* (2004) 32 Cal. 4th 1138, 1142), and assess whether *the evidence* would, if credited, permit the trier of fact to find in favor of the party opposing summary judgment under the applicable legal standards. (*Cf. Aguilar*, 25 Cal. 4th at 850.)

Truong v. Glasser (Fourth Dist. 2009) 181 Cal. App. 4th 102, 109-10 (emphasis added). "When deciding whether to grant summary judgment, the court must consider all of the evidence set forth in the papers (except evidence to which the court has sustained an objection). . . ." *Avivi v. Centro Medico Urgente Medical Center* (Second Dist. 2008) 159 Cal. App. 4th 463, 467 (citing *Aguilar*, 25 Cal. 4th at 843). "If the plaintiff opposing summary judgment presents evidence demonstrating the existence of a disputed material fact, the motion must be denied." *Spinks v. Equity Residential Briarwood Apts.* (Sixth Dist. 2009) 171 Cal. App. 4th 1004, 1021 (citing *Aguilar*, 25 Cal. 4th at 856). The Superior Court disregarded this law, and committed reversible error, when it refused to consider the record evidence showing that Bayer's infringement suit was objectively baseless. Order at 5 (A.A. 2686).[98]

IV. The Superior Court Had Jurisdiction to Determine Whether Appellants Showed a Triable Issue of Fact

The Superior Court held that, even if the Cartwright Act claim could advance to trial, applying the *Tamoxifen* standard would deprive it of jurisdiction because "the determination of fraud and inequitable conduct would involve substantial questions of patent law, which this Court does not have jurisdiction to decide." Order at 5 (A.A. 2686). This holding rested on a faulty premise: that applying *Tamoxifen* necessarily requires a

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[98] The Superior Court also stated: "Even if there were such allegations, inequitable conduct is only an equitable defense to a patent infringement suit which, if proven, can render the entire patent unenforceable." Order at 5 (citing *Hoffman-La Roche, Inc. v. Promega Corp.* (Fed. Cir. 2003) 323 F.3d 1354, 1372). This further demonstrates the Superior Court's misunderstanding of the law. Appellants do not seek to raise a separate cause of action arising from Bayer's inequitable conduct in obtaining the '444 patent. Instead, they offer the facts surrounding this conduct and the *Bayer v. Barr* litigation to overcome Respondents' affirmative defense under *Tamoxifen*.

verdict on whether Bayer engaged in inequitable conduct in obtaining the '444 patent. It does not; it only requires a finding as to whether Bayer's suit was a sham.

The Superior Court erred by revisiting an issue already decided when the federal district court presiding over the multi-district Cipro proceedings remanded this case to California. As the federal court found, "even if patent law would have legitimized the original Bayer Barr agreement which would otherwise have been unlawful under state law, that smacks of a defense more than that of a failure of plaintiffs to state a viable cause of action under state law." *Cipro*, 166 F. Supp. 2d at 748. The remand order's holding—that jurisdiction exists in this Court, not in the federal courts—has preclusive effect. *See Metropolitan Cas. Co. v. Stevens* (1941) 312 U.S. 563, 568-69 (federal court's refusal to exercise jurisdiction, and remand of claims to state court, estops any argument that state court lacks jurisdiction); *Mertan v. E.R. Squibb & Sons, Inc.* (C.D. Cal. 1980) 581 F. Supp. 751, 753 (federal court's remand of claims to state court "is *res judicata* and constitutes collateral estoppel"). The Superior Court never addressed the remand order.

The Second Circuit reached the same conclusion as the remand order when it declined to transfer the claims of the federal direct purchaser plaintiffs to the Federal Circuit because they "rely on several theories, including alternative theories that do not require the determination of any substantial question of patent law." *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, Second Circuit Case No. 05-2863, Docket Entry of Nov. 7, 2007.

Appellants' claims arise under California law, so the California courts have jurisdiction over them. It is well-established that

> there is broad state jurisdiction over matters affecting patents, the Supreme Court has clearly blessed such state

> power, and the federal courts have shown a clear lack of concern with state adjudication of such matters. . . . The state courts are said to be fully competent to adjudicate patent questions that come before them in contract, property and tort cases so long as the case itself does not arise under the patent laws. . . . Jurisdiction of the state court founded on contract or tort is not defeated because the existence, validity or construction of a patent may be involved. An aggrieved competitor can sue for damages in the state court for trade libel and unfair competition. . . .

