In the

Supreme Court

of the

State of California

S198616
IN RE CIPRO CASES I AND II

KARYN McGAUGHEY, et al.,
Petitioners,

v.

BAYER CORPORATION, et al.,
Respondents.

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

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

ANSWER BRIEF OF RESPONDENT BAYER CORPORATION

Peter B. Bensinger, Jr.*
BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP
Courthouse Place,
54 West Hubbard Street, Suite 300
Chicago, IL 60654
Telephone: (312) 494-4400
Facsimile: (312) 494-4440

Kevin D. McDonald*
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
Telephone: (202) 879-3939
Facsimile: (202) 626-1700

Charles A. Bird, *SBN: 056566*
Christopher J. Healey, *SBN: 105798*
Todd R. Kinnear, *SBN: 208831*
McKENNA LONG & ALDRIDGE LLP
600 West Broadway, Suite 2600
San Diego, CA 92101-3391
Telephone: (619) 236-1414
Facsimile: (619) 645-5321

**Admitted pro hac vice*

Attorneys for Defendant-Respondent Bayer Corporation

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51 Louisiana Avenue, N.W.
Washington, D.C. 20001
Telephone: (202) 879-3939
Facsimile: (202) 626-1700

**Admitted pro hac vice*

Attorneys for Defendant-Respondent Bayer Corporation

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

INTRODUCTION AND SUMMARY 1

STATEMENT OF FACTS 7

ARGUMENT 11

I. UNDER CALIFORNIA LAW, A SETTLEMENT WITHIN THE SCOPE OF THE PATENT IS LAWFUL 11

A. California and Federal Law Reject Plaintiff's Attempt To Ignore Bayer's Right To Exclude Infringing Competition 11

B. Plaintiffs' Attempt To Rewrite California and Federal Law Is Without Merit 16

C. The Scope of the Patent Rule Derives from Basic Principles of Antitrust and Patent Law 20

1. *Antitrust Law*: Plaintiffs Cannot Show that the Allegedly "Excluded" Competition Was Lawful 21

2. *Patent Law*: A Patentee Has the Right To Settle Within the Scope of the Patent, Unless the Patent Suit Was Objectively Baseless 23

3. The Scope of the Patent Rule Is Completely Consistent with U.S. Supreme Court Precedent 27

D. The Court of Appeal Correctly Applied the Scope of the Patent Rule To Affirm Summary Judgment 30

II. COURTS UNIFORMLY REJECT PER SE LIABILITY WHERE THE SETTLEMENT IS WITHIN THE SCOPE OF THE PATENT 32

A. Plaintiffs Do Not Attempt To Satisfy this Court's Requirements for Per Se Illegality 32

B. Plaintiffs Cannot Articulate a Theory of Harm to Lawful Competition Under the Rule of Reason 35

C. This Court Should Reject Plaintiffs' Request To Engage in Judicial Legislation 39

III. FEDERAL PATENT LAW WOULD PREEMPT ANY CALIFORNIA RULE THAT SETTLEMENTS WITHIN THE SCOPE OF A PATENT VIOLATE THE CARTWRIGHT ACT 41

A. Plaintiffs Misunderstand the Doctrine of Substantive Preemption 41

B. State Law May Not Add or Detract from the Fundamental Rights of Patent Holders 43

C. Patent Law Preempts Liability Here Without Proof that the Patent Suit Was Objectively Baseless 45

IV. ANY CALIFORNIA RULE OF LIABILITY BASED UPON ASSESSING THE "STRENGTH" OF THE PATENT WOULD BE SUBJECT TO EXCLUSIVE FEDERAL JURISDICTION 47

A. A State Law Cause of Action with an Embedded Federal Patent Issue May Still Arise Under Patent Law 47

B. A California Claim that Depends for Its Success on Evaluating Patent Strength Arises Under Patent Law 49

V. ANY PUTATIVE CLAIM THAT BAYER'S PATENT SUIT WAS OBJECTIVELY BASELESS FAILS FOR MULTIPLE OTHER REASONS 50

VI. PLAINTIFFS HAVE WAIVED ANY ARGUMENT BASED UPON THE UCL OR EVIDENTIARY RULINGS 52

CONCLUSION 54

CERTIFICATE OF WORD COUNT 56

TABLE OF AUTHORITIES

Page

CASES

Access Telecom, Inc. v. MCI Telecommunications Corp.
(5th Cir. 1999) 197 F.3d 694 21

Additive Controls & Measurement Systems, Inc. v. Flowdata, Inc.
(Fed.Cir. 1993) 986 F.2d 476 47

Alfred E. Mann Foundation for Scientific Research v. Cochlear Corp. (Fed.Cir. 2010) 604 F.3d 1354 ..... 24, 25

American Well Works Co. v. Layne & Bowler Co.
(1916) 241 U.S. 257 48

Andrx Pharmaceuticals, Inc. v. Biovail Corp. Internat.
(D.C. Cir. 2001) 256 F.3d 799 19

Arkansas Carpenters Health & Welfare Fund v. Bayer AG
(2d Cir. 2010) 604 F.3d 98, cert. denied
(2011) 131 S.Ct. 1606 ..... 1, 10, 15, 19, 33

Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.
(N.D.Ill. 2003) 289 F.Supp.2d 986 ..... 5, 23, 27, 36

Asahi Kasei Pharma Corp. v. CoTherix, Inc.
(2012) 204 Cal.App.4th 1 20

AT&T Mobility LLC v. Concepcion
(2011) 131 S.Ct. 1740 46

Bayer AG and Miles, Inc. v. Barr Laboratories, Inc.
(S.D.N.Y. No. 92 Civ. 0381) 7

Bayer AG v. Carlsbad Technologies, Inc.
(S.D. Cal. June 7, 2002 and Aug. 7, 2002, No. 01CV0867-B) 2, 9

Bayer AG v. Schein Pharmaceuticals, Inc.
(D.N.J. 2001) 129 F.Supp.2d 705, affd.
(Fed.Cir. 2002) 301 F.3d 1306 ..... 2, 9

Bement v. National Harrow Co.
(1902) 186 U.S. 70 ..... 3, 12, 25, 26, 34, 44, 46

Page

Biotechnology Industry Org. v. District of Columbia
(Fed.Cir.) 496 F.3d 1362, rehearing denied (2007)
505 F.3d 1343 ..... 24, 25, 44, 46

Blank v. Coffin
(1942) 20 Cal.2d 457 54

Bonito Boats, Inc. v. Thunder Craft Boats, Inc.
(1989) 489 U.S. 141 44

Brunswick Corp. v. Riegel Textile Corp.
(7th Cir. 1984) 752 F.2d 261 37

Buckman Co. v. Plaintiffs' Legal Committee
(2001) 531 U.S. 341 51

California ex rel. Van de Kamp v. Texaco, Inc.
(1988) 46 Cal.3d 1147, 1168 20

Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.
(1999) 20 Cal.4th 163 54

Chavez v. Whirlpool Corp.
(2001) 93 Cal.App.4th 363 53

Christianson v. Colt Industries Operating Corp.
(1988) 486 U.S. 800 ..... 47, 48, 49

Dawson Chemical Co. v. Rohm & Haas, Co.
(1979) 448 U.S. 176 ..... 3, 23

Duplan Corp. v. Deering Milliken, Inc.
(4th Cir. 1976) 540 F.2d 1215 ..... 26, 45

Exxon Corp. v. Superior Court
(1997) 51 Cal.App.4th 1672 ..... 4, 21

Flex-Foot, Inc. v. CRP, Inc.
(Fed.Cir. 2001) 238 F.3d 1362 38

Page

Franchise Tax Board of Cal. v. Construction Laborers Vacation Trust
(1983) 463 U.S. 1 48

FTC v. Watson Pharmaceuticals, Inc.
(2012) 2012 WL 1427789 ..... 1, 15, 16, 18, 22, 23, 25, 35, 38, 54

Fruit Machinery Co. v. F.M. Ball & Co.
(1953) 118 Cal.App.2d 748 ..... 1, 3, 5, 11, 12, 15-17, 24, 26

Globetrotter Software, Inc. v. Elan Computer Group, Inc.
(Fed.Cir. 2004) 362 F.3d 1367 ..... 27, 46

Golan v. Pingel Enterprise, Inc.
(Fed.Cir. 2002) 310 F.3d 1360 46

Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.
(2005) 545 U.S. 308 49

Grimes v. Hoschler
(1974) 12 Cal.3d 305 43

Harris v. Capital Growth Investors XIV
(1991) 52 Cal.3d 1142 54

Holiday Matinee, Inc. v. Rambus, Inc.
(2004) 118 Cal.App.4th 1413 ..... 47, 48, 49

Hunter Douglas, Inc. v. Harmonic Design, Inc.
(Fed.Cir. 1998) 153 F.3d 1318 ..... 44, 49

Hynix Semiconductor Inc. v. Rambus, Inc.
(N.D.Cal. 2007) 527 F.Supp.2d 1084 21

In re Canadian Import Antitrust Litig.
(8th Cir. 2006) 470 F.3d 785 1

In re Cardizem CD Antitrust Litigation
(6th Cir. 2003) 332 F.3d 896, cert. denied
(2004) 543 U.S. 939 ..... 16, 18, 19, 33, 34

In re Ciprofloxacin Hydrochloride Antitrust Litigation
(E.D.N.Y. 2001) 166 F.Supp.2d 740 10

Page

In re Ciprofloxacin Hydrochloride Antitrust Litigation
(E.D.N.Y. 2003) 261 F.Supp.2d 188 ..... 8, 22, 36

In re Ciprofloxacin Hydrochloride Antitrust Litigation
(E.D.N.Y. 2005) 363 F.Supp.2d 514 ..... 5, 9, 10, 15, 26, 28, 34, 37, 38, 51, 52

In re Ciprofloxacin Hydrochloride Antitrust Litigation
(Fed.Cir. 2008) 544 F.3d 1323, cert. denied
(2009) 129 S.Ct. 2828 ..... 1, 11, 15, 18, 19, 21, 26, 28, 31, 51, 52

In re Hoechst Marion Roussel, Inc.
(2001) 131 F.T.C. 924 34

In re Jose C.
(2009) 45 Cal.4th 534 42

In re Netflix Antitrust Lit.
(N.D.Cal. 2007) 506 F.Supp.2d 308 51

In re Tamoxifen Citrate Antitrust Litigation
(E.D.N.Y. 2003) 277 F.Supp.2d 121 46

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(2d Cir. 2006) 466 F.3d 187, cert. denied
(2007) 551 U.S. 1144 ..... 1, 14-16, 18-19, 22, 23, 34, 35

Jenkins v. Greyhound Lines, Inc.
(N.D. Cal. 1971) 1971 WL 529 21

Jersey Maid Milk Products Co. v. Brock
(1939) 13 Cal.2d 620 53

Kaiser Foundation Health Plan, Inc. v. Abbott Laboratories, Inc.
(9th Cir. 2009) 552 F.3d 1033 34

King Instruments Corp. v. Perego
(Fed.Cir. 1995) 65 F.3d 941 24

Korea Supply Co. v. Lockheed Martin Corp.
(2003) 29 Cal.4th 1134 53

Page

Landmark Screens, LLC v. Morgan, Lewis & Bockius, LLP
(2010) 183 Cal.App.4th 238 49

Lockwood v. Sheppard, Mullin, Richter & Hampton
(2009) 173 Cal.App.4th 675 ..... 49, 50

Loctite Corp. v. Ultraseal Ltd.
(Fed.Cir. 1985) 781 F.3d 861 39

Mallinckrodt, Inc. v. Medipart, Inc.
(Fed.Cir. 1992) 976 F.2d 700 13

Marin County Board of Realtors, Inc. v. Palsson
(1976) 16 Cal.3d 920 33

Mars v. Wedbush Morgan Securities, Inc.
(1991) 231 Cal.App.3d 1608 50

Mattel, Inc. v. Luce, Forward, Hamilton & Scripps
(2002) 99 Cal.App.4th 1179 ..... 48, 49