Mattel, Inc. v. Luce, Forward, Hamilton & Scripps (Second Dist. 2002) 99 Cal. App. 4th 1179, 1186 (internal quotation marks, alterations, and citations omitted).

Whether a claim "arises under" patent law is a question of law which "must be determined from what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration, unaided by anything alleged in anticipation or avoidance of defenses which it is thought the defendant may interpose." *Franchise Tax Board of Calif. v. Constr. Laborers Vacation Trust* (1983) 463 U.S. 1, 10 (citation omitted). Further, "a claim supported by alternative theories in the complaint may not form the basis for" exclusive federal jurisdiction under 28 U.S.C. § 1338(a) "unless patent law is essential to each of those theories." *Christianson v. Colt Indus. Operating Corp.* (1988) 486 U.S. 800, 810. The Fourth District recently applied this rule to hold that neither of "two *potential* patent law questions" could extinguish state-court jurisdiction over a licensing dispute because relief "would not *necessarily depend* on the resolution of such issues." *Applera Corp. v. MP Biomedicals, LLC* (Fourth Dist. 2009) 173 Cal. App. 4th 769, 784-85 (emphasis in original).

Here, neither the *per se* rule, the rule of reason, nor the rule of *Tamoxifen* depends on the resolution of a substantial question of patent law. But even if the enforceability of the patent had to be determined, the U.S. Supreme Court has held that state courts "must join federal courts in

judging whether an issued patent is valid." *Kewanee Oil Co. v. Bicron Corp.* (1974) 416 U.S. 470, 492 (citing *Lear*, 395 U.S. at 675 (vacating and remanding case to "the California Supreme Court . . . to pass on the question of patent validity")). Likewise, the First District Court of Appeal has found it "well settled that state courts have jurisdiction to determine matters of title, infringement or validity of patents where such determination is ancillary and necessary to the main action." *Blumenfeld v. Arneson Prods., Inc.* (First Dist. 1971) 172 U.S.P.Q. 76, 78. There, the court determined that the "validity of respondent's patent . . . could have been raised in the trial of the action" in state court. *Id.* at 81. *See also Mattel*, 99 Cal. App. 4th at 1186 (holding that "unfair competition" claims raising patent validity questions can proceed in the California courts).

Under the Superior Court's reasoning, the presence of any patent law issue in a case would deprive California courts of jurisdiction. However, the Federal Circuit's recent decision in *ClearPlay, Inc. v. Abecassis* (Fed. Cir. 2010) 602 F.3d 1364, confirms that not every question of patent law qualifies as "substantial." The parties in *ClearPlay*, ClearPlay and Nissim, had executed a patent licensing agreement to settle an infringement suit concerning patents for systems for filtering objectionable content from DVDs. *Id.* at 1364. A dispute then arose as to whether ClearPlay had breached the license. *Id.* at 1364-65. The district court adopted the Special Master's recommendation that no breach had occurred, at which point Nissim informed ClearPlay that it believed the court's interpretation terminated the license in light of its terms. *Id.* at 1365. The court disagreed. *Id.* at 1365-66. ClearPlay sought and secured a preliminary injunction prohibiting Nissim from continuing to represent to third parties that the license was void. *Id.* In its appeal, Nissim argued that the Federal Circuit, not the Eleventh Circuit sitting in diversity, should decide the dispute because it raised issues of patent law. *Id.* at 1366. The Federal

Circuit dismissed the argument and remanded the case to the Eleventh Circuit. The court held that exclusive federal patent jurisdiction "extends 'only to those cases in which a well-pleaded complaint establishes either [1] that federal patent law creates the cause of action or [2] that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims.'" *Id.* at 1366 (quoting *Christianson*, 486 U.S. at 809).