Oakland Raiders v. National Football League
(2005) 131 Cal.App.4th 621 50

Olszewski v. Scripps Health
(2003) 30 Cal.4th 798 43

Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.
(1993) 508 U.S. 49 31

Reid v. Google
(2010) 50 Cal.4th 513 54

Reynolds v. California Dental Service
(1988) 200 Cal.App.3d 590 33

Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.
(7th Cir. 1907) 154 F. 358 21

Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.
(Fed.Cir. 2000) 204 F.3d 1368 51

Page

SanDisk Corp. v. STMicroelectronics, Inc.
(N.D.Cal. 2008) 2008 WL 4615605 27

Schering-Plough Cartwright Act Cases
(Ala.Cty.Super.Ct. Dec. 17, 2009) JCCP No. 4559 13

Schering-Plough Corp. v. FTC
(11th Cir. 2005) 402 F.3d 1056, cert. denied
(2006) 548 U.S. 919 ..... 14, 16, 19, 37, 54

SCM Corp. v. Xerox Corp.
(2d Cir. 1981) 645 F.2d 1195 ..... 5, 14

Screen Extras Guild, Inc. v. Superior Court
(1990) 51 Cal.3d 1017 ..... 42, 43

Sears, Roebuck & Co. v. Stiffel Co.
(1963) 376 U.S. 225 ..... 3, 44

Sicom Systems Ltd. v. Agilent Technologies, Inc.
(Fed.Cir. 2005) 427 F.3d 971 25

Standard Oil Co. v. United States
(1931) 283 U.S. 163 30

T.B. Harms Co. v. Eliscu
(2d Cir. 1964) 339 F.2d 823 48

Therasense, Inc. v. Becton, Dickinson & Co.
(Fed.Cir. 2011) 649 F.3d 1279 52

Quanta Computer, Inc. v. LG Electronics, Inc.
(2008) 553 U.S. 617 29

United States v. General Electric Co..
(1926) 272 U.S. 476 12

United States v. Masonite Corp.
(1942) 316 U.S. 265 29

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(1963) 374 U.S. 174 29

Page

United States v. Studiengesellschaft Kohle, m.b.H.
(D.C.Cir. 1981) 670 F.2d 1122 ..... 3, 14, 24, 30, 37

United States v. Westinghouse Electric Corp.
(9th Cir. 1981) 648 F.2d 642 ..... 6, 26, 44

USM Corp. v. SPS Technologies, Inc.
(7th Cir. 1982) 694 F.2d 505 ..... 13, 17

Valley Drug Co. v. Geneva Pharmaceuticals, Inc.
(11th Cir. 2003) 344 F.3d 1294, cert. denied
(2004) 543 U.S. 939 ..... 14, 16, 18, 19, 22, 27, 32, 33, 36, 37, 38

Viva! Internat. Voice for Animals v. Adidas Promotional Retail Operations, Inc.
(2007) 41 Cal.4th 929 43

Vulcan Powder Co. v. Hercules Powder Co.
(1892) 96 Cal. 510 ..... 12, 13, 17, 24, 35

Walker, Inc. v. Food Machinery
(1965) 382 U.S. 172 ..... 28, 29, 31

Whitmore v. Arkansas
(1990) 495 U.S. 149 22

Zenith Electronics Corp. v. Exzec, Inc.
(Fed.Cir. 1999) 182 F.3d 1340 46

STATUTES

U.S. Const. art I, § 8 23

21 U.S.C. § 355 ..... 7, 10

28 U.S.C. § 1338 ..... 41, 47, 49

35 U.S.C. § 154 19

35 U.S.C. § 271 ..... 8, 36

35 U.S.C. § 282 23

Page

Drug Price Competition and Patent Term Restoration Act
Pub. L. No. 98-417, 98 Stat. 1585 7

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Cal. Rules of Court, rule 8.204 53

Cal. Rules of Court, rule 8.520 52

Cal. Rules of Court, rule 8.504 55

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H.R. 3995, 112th Cong. (2012) 40

S. 27, 112th Cong. (2011) 40

INTRODUCTION AND SUMMARY

The courts below and multiple federal circuit courts agree that a settlement within the exclusionary scope of a patent is legal unless the patent owner committed fraud on the Patent Office or the patent litigation was a sham. (E.g., Opn. 3; *FTC v. Watson Pharmaceuticals, Inc.* (11th Cir. 2012) 2012 WL 1427789 (*Watson*); *In re Tamoxifen Citrate Antitrust Lit.* (2d Cir. 2006) 466 F.3d 187 (*Tamoxifen*).) These holdings reflect the long-standing California principle that the antitrust laws do not restrict any "contract made ... in the exercise, and *within the scope*, of the rights given and the protection accorded by the patent." (*Fruit Machinery Co. v. F.M. Ball & Co.* (1953) 118 Cal.App.2d 748, 758 [emphasis added] (*Fruit Machinery*).)

The Court of Appeal correctly held that defendants had no antitrust liability arising from the settlement of patent litigation concerning Bayer's blockbuster antibiotic, Cipro. There is no dispute that the settlement was within the scope of Bayer's patent, and plaintiffs did not allege that Bayer procured its patent by fraud or engaged in sham litigation. The opinion below is consistent with an unbroken line of federal appellate decisions applying the "scope of the patent" rule to Hatch-Waxman settlements. Indeed, two different federal circuits have rejected antitrust claims—including Cartwright Act and UCL claims—based on *the same settlement* at issue here. (*In re Ciprofloxacin Hydrochloride Antitrust Lit.* (Fed.Cir. 2008) 544 F.3d 1323, 1336 (*Cipro-III*) [federal and California law]; *Arkansas Carpenters Health & Welfare Fund v. Bayer AG* (2d Cir. 2010) 604 F.3d 98, 106 (*Cipro-IV*) [federal law].)

The essential facts of this case demonstrate why so many courts have reached the same conclusion:

Bayer owned the patent on Cipro's sole active ingredient, ciprofloxacin hydrochloride. (10AA 2340.) Because all generic drugs must use the pioneer drug's active ingredient, all generic versions of Cipro infringed Bayer's patent. (Opn. 4.) Thus, when Barr sought permission from the Food and Drug Administration (FDA) to market its generic version of Cipro and Bayer brought an infringement suit, Barr stipulated that its product would infringe. (2AA 244, ¶98.) Barr claimed instead that the patent was invalid and unenforceable. (Opn. 6.)

Bayer and Barr later settled the patent suit. Barr agreed to honor the patent, and Bayer granted Barr a license permitting competing entry six months before patent expiration. Bayer agreed to make settlement payments to Barr, which ultimately totaled $398 million. Those payments constituted only 6.5% of Bayer's U.S. gross sales of Cipro tablets for the same period. (1RA 39, ¶3; 4AA 788 §4.01(a).)

After the settlement, Bayer submitted its patent to the Patent and Trademark Office ("PTO") for reexamination, and the PTO reaffirmed the Cipro claims. Subsequently, Bayer successfully defended the patent in three district court challenges, and in two appeals to the Federal Circuit. (See, e.g., 2AA 253 at ¶31; *Bayer AG v. Schein Pharmaceutical, Inc.* (D.N.J. 2001) 129 F.Supp.2d 705, affd. (Fed.Cir. 2002) 301 F.3d 1306 (*Schein*); 1RA 181-227 [*Bayer AG v. Carlsbad Technology, Inc.* (S.D.Cal. June 7, 2002 and Aug. 7, 2002, No. 01CV0867-B) (*Carlsbad*)].)

Plaintiffs do not, and cannot, dispute these facts. Nonetheless, they ask this Court to abandon both California and federal precedent and declare this settlement illegal per se. Plaintiffs' theory suffers from two principal flaws. *First*, it is contrary to California law. *Second*, if accepted, it would be preempted by federal patent law.

1. The Cartwright Act. "The grant of a patent is the grant of a statutory monopoly." (*Sears, Roebuck & Co. v. Stiffel Co.* (1963) 376 U.S. 225, 229 (*Sears*).) The Cipro patent thus gave Bayer the rights associated with a patent, including "the right to exclude others from profiting by the patented invention." (*Dawson Chemical Co. v. Rohm & Haas, Co.* (1979) 448 U.S. 176, 215 (*Dawson*).) In *Fruit Machinery*, the Court of Appeal held that the Cartwright Act does not restrict agreements "within the scope" of the patent, and permits "conditions of sale [that] are normally and reasonably adapted to secure pecuniary reward for the patentee's monopoly." (*Fruit Machinery, supra*, 118 Cal.App.2d at p.758.) As the U.S. Supreme Court stated long ago, "[t]he fact that the conditions in the contracts keep up the monopoly or fix prices does not render them illegal." (*Bement v. National Harrow Co.* (1902) 186 U.S. 70, 91 (*Bement*).)

The law is therefore clear that Bayer's patent rights may not be ignored, as plaintiffs urge. In California, as elsewhere, "the protection of the patent laws and the coverage of the antitrust laws are not separate issues." (*U.S. v. Studiengesellschaft Kohle, m.b.H.* (D.C. Cir. 1981) 670 F.2d 1120, 1128 (*Studiengesellschaft*).) Because antitrust law does not protect infringing competition, plaintiffs bear the burden of showing that

the generic competition they allege to have been excluded was lawful competition. Otherwise, they cannot satisfy the first step of any Cartwright Act analysis—to show a "substantially adverse effect on competition in the relevant market." (*Exxon Corp. v. Superior Court* (1997) 51 Cal.App.4th 1672, 1681 [citation omitted] (*Exxon*).) (See Part I.)

Plaintiffs' attempt to avoid this burden by invoking the per se rule cannot be supported. No court has applied such a rule to an agreement within the scope of a patent, and no enforcement agency has advocated one. Plaintiffs make no attempt to meet California's high standard for per se liability. (See Part II.A.)

Plaintiffs have no choice but to rely on the per se rule, because it *assumes* the competitive harm that they cannot prove. In a dozen years of Hatch-Waxman litigation, no plaintiff has articulated a theory under which a settlement within the scope of a patent causes *actual* harm to lawful competition. Courts recognize that plaintiffs' arguments prove too much, because (1) all settlements involve consideration to both parties based on perceived risk and (2) all settlements "halt adversarial testing" of the patent. (OB 25.) But neither the form of consideration nor its amount changes the analysis of whether the "excluded" competition was within the patent's scope. And no principle of law supports plaintiffs' insistence that patent disputes be litigated to the death. Indeed, plaintiffs' attempt to ignore the patent holder's right to exclude would render not just every settlement, but every patent *license*, per se illegal as well. The courts have correctly concluded that plaintiffs' theories are not simply wrong, but "would work a

revolution in patent law." (*In re Ciprofloxacin Hydrochloride Antitrust Lit.* (E.D.N.Y. 2005) 363 F.Supp.2d 514, 529 (*Cipro-II*).) (See Part II.B.)

2. Substantive Preemption. The second flaw is that plaintiffs' theory would place California law in direct conflict with federal patent law. Any attempt by California to impose liability for excluding competition within the scope of the patent would be preempted under the Supremacy Clause of the U.S. Constitution.

The grant of a patent bestows fundamental rights on the patent holder to enter into patent agreements or to refuse to do so; to place restrictions as to time, location, price, and quantity on the sale of the patented invention; to assert the patent in the marketplace and in the courts; and to withdraw or settle such suits. (E.g., *Fruit Machinery, supra*, 118 Cal.App.2d at pp.751-752; *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.* (N.D.Ill. 2003) 289 F.Supp.2d 986, 992-993 [Posner, J., by designation] (*Asahi Glass*).) Indeed, the right to settle infringement litigation is so fundamental that courts use it to determine whether a party actually "owns" the patent. (See Part I.C.2.)

Federal patent law protects the exercise of these fundamental rights from state liability. As long as the patent was not procured by fraud and its assertion was not objectively baseless, "conduct permissible under the patent laws cannot trigger any liability under the antitrust laws." (*SCM Corp. v. Xerox Corp.* (2d Cir. 1981) 645 F.2d 1195, 1206 (*SCM Corp.*).) State law may not adopt rules of liability that "alter and substantially reduce

the established scope of the patent monopoly." (*U.S. v. Westinghouse Electric Corp.* (9th Cir. 1981) 648 F.2d 642, 647-648 (*Westinghouse*).)

If it were to adopt a rule finding Bayer liable for entering an agreement no more exclusionary than the Cipro patent, this Court would be holding that "an antitrust violation may be found where a patent holder does precisely that which the patent laws authorize." (*Westinghouse, supra*, 648 F.2d at p.647.) That is a holding that federal patent law preempts. (See Part III.)

****

While these two flaws in plaintiffs' theories justify affirmance, there are many others. Part IV explains why the Court of Appeal correctly concluded that, assuming plaintiffs had pled an "objectively baseless" claim, California courts would lack jurisdiction to hear it. Part V then addresses several additional grounds on which the Court of Appeal rejected plaintiffs' attempt to satisfy the objectively baseless test. Finally, Part VI addresses plaintiffs' waiver of any UCL and evidentiary issues.

In the end, plaintiffs' argument devolves to a self-interested invocation of consumer "policy" that supposedly justifies limiting established patent rights. That policy assumes that the interest of consumers who may pay lower generic prices in the short run trumps the interest of consumers who prefer newly discovered, life-saving drugs in the long run. The Cartwright Act, like the Sherman Act, does not take sides in this debate. That is why the FTC and other disappointed plaintiffs have attempted since 2006 to have Congress pass a law banning "reverse

payment" settlements. (See Part II.C.) Congress is where any "controversy" over these settlements should be resolved. The Court should reject plaintiffs' invitation to engage in judicial legislation.

STATEMENT OF FACTS

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

The Regulatory Framework. The Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act," governs the interaction between patent protection and generic drugs. (Pub. L. No. 98-417, 98 Stat. 1585, as amended, 21 U.S.C. §355.) To obtain FDA approval for a generic drug under Hatch-Waxman, the manufacturer must file an Abbreviated New Drug Application ("ANDA").

To protect the rights of the pioneer drug manufacturer, a generic seeking approval prior to the expiration of any patent listed with the FDA must include a "Paragraph IV" certification that the patent "is invalid or ... will not be infringed by the ... the [generic] drug." (21 U.S.C. §355(j)(2)(A)(vii)(IV).) The ANDA filer must also show that the "active ingredient of [its proposed] new drug is the same as that of the listed [or pioneer] drug." (21 U.S.C. §355(j)(2)(A)(ii)(I).)

Bayer's U.S. Patent. In 1987, the PTO granted U.S. Patent Number 4,670,444. Claim 12 of the patent covers Cipro's active ingredient, the molecule ciprofloxacin hydrochloride. (2AA 243, ¶2.) Because any form of generic Cipro must contain the same active ingredient, it would infringe Bayer's "compound" patent by definition. (Opn. 4.)

The Patent Litigation. In 1991, Barr filed an ANDA for Cipro with a Paragraph IV certification. (2AA 243, ¶5.) Under Hatch-Waxman, Barr's FDA filing was a technical act of infringement, even though Barr had made no sales subjecting it to infringement damages. (See 35 U.S.C. §271(e)(2); *In re Ciprofloxacin Hydrochloride Antitrust Lit.* (E.D.N.Y. 2003) 261 F.Supp.2d 187, 251 (*Cipro-I*).)

On January 16, 1992, Bayer sued Barr for infringement, based on Barr's ANDA. (2AA 346-50.) Barr stipulated that its ciprofloxacin product would infringe the patent, (2AA 244, ¶8), but asserted counterclaims of invalidity and unenforceability. (2AA 352-58.) Because Barr had made no infringing sales, Bayer lacked the traditional leverage that a patent owner has against an alleged infringer—the threat of infringement damages. Barr's only exposure was the cost of litigation. Bayer, in contrast, faced an enormous risk: the loss of its patent.

In 1996, the patent court denied motions for summary judgment by both Bayer and Barr. (3AA 557-560.) In January 1997, the parties settled. (2AA 247, ¶17.) Barr agreed to a consent judgment affirming the validity of the Cipro patent. (2AA 248, ¶19.) Bayer agreed to supply Barr with ciprofloxacin for licensed resale at least six months before patent expiration. (See 4AA 770-774 §§3.01-3.03.) Bayer made settlement payments that eventually totaled $398.1 million (2AA 251, ¶24), representing 6.5% of U.S. gross sales of Cipro tablets for the payment period. (1RA 39, ¶3; 4AA 788 §4.01(a).)

Bayer's Subsequent Patent Victories. After settling, Bayer submitted the Cipro patent to the PTO for reexamination, and presented the PTO with a roadmap of Barr's invalidity arguments. (Compare 1RA 41-89 with 1RA 91-168.) The PTO issued a reexamination certificate (2AA 252, ¶28) confirming "the validity of claim 12, which was not substantively amended and which all parties agree covers ciprofloxacin hydrochloride." (*Cipro-II*, *supra*, 363 F.Supp.2d at p.519.)

The settlement and reexamination did not prevent later ANDA challenges. Bayer filed four Hatch-Waxman lawsuits against subsequent Cipro challengers (Ranbaxy, Schein, Mylan, and Carlsbad). (2AA 252, ¶29.) Bayer produced the full discovery record from the Barr case to each challenger. (See, e.g., 1RA 173, ¶2.)

The Ranbaxy challenge was dismissed as moot following Ranbaxy's withdrawal of its Paragraph IV certification. (1RA 231, ¶7.) Bayer defeated the validity challenges of Schein and Mylan on summary judgment, and the Federal Circuit affirmed. (See 2AA 253, ¶31; *Schein*, *supra*, 129 F.Supp.2d 705, affd. 301 F.3d 1306.) In *Carlsbad*, San Diego District Judge Brewster rejected Carlsbad's validity challenge after a nine-day bench trial. (See 2AA 254, ¶32; 1RA 181-227 [*Carlsbad*, *supra*, No. 01CV0867-B].) Carlsbad did not appeal.

Cipro Goes Generic. Barr began selling its ciprofloxacin product under the settlement on June 9, 2003. (2AA 255, ¶34.) The Cipro patent expired on December 9, 2003, but the FDA granted pediatric exclusivity to Bayer until June 9, 2004. (2AA 243, ¶¶3-4.) Barr thus entered a full year

before any other generic was authorized to enter. (See 21 U.S.C. §355a(b)(2)(A)(ii).) Since June 2004, numerous other generic versions of Cipro have entered the market. (2AA 255, ¶35.)

Procedural History. Beginning in 2000, various private plaintiffs brought actions attacking the Cipro settlement. Twenty-six federal cases were consolidated in a multi-district litigation (MDL) before the Hon. David Trager. (See *In re Ciprofloxacin Hydrochloride Antitrust Lit.* (E.D.N.Y. 2001) 166 F.Supp.2d 740.) The parties litigated the state and federal cases in tandem, agreeing that discovery in each case would apply to the others. (E.g., 6AA 1253.) The operative amended complaint in this action was filed on April 9, 2003. (2RA 235.)

In March 2005, Judge Trager granted summary judgment to the MDL defendants, holding: "Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." (*Cipro-II, supra*, 363 F.Supp.2d at p.535.)

Plaintiffs then agreed to stay this action pending the MDL appeal. (1RA 12.) All MDL plaintiffs appealed to the Second Circuit, but the defendants moved to transfer the appeal to the Federal Circuit, which has exclusive jurisdiction of cases arising under patent law. (See *Cipro-IV, supra*, 604 F.3d at p.103, fn.10.) The Second Circuit transferred the appeal of the indirect purchasers, whose complaint alleged that Bayer committed fraud and inequitable conduct in obtaining the Cipro patent. (*Ibid.*) The

Second Circuit retained the appeal of the direct purchasers, who made no such allegations. (*Ibid.*)

In 2008, the Federal Circuit affirmed Judge Trager's rulings and stated that Bayer had not committed fraud on the PTO as a matter of law. (*Cipro-III*, *supra*, 544 F.3d at pp.1336, 1341.) The Supreme Court denied certiorari. (*Cipro-III* (2009) 129 S.Ct. 2828.)[1]

After the Federal Circuit's affirmance, the California parties briefed summary judgment. (1RA 16.) In 2009, the superior court granted summary judgment for defendants because, inter alia, "California cases ... hold that conduct falling within the scope of a patent is not an antitrust violation." (11AA 2668.)

In 2011, the Court of Appeal unanimously affirmed.

ARGUMENT

I. UNDER CALIFORNIA LAW, A SETTLEMENT WITHIN THE SCOPE OF THE PATENT IS LAWFUL

A. California and Federal Law Reject Plaintiffs' Attempt To Ignore Bayer's Right To Exclude Infringing Competition

California measures the legality of agreements related to patents by considering at the outset the patent holder's right to exclude infringing competition. Most courts refer to this inquiry as determining "the scope" of the patent. (*Fruit Machinery*, *supra*, 118 Cal.App.2d at p.758.) The U.S. Supreme Court made the point in 1902, when it first considered a Sherman Act claim based on a patent agreement: "The first important and most

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[1] In 2010, the Second Circuit affirmed Judge Trager's opinion as well. (See Part I.A.)

material fact in considering this question is that the agreements concern articles protected by letters patent ...." (*Bement, supra*, 186 U.S. at p.88.) As in *Bement*, when the agreements exclude no more competition than the patent itself, they do not restrain lawful competition. (*Id.* at p.91.) The Court subsequently confirmed that the rule applies even to setting prices under a license, which is "the essence of that which secures proper reward to the patentee." (*U.S. v. General Electric Co.* (1926) 272 U.S. 476, 490.)

The first California decision applying the scope of the patent rule under the Cartwright Act was *Fruit Machinery, supra*, 118 Cal.App.2d 748. There, a patentee sued a licensee for failure to pay royalties. The licensee contended that certain restrictions in the license restrained trade, making the license unenforceable. (*Id.* at p.750.) The licensee argued that the agreement reduced competition by allowing discriminatory royalties. (*Id.* at p.762.)

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

The principle guiding the court in *Fruit Machinery* was not new. In fact, this Court applied the scope of the patent rule well before the Cartwright Act existed, in *Vulcan Powder Co. v. Hercules Powder Co.*

(1892) 96 Cal. 510 (*Vulcan Powder*). *Vulcan Powder* concerned a contract between several dynamite producers setting the terms on which they would compete. (*Id.* at p.514.) Some of the parties had patents on dynamite, but not on all grades. Nonetheless, the agreement covered all sales of dynamite, infringing or not. (*Id.* at p.516.) This Court voided the contract because it went beyond the scope of the patents. (*Ibid.* ["[T]he contract before us is not confined to dynamite produced under the processes of the named patents."]

The two lower courts in this case are not the only California courts to recognize that the same scope of the patent rule applies to a Hatch-Waxman settlement. (*Schering-Plough Cartwright Act Cases* (Ala.Cty.Super.Ct. Dec. 17, 2009) JCCP No. 4559, at *5 ["[O]nly restrictive conduct *outside the scope of the patent grant* will give rise to an antitrust violation." (emphasis added)].) The court in *Schering-Plough* confirmed that a settlement "within the lawful scope of the patent" does not violate California law "even when the settlement involves a reverse payment from the patent holder to the alleged infringer." (*Ibid.*)

Federal Law. The California decisions are consistent with the longstanding federal rule that the antitrust analysis of patent agreements must begin with the exclusionary effect of the patent. (*Mallinckrodt, Inc. v. Medipart, Inc.* (Fed.Cir. 1992) 976 F.2d 700, 708 ["Should the restriction be found to be reasonably within ... the scope of the patent claims, that ends the [antitrust] inquiry."]; *USM Corp. v. SPS Technologies, Inc.* (7th Cir. 1982) 694 F.2d 505, 513 [Antitrust liability may lie "only upon proof of an

anticompetitive effect beyond that implicit in the grant of the patent."] (*USM Corp.*); *Studiengesellschaft, supra*, 670 F.2d at p.1128 ["[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by the patent, and is otherwise legal."]; *SCM Corp., supra*, 645 F.2d at p.1206 ["[W]here a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger [antitrust] liability."].)