Patent law is not a "necessary element of one of the well-pleaded claims" in this case. *Id.* As the federal court already found, simply because Bayer might raise the strength of its patent as part of its affirmative defense under *Tamoxifen* does not extinguish the California courts' jurisdiction. A case "raising a federal patent law defense does not, for that reason alone, 'arise under' patent law, for jurisdiction purposes even if the defense is anticipated in the plaintiffs' complaint, and even if both parties admit that the defense is the only question truly at issue in the case." *Christianson*, 486 U.S. at 809 (internal quotation marks and citation omitted). *See, e.g.*, *Durgom v. Janowiak* (Fourth Dist. 1999) 74 Cal. App. 4th 178, 183 (a patent issue raised as a defense cannot divest a state court of jurisdiction); *ClearPlay*, 2010 WL 1568582, at *4 (remanding claims to state court despite the possibility "that patent law issues could arise in the course of litigating any one of" the claims for relief).[99]

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[99] In support of its jurisdictional holding, the Superior Court relied on *Lockwood v. Sheppard, Mullin, Richter & Hampton* (Second Dist. 2009) 173 Cal. App. 4th 675. Nothing in that decision suggests the California courts lack jurisdiction here. *Lockwood* involved an attorney malpractice claim which, unlike these antitrust and unfair competition claims, could be resolved only if the court stood in the shoes of the Patent Office to decide whether the Patent Office would have denied a petition for re-examination had attorneys not misrepresented facts to it. *Id.* at 687. By contrast, here, the finder of fact need not stand in the shoes of the Patent Office.

V. The Superior Court Erred in Granting Summary Judgment to Watson

The Superior Court mistakenly held that Watson could not be held liable for the violations embodied in the Cipro Agreements because it was "not involved" in them and "had no relationship to HMR or Rugby when those agreements were made." Order at 13 (A.A. 2694). In fact, Watson belongs in this case because it knowingly received payments in accordance with the Cipro Agreements.

Watson acquired Rugby from HMR in 1998 with the specific intent to benefit from the Cipro Agreements. Pursuant to the Side Letter Agreement between Watson and HMR, Watson was entitled to receive numerous rights, benefits, and other rewards from the unlawful agreements.[100] And discovery has shown that Watson in fact did receive financial benefits from the Cipro Agreements.[101] Watson's own summary judgment brief conceded that "Watson received half of the proceeds from ciprofloxacin proceeds that HMR received from Barr." Watson Mot. at 4.

Barr gained $496 million in revenues from selling Bayer-manufactured ciprofloxacin at supra-competitive prices between June 2003 and June 2004.[102] Barr was required to provide half of those proceeds to HMR.[103] HMR, in turn, was required to provide half of that sum to Watson.[104] Watson, then, received approximately $124 million from its participation in the conspiracy that resulted in the Cipro Agreements.

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[100] *See* Side Letter Agreement. (A.A. 651).

[101] Responses and Objections of HMR and Rugby to MDL Plaintiffs' First Request for Admissions to Defendants, dated Dec. 2, 2003. (A.A. 862).

[102] Barr Press Release dated Aug. 5, 2004. (A.A. 1606).

[103] Amendment to Agreement By and Between Rugby and Barr, dated Mar. 29, 1996. (A.A. 647).

[104] Side Letter Agreement. (A.A. 651).

The Superior Court's conclusion that Watson never joined the conspiracy is contradicted by the facts. Barr and HMR did not pay Watson $124 million for nothing. The evidence shows that Watson was paid to guarantee that Rugby complied with its agreement not to compete with Cipro, to ensure that Watson would not help other firms compete with Cipro, and in exchange for Watson's promise not to develop any ANDAs for ciprofloxacin.[105] As the HMR executive who negotiated the Side Letter Agreement testified: "Watson wanted to be a party and be -- have benefit to the proceeds of those agreements. . . .Watson had requested to be a beneficiary of the settlement on Cipro as part of the purchase of Rugby."[106] A Watson executive who was involved in the negotiations testified that the Side Letter Agreement includes "a prohibition against Watson selling a competing product. And we negotiated that point fairly extensively . . . ."[107]

The Superior Court neglected to mention the evidence demonstrating that Watson consented to and benefited from the unlawful agreements. This evidence dictates that the claims against Watson should proceed to trial. *See DeVries v. Brumback* (1960) 53 Cal. 2d 643, 648 (under California law, "every one who enters into such a common design is in law a party to every act previously or subsequently done by any of the others in pursuance of it."); CACI 3601 (jury instructions for "ongoing conspiracy" state: "If you decide that [name of defendant] joined the conspiracy to

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[105] Amendment to Agreement By and Between Rugby and Barr, dated Mar. 29, 1996 (A.A. 647); Settlement Agreement and Mutual Release, dated Jan. 8, 1997, Between and Among Bayer, HMR, and Rugby (A.A. 734); Stock Purchase Agreement Among HMR, Marisub, Inc., and Watson, dated Aug. 25, 1997 (A.A. 1614).