Six federal appellate opinions have applied these principles to reject antitrust claims based on Hatch-Waxman settlements within the patent's exclusionary effects. The first was *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.* (11th Cir. 2003) 344 F.3d 1294 (*Valley Drug*). There, the Eleventh Circuit reversed a district court decision finding a reverse payment settlement per se unlawful because the "court failed to consider the exclusionary power of Abbott's patent in its antitrust analysis." (*Id.* at p.1306.) The Eleventh Circuit subsequently applied that reasoning in *Schering-Plough Corp. v. FTC* (11th Cir. 2005) 402 F.3d 1056 (*Schering-Plough*), vacating a FTC order condemning a settlement with reverse payments. The FTC's analysis had failed to consider properly whether "the challenged agreements restrict competition beyond the exclusionary effects of the ... patent." (*Id.* at p.1068.)

The Second Circuit decided *Tamoxifen* not long after Judge Trager granted summary judgment to these defendants in *Cipro-II*. *Tamoxifen* cited Judge Trager's opinions seventeen times, and adopted his description of the controlling rule: "[Absent fraud or a lawsuit that is] objectively

baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." (*Tamoxifen*, *supra*, 466 F.3d at p.213 [quoting *Cipro-II*, *supra*, 363 F.Supp.2d at p.535].)

The Federal Circuit then decided the first of the Cipro appeals, brought by a proposed class of indirect purchasers that included California residents suing under California law. (*Cipro-III*, *supra*, 544 F.3d 1323.) The Federal Circuit unanimously affirmed, confirming that "[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent." (*Id.* at p.1336.)

In 2010, the Second Circuit likewise upheld Judge Trager's ruling in the direct purchasers' Cipro appeal, finding that *Tamoxifen* controlled. (*Cipro-IV*, *supra*, 604 F.3d at p.105 [The Cipro settlements "fall within the terms of the exclusionary grant conferred by the branded manufacturer's patent."].)

Most recently, the Eleventh Circuit reaffirmed the scope of the patent rule set forth in its prior decisions: "Our ... decisions establish the rule that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall *within the scope of the exclusionary potential of the patent*." (*Watson*, *supra*, 2012 WL 1427789 at *11 [emphasis added].)

In sum, the California and federal appellate courts are in harmony. Indeed, every circuit court to consider "reverse payments" has cited Judge Trager's analysis of this same Cipro settlement with approval. (E.g., Opn.

17-21, 38-42; *Watson, supra*, 2012 WL 1427789 at *12; *Tamoxifen, supra*, 466 F.3d at p.213; *Schering-Plough, supra*, 402 F.3d at p.1068; *Valley Drug, supra*, 344 F.3d at p.1306; *In re Cardizem CD Antitrust Lit.* (6th Cir. 2003) 332 F.3d 896, 908, fn.13 (*Cardizem*).)

B. Plaintiffs' Attempt To Rewrite California and Federal Law Fails

Plaintiffs try to evade the impact of these uniform decisions. They argue that the California cases do not mean what they say, and that the federal cases are inconsistent and conflicting. Plaintiffs are wrong.

Though both lower courts in this case embraced *Fruit Machinery*, plaintiffs discuss it in a single paragraph. (OB 34-35.) They claim that, despite the court's express language, it did not rely on the scope of the patent rule. The patentee prevailed, they argue, only "because the 'differential in royalty rates' bore 'a reasonable relationship to differences in costs and capital risks.'" (*Ibid.*)

Plaintiffs misread *Fruit Machinery*. The court first observed that the discriminatory royalty allegation was untrue. (*Fruit Machinery, supra*, 118 Cal.App.2d at p.762 [noting that the royalty "bears a reasonable relationship to [costs] ..., thus "*not giving the canner-owners the 'advantage' which defendant asserts*" (emphasis added)].) But the court then emphasized that nothing in its analysis implied that discriminatory royalties, even if "advantageous," were beyond the scope of the patent:

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

(*Ibid*; accord *USM Corp.*, *supra*, 694 F.2d at p.512 ["[T]here is no antitrust prohibition against a patent owner's using price discrimination to maximize his income from the patent."].)

Plaintiffs also argue that the court's statement that the patentee had both exercised its patent rights and not "abused any rights" means that the scope of the patent rule was not dispositive. (OB 34-35.) Plaintiffs' conclusion does not follow. There was no dispute in *Fruit Machinery* that the patentee had the right to enter into licensing agreements. (118 Cal.App.2d at p.759 ["The patentee may make and grant a license to another ...."].) The issue was whether the patentee had abused that right by going beyond the scope of the patent. *Fruit Machinery*'s answer was no. (*Id.* at p.762.) Thus, the court rejected claimant's caselaw solely because it involved conduct that "went beyond ... the scope of [the] patent." (*Id.* at p.763.)

As for *Vulcan Powder*, plaintiffs concede that the Court "noted that the restraints at issue ... went beyond the technological scope of the patent." (OB 33.) Nonetheless, they argue again that the scope of the patent was not dispositive. (*Ibid.*) This Court, however, was explicit:

> [T]he contract before us *is not confined to dynamite produced under the processes of the named patents.* It speaks ... of 'dynamite' generally, and [forbids sales] ... 'in competition to the parties hereto'.... (*Vulcan Powder*, *supra*, 96 Cal. at p.516 [emphasis added].)

Contrary to plaintiffs' argument, commentators read *Vulcan Powder* as applying the scope of the patent rule. (E.g., 10A William Meade Fletcher (supp. 2012) *Cyclopedia of the Law of Corporations* §5027 [citing *Vulcan*

Powder to hold that "patent laws do not confer ... immunity from the antitrust laws as to acts *not within the limited scope of the monopoly* granted" (emphasis added)].) If plaintiffs' interpretation were correct, this Court would have had no occasion to consider whether the contract was "confined" to the patented processes. It would have stated that the patent's scope was irrelevant. But the Court did not, because plaintiffs' wishful reading is wrong.

Plaintiffs' assertion that federal courts have adopted multiple, inconsistent rules is equally flawed. Indeed, the Eleventh Circuit recently confirmed that its rule is identical to that of the Second and Federal Circuits. The court rejected the very argument plaintiffs make here, *i.e.*, that legality in the Eleventh Circuit turns on "an analysis of the patent's likely ability to exclude infringing use." (OB 43.) On the contrary, "the potential exclusionary scope of the patent ... is[] *the exclusionary rights appearing on the patent's face* and not the underlying merits of the infringement claim." (*Watson, supra*, 2012 WL 1427789 at *10, fn.8 [emphasis added].)

All of the circuits, moreover, reject plaintiffs' assertion that the Sixth Circuit's decision in *Cardizem* declared all reverse payments illegal per se. Every circuit to discuss *Cardizem* has observed that the settlement at issue imposed restraints *beyond* the exclusionary scope of the patent. (See, e.g., *Cipro-III, supra*, 544 F.3d at p.1335; *Tamoxifen, supra*, 466 F.3d at p.214; *Valley-Drug, supra*, 344 F.3d at p.1311, fn.26.) Indeed, *Cardizem* cited Judge Trager's *Cipro-I* opinion rejecting a per se rule against payments

with approval. (*Cardizem, supra*, 332 F.3d at p.908, fn.13.) In *Cardizem* itself, the U.S. Solicitor General, the FTC, and the DOJ all informed the Supreme Court that the circuit court did not adopt a per se rule against payments. (Brief for the United States at 7, 12-15, *Cardizem* (2004) 543 U.S. 939 (No. 03-779) (*Cardizem* Br.).) Since then, the United States has twice more informed the U.S. Supreme Court that *Cardizem* does not represent a circuit split. (Brief for United States at 16 n.7, *Tamoxifen* (2007) 551 U.S. 1144 (No. 06-830); Brief for the United States at 16-17, *Schering-Plough* (2006) 548 U.S. 919 (No. 05-273).)[2] And that court has denied certiorari in all six cases concerning Hatch-Waxman settlements (including both of the *Cipro* cases).[3]

In sum, the Court of Appeal correctly concluded that "every reported decision to date addressing the legality of a reverse-payment settlement of Hatch-Waxman litigation *that does not restrain competition beyond the exclusionary scope of the patent* has concluded that the settlement does not violate antitrust law." (Opn. 37-38.)

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[2] Plaintiffs' reliance on *Andrx Pharmaceuticals, Inc. v. Biovail Corp. Internat.* (D.C. Cir. 2001) 256 F.3d 799 is unfounded. The D.C. Circuit did not address the legality of reverse payments, much less hold them to be per se illegal. It *assumed* the illegality of the agreement for purposes of determining antitrust injury (*id.* at p.813), and it affirmed the dismissal of the complaint, but permitted repleading. (*Id.* at p.801.) No court – not even *Cardizem*, which construed the same settlement but failed to mention *Andrx* – has read *Andrx* as containing a holding concerning the legality of reverse payments.

[3] *Cipro-IV* (2011) 131 S.Ct. 1306; *Cipro-III* (2009) 129 S.Ct. 2828; *Tamoxifen* (2007) 551 U.S. 1144; *Schering-Plough* (2006) 548 U.S. 919; *Valley Drug* (2004) 543 U.S. 939; *Cardizem* (2004) 543 U.S. 939.

C. The Scope of the Patent Rule Derives from Basic Principles of Antitrust and Patent Law

The California rule that governs this case is identical to the federal rule not because the federal cases are controlling, but because they are compelling. While this Court stated in *California ex rel. Van de Kamp v. Texaco, Inc.* (1988) 46 Cal.3d 1147, 1168, that "the Sherman Act is not ... directly probative on interpretation of the Cartwright Act," it also expressly rejected the assertion "that the Cartwright Act is somehow broader than the Sherman Act and the common law." (*Ibid.*) Indeed, because "the Cartwright Act is currently believed to be 'not only harmonious' with the Sherman Act, but shares its 'identical objectives,' we may expect the two laws to move forward in the foreseeable future in a complementary fashion ...." (Donald T. Hibner, Jr. & Heather M. Cooper, *The Cartwright Act at 100—A History of Complementary Antitrust Enforcement—A Celebration* (Fall 2008) 17 Competition 81, 83-84.) Thus, California courts routinely observe that "federal cases interpreting the Sherman Act [are] an aid in interpreting our own Cartwright Act." (*Asahi Kasei Pharma Corp. v. CoTherix, Inc.* (2012) 204 Cal.App.4th 1, 12 [collecting cases].)

As both lower courts observed here, moreover, plaintiffs point to nothing in the Cartwright Act's language or precedent that calls for a different result from the federal cases *on the issue in this appeal.* Nor can they, because "whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the

patent," *Cipro-III, supra*, 544 F.3d at p.1336, the scope of the patent remains the essential inquiry.

1. *Antitrust Law*: Plaintiffs Cannot Show that the Allegedly "Excluded" Competition Was Lawful

The first step in any rule of reason analysis is to show a "substantially adverse effect on competition in the relevant market." (*Exxon, supra*, 51 Cal.App.4th at p.1681 [citation omitted].) By the time the Cartwright Act was passed in 1907, however, it was settled that "the public [is] not entitled to profit by competition among infringers." (*Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.* (7th Cir. 1907) 154 F. 358, 364; see also *Hynix Semiconductor Inc. v. Rambus, Inc.* (N.D.Cal. 2007) 527 F.Supp.2d 1084, 1096 ["[A]n infringer" has "no legal right to be competing in the product market."].) Thus, an antitrust plaintiff always has the burden of demonstrating that the allegedly excluded competition would have been lawful. (See, e.g., *In re Canadian Import Antitrust Lit.* (8th Cir. 2006) 470 F.3d 785, 790-792 [no antitrust liability for conspiring to preclude the importation of illegal drugs]; *Access Telecom, Inc. v. MCI Telecommunications Corp.* (5th Cir. 1999) 197 F.3d 694, 712 ["If there is no legal U.S. export market ..., then there is no antitrust injury."]; *Jenkins v. Greyhound Lines, Inc.* (N.D.Cal. 1971) 1971 WL 529 at *1 [no antitrust claim will "lie where the business ... alleged to have been restrained ... was itself unlawful."].) Because they have not tried to carry that burden here, plaintiffs fail at the rule of reason's first step. (*Cipro-III, supra*, 544 F.3d at p.1332 [where "plaintiffs failed to meet their burden under the first step of

the rule of reason analysis," it was not "necessary to consider the second or third steps of the analysis."].)

In other Hatch-Waxman cases, plaintiffs have sought to satisfy the rule of reason's first step with a showing less stringent than the "objectively baseless" test applied below. But the courts are clear that any lesser standard, such as having an antitrust jury choose a "likely" winner of the settled patent case, is unduly speculative. (*Cipro-I*, *supra*, 261 F.Supp.2d at pp.200-201 [A "legal theory dependent on predicting the outcome of a specific lawsuit is unduly speculative." (citing *Whitmore v. Arkansas* (1990) 495 U.S. 149, 159-160)]; *Tamoxifen*, *supra*, 466 F.3d at p.203 ["[I]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case." (quotation omitted)].)

The Eleventh Circuit rejected such inquiries into the patent merits only last month in *Watson*, *supra*, 2012 WL 1427789. The FTC argued that the patent should be deemed to have no exclusionary power at all if the FTC could show that "it is more likely than not that the patent would not have blocked generic entry." (*Id.* at *11.) The Eleventh Circuit explained the fallacy in this view:

> The FTC's position equates a likely result (failure of an infringement claim) with an actual result, but it is simply not true that an infringement claim that is "likely" to fail actually will fail. (*Ibid.*)
>
> Predicting the future is precarious at best; retroactively predicting from a past perspective a future that never occurred is even more perilous. And it is too perilous an enterprise to serve as a basis for antitrust liability and treble damages. *See Valley Drug*, 344 F.3d at 1308 ("Patent litigation is too complex and the results too uncertain for parties to accurately

> forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.") .... (*Id.* at *12.)

Courts have thus concluded that only a showing of objective baselessness will suffice to meet the antitrust plaintiff's burden without undue speculation. Plaintiffs must show that no reasonable person could doubt that the generic would have prevailed in the underlying litigation:

> A firm that has received a patent from the patent office (and not by fraud ...), and thus enjoys the presumption of validity that attaches to an issued patent, 35 U.S.C. § 282, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment.

(*Asahi Glass*, *supra*, 289 F.Supp.2d at pp.992-993; *id.* at p.993 [patent litigation must be "*objectively* baseless"].) Unless plaintiffs satisfy this test, there is no basis to conclude that lawful competition has been harmed.

2. *Patent Law*: A Patentee Has the Right To Settle Within the Scope of the Patent, Unless the Patent Suit Was Objectively Baseless

The same conclusion flows if the analysis begins with the rights United States patents bestow on a patent owner for the constitutional purpose of "promot[ing] science and the useful arts." (U.S. Const. art I, §8.) A granted patent, which is statutorily presumed valid (35 U.S.C. §282), provides "the right to exclude others from profiting by the patented invention." (*Dawson*, *supra*, 448 U.S. at p.215.) As the Court of Appeal held in *Fruit Machinery*, that right necessarily entails "control over the

invention and *protection in the exercise of the rights* accorded [the inventor] as patentee." (*Fruit Machinery, supra*, 118 Cal.App.2d at p.762 [emphasis added].) Thus, a "patent is, in effect, a bundle of rights which may be divided and assigned, or retained in whole or in part." (*Alfred E. Mann Foundation for Scientific Research v. Cochlear Corp.* (Fed.Cir. 2010) 604 F.3d 1354, 1360 [quotation omitted] (*Mann Foundation*).) In the words of this Court:

> [A]s a patent is a sort of monopoly, the owner may manufacture under it, or not, as he pleases, and may make either a partial or entire assignment of it, and may protect his assignee, not only by an agreement not to use the patent ..., but by a covenant not to interfere in any way with the profits to be derived from the assigned patent.

(*Vulcan Powder, supra*, 96 Cal. at p.516; see, e.g., *Studiengesellschaft, supra*, 670 F.2d at p.1127 [describing array of patent rights].)

As this list demonstrates, a patent's exclusionary right includes not only the "stick" of patent enforcement suits, but the "carrot" of profit from agreements that exploit that exclusivity. (E.g., *King Instruments Corp. v. Perego* (Fed.Cir. 1995) 65 F.3d 941, 950 ["The Act supplies a carrot in the form of economic rewards resulting from the right to exclude."]; *Biotechnology Industry Org. v. District of Columbia* (Fed.Cir. 2007) 496 F.3d 1362, 1372 (*Biotechnology-I*).) These principles do not change, but are emphasized, in the context of Hatch-Waxman litigation.

> But the right [to exclude] ... is not granted in a vacuum or for its own sake.... [T]he primary mechanism by which the right to exclude promotes such innovation is by providing the patentee with the opportunity to obtain greater profits than it could have obtained without such a right to exclude. The Hatch-Waxman Act which extended the patent term for

> pharmaceutical products to account for the costs and delays of the FDA approval process, and its legislative history, make this link especially clear for patented drugs.

(*Biotechnology Industry Org. v. District of Columbia* (Fed.Cir. 2007) 505 F.3d 1343, 1346 [Gajarsa, J., concurring on rehearing denial] (*Biotechnology-II*).) As the Eleventh Circuit recently observed,

> Only one in every 5,000 medicines tested for the potential to treat illness is eventually approved for patient use, and studies estimate that developing a new drug takes 10 to 15 years and costs more than $1.3 billion. No rational actor would take that kind of a risk over that period of time without the prospect of a big reward.

(*Watson, supra*, 2012 WL 1427789 at *1 [footnote omitted.)

The law is equally clear that the "bundle" of patent rights includes the right to settle infringement suits. The agreements that the U.S. Supreme Court upheld in the first Sherman Act patent case in 1902 were settlement agreements. (*Bement, supra*, 186 U.S. at p.93 ["This execution of these contracts did in fact settle a large amount of litigation regarding the validity of many patents .... This was a legitimate and desirable result in itself."].) Indeed, the right to settle infringement litigation is so fundamental that courts use it as a test of whether a given party actually owns the patent. (See *Sicom Systems Ltd. v. Agilent Technologies, Inc.* (Fed.Cir. 2005) 427 F.3d 971, 979 ["Sicom ... has failed to show that it has all substantial rights under the patent. For instance, Sicom does not have the right to settle litigation ...."]; *Mann Foundation, supra*, 604 F.3d at p.1361 [licensor's right to sue is rendered "illusory" without the right to settle].) As courts have recognized in Hatch-Waxman cases, settlement is a critical means by which the benefits of patent rights are realized: "There is simply no legal

basis for restricting the rights of patentees to choose their enforcement vehicle (*i.e.*, settlement versus litigation)." (*Cipro-II, supra*, 363 F.Supp.2d at pp.531-532; *Cipro-III, supra*, 544 F.3d at p.1337 [finding Bayer's conduct "well within [its] rights as the patentee"].)

Because patent law grants "protection in the exercise" of these fundamental rights, (*Fruit Machinery, supra*, 118 Cal.App.2d at p.762), courts have long interpreted the antitrust laws accordingly. (*Bement, supra*, 186 U.S. at p.92 ["But that statute clearly does not refer to that kind of a restraint of interstate commerce which may arise from reasonable and legal conditions imposed upon the assignee or licensee of a patent .... Such a construction of the [Sherman] act we have no doubt was never contemplated by its framers."].) Courts thus reject the conclusion that "an antitrust violation may be found where a patent holder does precisely that which the patent laws authorize." (*Westinghouse, supra*, 648 F.2d at p.647.)

Where, as here, the agreement does not extend the scope of the patent, the exercise of traditional patent rights—including the right to settle—cannot be the basis of antitrust liability, as long as the patent is asserted in what the federal courts call "good faith." (*Duplan Corp. v. Deering Milliken, Inc.* (4th Cir. 1976) 540 F.2d 1215, 1220 ["It is only when settlement agreements are entered into in bad faith and are utilized as part of a scheme to restrain or monopolize trade that antitrust violations may occur."] (*Duplan*).) And bad faith in this context is not a subjective test, but requires proof that the patent claim was objectively baseless.

(*Globetrotter Software, Inc. v. Elan Computer Group, Inc.* (Fed.Cir. 2004) 362 F.3d 1367, 1375 ["[T]he bad faith standard ... [cannot] be satisfied in the absence of a showing that the claims asserted were objectively baseless."] (*Globetrotter*); *SanDisk Corp. v. STMicroelectronics, Inc.* (N.D.Cal. 2008) 2008 WL 4615605 at *10 ["Federal patent law preempts claims for unfair competition under California law unless the case involves objectively baseless allegations of infringement."].) The "objectively baseless" test is thus the standard in a Hatch-Waxman case, because "[i]t is not 'bad faith' to assert patent rights that one is not certain will be upheld ... and to settle the suit to avoid risking the loss of the rights." *Asahi Glass, supra*, 289 F.Supp.2d at p.993 [citation omitted].)

3. The Scope of the Patent Rule Is Completely Consistent with U.S. Supreme Court Precedent

These fundamental principles of patent and antitrust law came together in *Walker, Inc. v. Food Machinery* (1965) 382 U.S. 172 (*Walker Process*). *Walker Process* represents "[t]he only time the [U.S.] Supreme Court has addressed the circumstances under which the patent immunity from antitrust liability can be pierced" when the defendant's conduct is within the scope of a patent. (*Valley Drug, supra*, 344 F.3d at p.1307.)

Walker Process held that proof of actual fraud in securing a patent "would be sufficient to strip [the patentee] of its exemption from the antitrust laws," and thus allow an antitrust claim for wrongful enforcement. (382 U.S. at p.177.) Beyond such intentional misconduct in obtaining the patent, however, the court stressed that the patentee's "good faith would furnish a complete defense" to antitrust claims. (*Ibid.*) In his oft-cited

concurrence, Justice Harlan emphasized that antitrust liability does not attach merely on the basis of invalidity "under one or more of the numerous technicalities attending the issuance of a patent," but only on evidence of actual fraud. (*Id.* at p.180 [Harlan, J., concurring].)

The Court of Appeal was correct to find support in *Walker Process*. (Opn. 21-22 & 31.) The scope of the patent rule and its "objectively baseless" exception flow from the court's admonition that "good faith" reliance on patent rights furnishes a "complete defense" to antitrust liability. (*Walker Process, supra*, 382 U.S. at p.177.) Basing an antitrust claim against parties acting within the scope of a patent on anything less than a sham patent claim would thus conflict with the express exclusion of private antitrust claims "showing no more than invalidity of the patent." (*Id.* at p.179 [Harlan, J., concurring].)

The federal courts that have analyzed the Cipro settlement agree. Citing only *Walker Process*, the Federal Circuit stated that the scope of the patent rule "adopted by the Second and the Eleventh Circuits [is] ... completely consistent with Supreme Court precedent." (*Cipro-III, supra*, 544 F.3d at p.1336.) Judge Trager warned that plaintiffs' theories "would overstep the bright-line rule adopted by the Supreme Court in *Walker Process*, ... and relied upon by the patent bar for the past forty years." (*Cipro-II, supra*, 363 F.Supp.2d at p.530.)