[106] Downey Dep., at 316:20-22, 325:10-12. (A.A. 549, 552).

[107] Excerpts from the May 16, 2003 Deposition of David Lawrence, at 88:24-89:1. (A.A. 1677-78.)

commit [insert tort theory], then [he/she] is responsible for all acts done as part of the conspiracy, whether the acts occurred before or after [he/she] joined the conspiracy.").

Watson's entrance into the conspiracy to share monopoly profits from the sale of Cipro does not get a free pass from antitrust liability simply because Watson was not an original party to the anticompetitive agreement. "One who enters a conspiracy late, with knowledge of what has gone before, and with the intent to pursue the same objective, may be charged with preceding acts in furtherance of the conspiracy." *Indus. Bldg. Materials, Inc. v. Interchem. Corp.* (9th Cir. 1970) 437 F.2d 1336, 1343. *See also DeVries*, 53 Cal. 2d at 648.

VI. The Superior Court's Failure to Provide Any Explanation for Its Evidentiary Ruling Was Reversible Error

Appellants submitted 30 individual objections to the evidence offered by Respondents in support of their motions for summary judgment. *See* Plaintiffs' Objections to Defendants' Evidence Submitted in Defendants' Motions for Summary Judgment (A.A. 233). Among other things, Appellants objected to the admissibility of the litigations occurring after the Cipro Agreements that involved a narrowed Cipro patent. *See id.* at Objections to Bayer's Exhibits, Objection Nos. 8-10; Objections to Generic Defendants' Evidence, Objection Nos. 5-7 (A.A. 235-38). Not only did the Superior Court rely heavily on this inadmissible evidence in rendering judgment, Order at 5 (A.A. 2686), but it overruled all of Appellants' objections with a one-line statement: "Plaintiffs' evidentiary objections are overruled." Order at 7 (A.A. 2688). This threadbare ruling warrants reversal.

A similar one-line statement was held to be "a manifest abuse of discretion" in *Nazir v. United Airlines, Inc.* (First Dist. 2009) 178 Cal. App. 4th 243, 257. The court explained: "This is hardly a ruling, as it could not

provide any meaningful basis for review." *Id.* at 255. Therefore, the court "could not agree more" with the plaintiff's contention that the "trial court's blanket ruling sustaining all but one of defendants' objections was error." *Id.* The ruling violated the well-settled principle that "a trial court presented with timely evidentiary objections in proper form must expressly rule on the individual objections. . . ." *Id.* at 255 (quoting *Demps v. San Francisco Housing Auth.* (First Dist. 2007) 149 Cal. App. 4th 564, 578).

The Superior Court's blanket statement overruling all of Appellants' evidentiary objections provides no meaningful basis for review, and should be reversed.

CONCLUSION

For the foregoing reasons, the Court should reverse the grant of summary judgment and remand the claims for trial.

Respectfully submitted,

Dated: July 1, 2010

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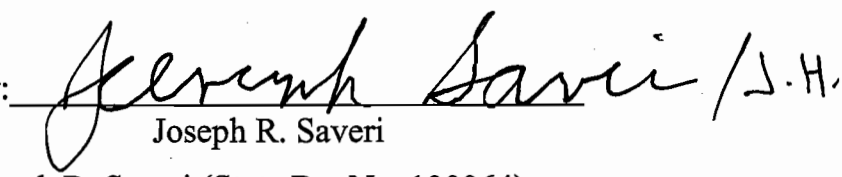
By:  /J.H.
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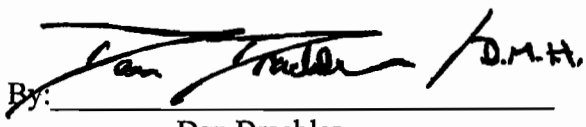
By: 

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CERTIFICATE OF WORD COUNT

[California Rule of Court 8.204(c)(1)]

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