Plaintiffs mention *Walker Process* only once, in a footnote conceding that they have not alleged that Bayer procured its patent through fraud. (OB 57, fn.30.) Rather than discuss *Walker Process*, plaintiffs cite

various other U.S. Supreme Court cases, (OB 24-25, 31-35), none of which is germane. (See, e.g., *United States v. Masonite Corp.* (1942) 316 U.S. 265, 279 [doctrine of patent exhaustion[4] rendered conduct beyond the scope of the patent by definition].) Plaintiffs' reliance (OB 35) on the majority and concurring opinions in *United States v. Singer Manufacturing Co.* (1963) 374 U.S. 174, is also misplaced. *Singer* condemned a horizontal conspiracy by U.S. and European competitors to refuse to license Japanese competitors, which included the aggregation of additional patents and unwritten agreements as to how and against whom they would be enforced. (*Id.* at pp.194-196.) The concurrence, moreover, regarded a settlement of a patent interference proceeding as ordinarily "unexceptionable." (*Id.* at p.199 [White, J., concurring].) Justice White objected not to the settlement, but to "collusion among applicants to prevent prior art from coming to ... [the PTO's] attention." (*Id.* at p.200.) It is telling that the Indirect Purchaser plaintiffs in *Cipro-III* did not cite any of these cases to the U.S. Supreme Court itself when they sought certiorari. (Petition for Certiorari, *Cipro-III, supra*, (2009) 129 S.Ct. 2828 (No. 08-1194).) The cases are no more relevant here.

More fundamentally, however, plaintiffs' conclusion from these cases that settlements are anticompetitive when they "*halt* adversarial testing" of patents (OB 25) is insupportable. Under that view, every patent

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[4] "The longstanding doctrine of patent exhaustion provides that the initial authorized sale of a patented item terminates all patent rights to that item." (*Quanta Computer, Inc. v. LG Electronics, Inc.* (2008) 553 U.S. 617, 625.) There is no claim that the exhaustion doctrine applies here.

settlement is anticompetitive—with or without "reverse" payments. That is not the law. "Where there are legitimately conflicting [patent] claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [antitrust laws]." (*Standard Oil Co. v. U.S.* (1931) 283 U.S. 163, 171.)

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In conclusion, the proper analysis of a Hatch-Waxman settlement, or any other patent agreement, flows from a single principle: Where a patent is present, "the protection of the patent laws and the coverage of the antitrust laws are not separate issues." (*Studiengesellschaft, supra*, 670 F.2d at p.1128.) The scope of the patent rule governs the analysis.

D. The Court of Appeal Correctly Applied the Scope of the Patent Rule To Affirm Summary Judgment

On this appeal, application of the scope of the patent rule is straightforward because plaintiffs concede the rule's three essential elements:

(1) Plaintiffs concede that the settlement was within the scope of the Cipro patent. (OB 36 ["That Respondents' agreement was limited to the patent parameters says nothing about whether the patent actually supplied legitimate grounds for the monopoly."]; OB 31 ["The Court of Appeal [found] ...that the Cipro agreements' terms ... granted no exclusion other than what was already subsumed within its 'exclusionary zone.' This is not a virtue."].) Even without this concession, plaintiffs cannot dispute that Bayer's patent was a compound patent that by definition excluded all generic versions of Cipro for the life of the patent. (Opn. 4.)

(2) Plaintiffs concede that they make no claim for fraud on the PTO. (Opn. 43, fn.13 ["Plaintiffs emphasize on appeal that they are not asserting a claim of fraud on the PTO."]; OB 57, fn.30 ["Plaintiffs did not assert a fraud claim under *Walker Process* ...."].) It is noteworthy that the indirect purchaser plaintiffs in the MDL tried to prove fraud and failed. (*Cipro-III, supra*, 544 F.3d at p.1341 ["[W]e agree[] that no fraud occurred."].)

(3) Plaintiffs concede that they did not allege that Bayer's patent suit against Barr was objectively baseless. (OB 59, fn.31 [acknowledging the absence of any sham claim in the complaint, but asserting that "it is unreasonable to expect them to have predicted the future."].) Indeed, they did not allege patent invalidity or unenforceability at all. (2RA 235-282.)

The only one of these concessions from which plaintiffs try to shake free is the last one. Plaintiffs contend that, despite their pleading failure, they should have been allowed to argue on summary judgment that Bayer's patent claim was objectively baseless due to inequitable conduct before the PTO. (OB 57-59 [discussing plaintiffs' argument on inequitable conduct].) As both lower courts held, however, California law precludes such gamesmanship when opposing summary judgment. (Opn. 40.)

On this appeal, moreover, plaintiffs could not satisfy the objectively baseless test if they tried. Bayer asserted its patent in court and won on three separate occasions. Because "[a] winning lawsuit is by definition ... not a sham," (*Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.* (1993) 508 U.S. 49, 60, fn.5), Bayer's patent claim was not objectively baseless as a matter of law. (Opn. 41-42.) While these grounds

suffice to reject any claim that Bayer's patent was objectively baseless, we show below that the claim would fail for several additional reasons. (Parts IV-V.)

II. COURTS UNIFORMLY REJECT PER SE LIABILITY WHERE THE SETTLEMENT IS WITHIN THE SCOPE OF THE PATENT

Plaintiffs seek to evade Bayer's patent rights by ignoring them. Plaintiffs ask this Court to condemn the Cipro settlements as a per se illegal market allocation. This is elementary error:

> If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's order. This is not such a case, however, because one of the parties owned a patent. (*Valley Drug, supra*, 344 F.3d at p.1304.)

If one were free to disregard the patent, virtually all patent licenses would be per se illegal. (XII Herbert Hovenkamp et al. (2d ed. 1999) *Antitrust Law* ¶2040b, at 199 ["*In the absence of a patent license*, these agreements would generally be classified as per se unlawful naked price fixing, or as per se unlawful naked horizontal market divisions." (emphasis added)].) The patent makes all the difference.

A. Plaintiffs Do Not Attempt To Satisfy this Court's Requirements for Per Se Illegality

California law, like federal Sherman Act law, reserves per se treatment for "certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal." (*Marin County Board of Realtors, Inc. v. Palsson* (1976) 16 Cal.3d 920, 931 [quoting Sherman Act precedent].) "[I]t is only after considerable

experience with certain business relationships that courts classify them as *per se* violations." (*Reynolds v. California Dental Service* (1988) 200 Cal.App.3d 590, 597 [quotation omitted].)

As shown in Part I.A, *supra*, California and federal courts have "considerable experience" with Hatch-Waxman settlements, and *not one* has declared reverse payments to be illegal, much less per se illegal. (E.g., *Tamoxifen*, *supra*, 466 F.3d at p.206; *Valley Drug*, *supra*, 344 F.3d at p.1309 ["To hold that an ostensibly reasonable settlement of patent litigation gives rise to *per se* antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby ... decreasing the value of patent protection generally."].)

As shown in Part I.B, moreover, the *Cardizem* case on which plaintiffs rely did not adopt a per se rule against settlement payments. Indeed, when the U.S. Solicitor General, the DOJ Antitrust Division, and the FTC explained to the U.S. Supreme Court that *Cardizem* did "not deem illegal per se every settlement agreement that includes a reverse payment," they also agreed that "[i]f construed in that manner, the court of appeals' decision would be erroneous." (*Cardizem* Br., *supra*, at p.12.) The current DOJ Antitrust Division agrees that "per se condemnation of patent settlements under the Sherman Act is not justified." (Brief of the United States at 20, *Cipro-IV*, *supra*, 604 F.3d 98 (No. 05-2851).) Thus, the per se rule has been rejected not only by courts, but also by the same enforcement agencies and commentators on whom plaintiffs rely. (See Herbert Hovenkamp, Mark Janis, and Mark A. Lemley, *Anticompetitive Settlement*

of Intellectual Property Disputes (2003) 87 Minn.L.Rev. 1719, 1725, 1749.)

The per se rule is particularly inappropriate here, where the cumulative experience of Hatch-Waxman settlements belies plaintiffs' claim that they invariably cause consumer harm. On the contrary, in this case and *Tamoxifen*, generic entrants were excluded by the patents themselves, which were validated multiple times in subsequent litigation. (*Cipro-II*, *supra*, 363 F.Supp.2d at p.530, fn.14; *Tamoxifen*, *supra*, 466 F.3d at p.195.) But even in *Cardizem*, where the agreement was struck down for exceeding the scope of the patent, the FTC later found that the settlement had caused no delayed generic entry. (*In re Hoechst Marion Roussel, Inc.* (2001) 131 F.T.C. 925, 955 ["[I]t does not appear that there was any delay in the entry into the market ..., or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD."].) In the settlement involving the branded-drug Hytrin, which also went beyond the scope of the patent by restricting non-infringing drugs, a jury subsequently found that the settlement caused no delay in the availability of generic drugs. (*Kaiser Foundation Health Plan, Inc. v. Abbott Laboratories, Inc.* (9th Cir. 2009) 552 F.3d 1033, 1041 [jury verdict of $0 damages].)

Finally, even if a per se rule did apply, the logic of the scope of the patent rule still holds. The rule has its origins in cases decided well before 1911, when the U.S. Supreme Court first formulated the rule of reason. (See *Bement*, *supra*, 186 U.S. at pp.88, 92 [noting in 1902 that the Sherman Act condemned "any restraint of commerce, whether reasonable or

unreasonable"].) And this Court's decision in *Vulcan Powder* was based on the (then) per se prohibition of former Section 1673 of the Civil Code. Yet, the Court went on to consider whether the agreements were nonetheless "confined" to the scope of the relevant patents before striking them down. (96 Cal. at p.516.) Neither federal nor California courts have ever construed the rules of antitrust liability, per se or otherwise, to limit the exercise of traditional patent rights.

B. Plaintiffs Cannot Articulate a Theory of Harm to Lawful Competition Under the Rule of Reason

Plaintiffs insist on a per se rule, which presumes competitive harm in every case, because they cannot demonstrate actual harm in this case. Despite attacking Hatch-Waxman settlements for over 12 years, the FTC and private plaintiffs have yet to articulate a credible theory of harm to lawful competition under the rule of reason. The FTC has revised its theories several times, but the courts remain unpersuaded. (See, e.g., *Watson, supra*, 2012 WL 1427789 at *13 [noting the inconsistency and "reject[ing] the FTC's new approach"].) Like the courts below, the federal decisions have exposed the flaws in plaintiffs' arguments.

First, plaintiffs ignore the incentives that Hatch-Waxman created. Under the statute, an ANDA filer infringes simply by filing its Paragraph IV certification. (35 U.S.C. §271(e)(2)(A).) The generic challenger, with no damages exposure from actual sales, thus "has relatively little to lose ... beyond litigation costs," while the innovator could "be stripped of its patent monopoly." (*Tamoxifen, supra*, 466 F.3d at pp.206-207.) Where the innovator has everything to lose, and the generic challenger has everything

to gain, consideration naturally flows from the innovator to the challenger. (*Ibid.*; accord *Asahi Glass*, *supra*, 289 F.Supp.2d at p.994 [the generic challenger "would not settle unless he had something to show for the settlement."]; *Cipro-I*, *supra*, 261 F.Supp.2d at p.252 ["[S]o-called reverse payments are a natural by-product of the Hatch-Waxman process."].)

Second, plaintiffs cannot explain why the antitrust analysis should change when the settlement's consideration takes the form of payments. The presence of payments is not legally relevant because it is the "failure to produce the competing ... drug, rather than the payment of money, [that] is the exclusionary effect." (*Valley Drug*, *supra*, 344 F.3d at p.1309.) No matter what the form of consideration, "if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent." (*Asahi Glass*, *supra*, 289 F.Supp.2d at p.994.) Because all settlements are compromises that provide consideration to both sides, moreover, "*any* settlement agreement can be characterized as involving 'compensation' to the [generic]." (*Ibid.*) Under Hatch-Waxman, therefore, "payments from the patent owner to the infringer become explicit rather than implicit, but it does not change the underlying nature of the payments or make them more anti-competitive." (Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles* (2006) 15 Fed.Cir. B.J. 617, 621.)

The courts have thus noted that plaintiffs' theory that consumers are always harmed by payments would apply equally to settlements with

licenses, "unless the license is royalty-free." (*Cipro-II, supra*, 363 F.Supp.2d at p.533) As Judge Trager warned, however, "[t]o open royalty-bearing patent license agreements to antitrust scrutiny simply because patents are often held invalid when tested in litigation would undermine the settled expectations of patentees and potential infringers/licensees across countless industries." (*Ibid.*)[5]

Third, the courts also reject plaintiffs' attempt to find legal significance in the size of the settlement payments. (*Schering-Plough, supra*, 402 F.3d at pp.1075-76 ["[T]he size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy."]; *Valley Drug, supra*, 344 F.3d at p.1310 [The court "cannot confidently draw the conclusion, merely from the size of the payments, that there were no genuine disputes over the validity of the patent."].)

Here, Bayer's total payments ($398 million) represented a net present value of $280 million at the time of the settlement on a drug expected to generate over $4 billion in additional revenue. (See *Cipro-II, supra*, 363 F.Supp.2d at p.534, fn.16; 1AA 149.) In fact, Bayer's payments constituted just over 6% of its revenue from Cipro tablet sales over the payment period. (See 1RA 39, ¶3.) The settlement thus made economic

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[5] Plaintiffs suggest that licenses are always more procompetitive than settlements, but that is not true. A patent license may be wholly exclusive, allowing only one seller charging the full monopoly price. (E.g., *Studiengesellschaft, supra*, 670 F.2d at p.1127; *Brunswick Corp. v. Riegel Textile Corp.* (7th Cir. 1984) 752 F.2d 261, 267 ["[T]here would not be more competition if the 'competitors' were constrained by the terms of the patent license to charge the monopoly price."].)

sense for Bayer even if victory was virtually certain. (*Cipro-II, supra*, 363 F.Supp.2d at pp.540-541 ["The fact that Bayer paid what in absolute numbers is a handsome sum to Barr to settle its lawsuit does not necessarily reflect a lack of confidence in the '444 Patent, but rather the economic realities of what was at risk."].)

Fourth, the courts emphatically reject the idea that an antitrust court could determine, after the fact, whether the patent claim—even though not objectively baseless—was somehow too "weak" to permit settlement. (See Part I.B.) Although the FTC had once described such an exercise as legally inappropriate, it recently reversed course, asking the Eleventh Circuit to allow it—without success. (*Watson, supra*, 2012 WL 1427789 at *13 ["The FTC was right then for the same reasons it is wrong now."].)

Moreover, any patent "strength" standard (OB 43-45) merely raises the question: how strong is strong enough to avoid antitrust liability? 70% chance of winning? 80%? 90%? And how can a lay jury with no patent training determine those odds when trained patent lawyers and judges cannot? (*Valley Drug, supra*, 344 F.3d at p.1308 ["Patent litigation is too complex and the results too uncertain for parties to accurately forecast ...."].) Moreover, "[t]he FTC's retrospective predict-the-likely-outcome-that-never-came approach," (*Watson, supra*, 2012 WL 1427789 at *13), removes all incentives for the parties to settle in the first place, contrary to the public policy favoring settlements. (E.g., *Flex-Foot, Inc. v. CRP, Inc.* (Fed.Cir. 2001) 238 F.3d 1362, 1370.)

Plaintiffs offer no answer to these objections. Instead, they would evade these issues by invoking a per se rule that every court rejects. This Court should reject it as well.

C. This Court Should Reject Plaintiffs' Request To Engage in Judicial Legislation

Plaintiffs urge the Court to disregard settled law on grounds of "public policy." But plaintiffs invoke a strangely one-sided "policy"—one that assumes that consumers benefit only when a patent holder loses in court; one that assumes that consumers always prefer the short-term benefits of lower generic prices to the long-term benefits of newly discovered, life-saving drugs like Cipro. Plaintiffs fail to recognize that the exercise of the patentee's right to exclude "serves a very positive function in our system of competition, *i.e.*, the encouragement of investment based risk." (*Loctite Corp. v. Ultraseal Ltd.* (Fed.Cir. 1985) 781 F.3d 861, 876 [quotation omitted].) In any event, plaintiffs support their policy arguments with unpersuasive assertions based not on the record, but on public pronouncements by interested third parties.

For example, plaintiffs' assertion that settlements cost consumers "billions" are based on a recent FTC "Study" whose title reflects its bias. (Federal Trade Commission (2010) *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions: An FTC Staff Study.*) Commentators have shown that the study is flawed and its central conclusion on consumer benefits "is not reliable." (E.g., Bret Dickey et al. (2010) *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on 'Reverse Payment' Settlements* 2, *available at*

http://newsroom.law360.com/articlefiles/186893-Analysis.pdf.) And even the flawed study concedes that the consumer loss it claims could fall by over 82% if some of its (undisclosed) "assumptions," were "varied." (FTC Staff Study, at p.10.)

Plaintiffs also claim that "three-quarters of litigated pharmaceutical patents are struck down." (OB 27.) This is simply wrong. In fact, the first study plaintiffs cite is the American Intellectual Property Law Association Quarterly Journal, which found that three-quarters of litigated pharmaceutical patents are held to be *valid.* (9AA 2077.) The FTC study that plaintiffs cite (6AA 1177) found that a generic prevailed in a final decision in twenty-two cases involving the first ANDA filer (29% of the sample). (Federal Trade Commission (2002) *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 14-16.) To arrive at the figure of 73%, the FTC ignored all settled cases, and counted repeated wins for the patent holder—such as Bayer's three Cipro victories—only once. (*Id.* at 1-2.)

In the end, plaintiffs base their policy arguments on extra-judicial materials irrelevant to the legal issues presented here. For years, the FTC has supported legislation to ban reverse-payment settlements. Bills to that effect remain pending before Congress. (See, e.g., H.R. 3995, 112th Cong. (2012); S.27, 112th Cong. (2011).) Whatever their merit, plaintiffs' policy arguments should be addressed to a legislature, not to this Court.

III. FEDERAL PATENT LAW WOULD PREEMPT ANY CALIFORNIA RULE THAT SETTLEMENTS WITHIN THE SCOPE OF THE PATENT VIOLATE THE CARTWRIGHT ACT

Departing from the scope of the patent rule would do more than change California law. Such a ruling would interfere with one of the fundamental attributes of the federal patent right, and thus be preempted by the Supremacy Clause of the U.S. Constitution.

A. Plaintiffs Misunderstand the Doctrine of Substantive Preemption

Plaintiffs argue that the Court of Appeal found their claims to be substantively preempted. (OB 49.) That is not so. It is true that defendants raised and preserved their substantive preemption argument below. But because both courts correctly interpreted the Cartwright Act, neither had to resolve the substantive preemption issue that would have arisen if the court had departed from the scope of the patent rule.

On the other hand, both courts did address the issue of *jurisdictional* preemption in responding to plaintiffs' summary judgment argument that Bayer's patent suit against Barr was objectively baseless due to inequitable conduct before the PTO. Both courts recognized that such a claim would arise under patent law and would have to be dismissed for lack of subject-matter jurisdiction. (Opn. 44; 11AA 2270.)

It is clear that the Court of Appeal discussed only jurisdictional preemption:

> [W]e conclude that plaintiffs' sham-litigation claim is preempted by federal patent law. "The district courts [of the United States] shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents ..." (28 U.S.C. § 1338(a).)

(Opn. 42-43; see Opn. 44 ["[W]hether alleged inequitable conduct in the procurement of a patent constitutes unfair competition is within the exclusive jurisdiction of the Federal Circuit Court of Appeals."].) Nowhere in the opinion did the Court of Appeal analyze substantive preemption; nowhere did it address whether California law would conflict with federal patent law.

Plaintiffs now take the position that "[t]here is no such thing as 'jurisdictional preemption.'" (Reply on Petition for Review 13, fn.12.) But plaintiffs are confused about California nomenclature: "Preemption cases may be divided into two types: substantive or jurisdictional." (*Screen Extras Guild, Inc. v. Superior Court* (1990) 51 Cal.3d 1017, 1022 (*Screen Extras*).) In *In re Jose C.*, this Court warned that "whether Congress has preempted state court *jurisdiction* is not to be confused with whether it has preempted [substantive] state *legislative action*." (*In re Jose C.* (2009) 45 Cal.4th 534, 546; *id.* at p.538.)

Under the heading "Substantive Preemption," *In re Jose* also explained that there are four types: "express, conflict, obstacle, and field preemption." (45 Cal.4th at pp.549-550.) Obstacle preemption occurs when state law conflicts with the "full purposes and objectives of Congress." (*Ibid.* [quotation omitted].) The Court has also noted that "[w]e and the United States Supreme Court have often ... group[ed] conflict preemption and obstacle preemption together in a single category." (*Viva! Internat. Voice for Animals v. Adidas Promotional Retail Operations, Inc.* (2007) 41 Cal.4th 929, 933, fn.3 (*Viva!*).)

Plaintiffs argue incorrectly that *Viva!* requires a presumption against preemption in all cases. On the contrary, the Court stated that, when a case juxtaposes an area of traditional state regulation (there, wildlife management) with an area of special federal concern (there, foreign affairs), "no particular presumption applies." (*Viva!, supra*, 41 Cal.4th at p.937.) So, here, the state's interest in regulating competition is set against the uniquely federal interest in patent rights. In this case, as in any question of substantive preemption, "congressional intent is the ultimate touchstone." (*Ibid.* [quotation omitted].)

If this Court rejects the extreme reading of the Cartwright Act that plaintiffs advocate, and adheres to the scope of the patent rule, then it need not reach the question of substantive preemption. If, however, the Court were to hold that California law may impose liability upon defendants for a settlement within the scope of the patent, then substantive preemption would become central to this appeal.

B. State Law May Not Add or Detract from the Fundamental Rights of Patent Holders

This Court recognizes that "[s]tate law is unquestionably preempted where a valid act of Congress fairly interpreted is in actual conflict with the law of the State." (*Screen Extras, supra*, 51 Cal.3d at p.1023 [quotation omitted].) Such conflict may exist even where compliance with both laws is possible, but the state law obstructs the federal purpose. (*Ibid.* [state wrongful discharge claim preempted by federal labor law]; accord *Olszewski v. Scripps Health* (2003) 30 Cal.4th 798 [state statute allowing provider liens preempted by federal Medicaid regulations]; *Grimes v.*

Hoschler (1974) 12 Cal.3d 305 [law governing state contractors preempted by federal bankruptcy law].)

These principles apply to the federal interest in patent rights. (*Bonito Boats, Inc. v. Thunder Craft Boats, Inc.* (1989) 489 U.S. 141, 152 ["[S]tate regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws."]; *Sears, supra*, 376 U.S. at p.231 ["[A State] cannot, under some other law, such as that forbidding unfair competition, give protection of a kind that clashes with the objectives of the federal patent laws."].) The state may enact neutral regulations regarding safety, taxes, and other police powers, but it may not "alter and substantially reduce the established scope of the patent monopoly." (*Westinghouse, supra*, 648 F.2d at p.648.)

Accordingly, "[i]f a plaintiff bases its tort action on conduct that is *protected or governed* by federal patent law," the state law remedy "must be preempted for conflict with federal patent law." (*Hunter Douglas, Inc. v. Harmonic Design, Inc.* (Fed.Cir. 1998) 153 F.3d 1318, 1335 [emphasis added] (*Hunter Douglas*).) As shown in Part I.C.2, *supra*, the right of a patentee to enter agreements within the scope of the patent is fully protected by patent law. When within the patent's scope, "any conditions [of a contract] which are not in their very nature illegal ... imposed by the patentee and agreed to by the licensee ... will be upheld by the courts." (*Bement, supra*, 186 U.S. at p.91.)

The Federal Circuit's decisions in *Biotechnology Industry Organization* are instructive. There, the Federal Circuit found preempted a

District of Columbia ordinance prohibiting the sale of patented drugs at "an excessive price." (*Biotechnology-I, supra*, 496 F.3d at p.1365.) The court acknowledged that "[t]here is no express provision in the patent statute that prohibits states from regulating the price of patented goods." (*Id.* at p.1372.) Nonetheless, the statute interfered with "Congress's intention to provide ... pharmaceutical patent holders with the pecuniary reward that follows from the right to exclude." (*Ibid.*) The District was, therefore, foreclosed from "diminishing the reward to patentees in order to provide greater benefit to District drug consumers." (*Id.* at p.1374.)

> Congress' clear purpose to spur innovation by providing a right to exclude can, thus, be obstructed not only by directly preventing an inventor from excluding others, but also by systematically preventing a patentee from reaping the increased profits that would otherwise come from its exclusionary rights. (*Biotechnology-II, supra*, 505 F.3d at p.1346 [Gajarsa, J., concurring on rehearing denial].)

Just as Congress did not intend for state juries to determine when a price charged for a patented product is "excessive," it did not intend for juries to decide when a patent claim brought in good faith is nonetheless too "weak" to permit a settlement within the patent's scope.

C. Patent Law Preempts Liability Here Without Proof that the Patent Suit Was Objectively Baseless

As shown in Part I.C, *supra*, patent law protects the patentee's exercise of its bundle of patent rights as long as its conduct does not go beyond the scope of the patent. The law, however, requires that the patentee exercise those rights in "good faith," by not asserting a patent claim that is objectively baseless. (E.g., *Duplan, supra*, 540 F.2d at p.1220

["It is only when settlement agreements are entered into in bad faith ... that antitrust violations may occur."].) Thus, courts have repeatedly found California state claims preempted when plaintiffs sought to restrict the good faith exercise of patent rights. (*Globetrotter, supra*, 362 F.3d at p.1375 [California claims preempted unless suit was "objectively baseless."]; *Golan v. Pingel Enterprise, Inc.* (Fed.Cir. 2002) 310 F.3d 1360, 1363 [same; §17200 claims preempted]; *Zenith Electronics Corp. v. Exzec, Inc.* (Fed.Cir. 1999) 182 F.3d 1340, 1353 ["[B]ad faith is a prerequisite ...; without it, the claim is preempted ...."].)

Among the most fundamental of patent rights is the right to enter agreements that do not extend the patent's scope. From the time of *Bement* (1902), good faith patent agreements have been shielded from antitrust liability. Like the agreements in *Bement*, the Cipro agreements here involved both a settlement and a license. To bring a state claim attacking a Hatch-Waxman settlement, therefore, courts are explicit that "bad faith must be alleged and ultimately proven." (*In re Tamoxifen Citrate Antitrust Lit.* (E.D.N.Y. 2003) 277 F.Supp.2d 121, 139 [California unfair competition claims preempted where "the Complaint fails to allege ... that [the defendants] acted in bad faith in settling their patent litigation"].) If this Court allowed a lesser standard, it would be restricting one of the "fundamental attributes" of the federal patent right. (See *AT&T Mobility LLC v. Concepcion* (2011) 131 S.Ct. 1740, 1748 [preempting California rule mandating class arbitration because it "interferes with the fundamental attributes of arbitration"].)

As plaintiffs concede, they made no allegation that Bayer's patent suit was objectively baseless. Patent law thus prohibits California from imposing liability on this settlement, which was within the scope of the Cipro patent.

IV. ANY CALIFORNIA RULE OF LIABILITY BASED UPON ASSESSING THE "STRENGTH" OF THE PATENT WOULD BE SUBJECT TO EXCLUSIVE FEDERAL JURISDICTION

The issue of exclusive federal jurisdiction arose below because plaintiffs contended for the first time in opposing summary judgment that Bayer's infringement suit against Barr was objectively baseless. The Court of Appeal correctly concluded that plaintiffs' new contention would be subject to exclusive federal jurisdiction. (Opn. 38-43.) So, here, if this Court were to construe plaintiffs' complaint as allowing proof that the Bayer-Barr litigation was objectively baseless, or otherwise too weak to permit settlement, the Court would have to dismiss it for lack of jurisdiction.

A. A State Law Cause of Action with an Embedded Federal Patent Issue May Still Arise Under Patent Law

Federal courts have exclusive jurisdiction under 28 U.S.C. §1338 in two circumstances: (1) when "patent law creates the cause of action," *or* (2) when "plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law." (*Christianson v. Colt Industries Operating Corp.* (1988) 486 U.S. 800, 809.) Under the second step of the *Christianson* test, patent law questions may be "embedded" in claims created by state statutory or common law. (See *Holiday Matinee, Inc. v. Rambus, Inc.* (2004) 118 Cal.App.4th 1413, 1424-1425 [citing *Additive*

Controls & Measurement Systems, Inc. v. Flowdata, Inc. (Fed.Cir. 1993) 986 F.2d 476, 479] (*Holiday Matinee*).)

Plaintiffs ignore this controlling standard and argue that exclusive jurisdiction turns on which sovereign created the cause of action. (OB 56.) Plaintiffs rely on *Mattel, Inc. v. Luce, Forward, Hamilton & Scripps* (2002) 99 Cal.App.4th 1179 (*Mattel*), which held that federal jurisdiction did not lie solely because the cause of action was "a tort claim 'arising under' the common law of California." (*Id.* at p.1185.) Plaintiffs include (OB 56) a lengthy quotation from Justice Holmes in *American Well Works Co. v. Layne & Bowler Co.* (1916) 241 U.S. 257, 260 (*American Well Works*), a case in which he famously asserted that "[a] suit arises under the law that creates the cause of action."

Plaintiffs' argument is wrong because it reads the second step of the *Christianson* test out of the law. Courts ultimately rejected Justice Holmes's statement in *American Well Works* as incorrect. "The path-breaking opinion to this effect was *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921), pointedly rendered over a dissent by Mr. Justice Holmes, 255 U.S. at 213-215." (*T.B. Harms Co. v. Eliscu* (2d Cir. 1964) 339 F.2d 823, 827 [Friendly, J.]; accord *Franchise Tax Board of Cal. v. Construction Laborers Vacation Trust* (1983) 463 U.S. 1, 8-9 ["[E]ven the most ardent proponent of the Holmes test has admitted that it has been rejected ...."].)

The *Mattel* decision upon which plaintiffs rely cites only pre-*Christianson* caselaw. Post-*Christianson* cases like *Holiday Matinee* and

Landmark Screens, LLC v. Morgan, Lewis & Bockius, LLP (2010) 183 Cal.App.4th 238, 244 (*Landmark Screens*), refute *Mattel*'s analysis. After *Christianson*, a claim created by state law may also arise under patent law if its success depends on evaluating the scope and strength of patent rights. (*Landmark Screens*, 183 Cal.App.4th at p.248 [evaluating "[t]he nature and extent of those patent rights present[s] a substantial issue of federal patent law."].)

B. A California Claim that Depends for Its Success on Evaluating Patent Strength Arises Under Patent Law

Questions of validity, enforceability, and infringement are "substantial" questions of patent law under §1338. (*Hunter Douglas, supra*, 153 F.3d at p.1330.) Here, the success of plaintiffs' "objectively baseless" claim turns on the patent's enforceability, and thus "depend[s] upon the resolution of a substantial question of patent law." (*Holiday Matinee, supra*, 118 Cal.App.4th at p.1422.) In this case, moreover, where the settlement is concededly within scope of the patent, the enforceability of the patent would supply the *only* disputed issue of liability, and hence satisfy the requirement of *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.* (2005) 545 U.S. 308, 314, that the patent issue be "actually disputed and substantial."

In this case, moreover, the jurisdictional question is easily resolved because plaintiffs' supposed state law claim turns on whether the patentee committed inequitable conduct. (*Lockwood v. Sheppard, Mullin, Richter & Hampton* (2009) 173 Cal.App.4th 675, 686 ["[W]hether alleged inequitable conduct in prosecution of a patent application constitutes unfair

competition is within exclusive jurisdiction of the Federal Circuit." (citation omitted)] (*Lockwood*).) In *Lockwood*, plaintiff sued for malicious prosecution and other state law torts based on defendant's inequitable conduct during a patent reexamination. (*Id.* at p.687.) The court explained why it lacked jurisdiction:

> Obviously, therefore, the court would be presented with substantial questions of patent law, effectively having to put itself in the position of a 'reasonable' patent examiner and determine whether the prior art would be considered important in deciding the patentability of Lockwood's patent claims. (*Ibid.*)

Both courts below relied expressly on *Lockwood*. (Opn. 44; 11AA 2670.) Plaintiffs fail to cite it.

In sum, plaintiffs cannot omit an attack on Bayer's patent from the complaint to preserve state jurisdiction, but now request a trial to show "the objective baselessness of Bayer's suit," *i.e.*, "[w]hether Bayer purposefully mislead the PTO[.]" (OB 62.) The Court of Appeal correctly held that plaintiffs cannot have it both ways. (Opn. 43-45.)

V. ANY PUTATIVE CLAIM THAT BAYER'S PATENT SUIT WAS OBJECTIVELY BASELESS FAILS FOR MULTIPLE OTHER REASONS

For several reasons beyond jurisdiction, the courts below rejected plaintiffs' request to show that Bayer's patent suit was objectively baseless due to inequitable conduct before the PTO.

First, on a motion for summary judgment, "the opposing papers may not create issues outside of the pleadings." (*Mars v. Wedbush Morgan Securities, Inc.* (1991) 231 Cal.App.3d 1608, 1613-14 [citation omitted].) In their petition for review, plaintiffs did not challenge the Court of

Appeal's conclusion on this issue, but now claim in a footnote that it was "error." (OB 59, fn.31.) But the court was correct. Plaintiffs neither pleaded that the patent was infirm, nor sought leave to do so. (*Oakland Raiders v. National Football League* (2005) 131 Cal.App.4th 621, 648 ["A plaintiff wishing to rely upon unpleaded theories to defeat summary judgment must move to amend the complaint before the hearing." (quotation omitted)].)

Second, a claim based on inequitable conduct would also be substantively preempted. In the MDL proceedings, both Judge Trager and the Federal Circuit held that a Cartwright Act claim based on inequitable conduct was preempted. (*Cipro-II, supra*, 363 F.Supp.2d at pp.542-545, affd. *Cipro-III, supra*, 544 F.3d at pp.1340-1341 [citing, inter alia, *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.* (Fed.Cir. 2000) 204 F.3d 1368, 1382 (A "state cause of action predicated so squarely on the acts of inequitable conduct would be contrary to Congress' preemptive regulation in the area of patent law." [quotation omitted])]; see also *In re Netflix Antitrust Lit.* (N.D.Cal. 2007) 506 F.Supp.2d 308, 319-320 ["At most, [plaintiffs assert] ... a claim for inequitable conduct. Such claims are preempted by federal patent law."].)[6]

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[6] This is a form of obstacle preemption that differs from that discussed in Part III, *supra*. The "obstacle" in Part III occurs whenever a state penalizes the exercise of fundamental patent rights within the patent's scope. This preemption, however, is based on the need for uniformity in federal standards governing PTO behavior. (See, e.g., *Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341, 350 [claim alleging fraud on the FDA preempted because "complying with the FDA's detailed

Third, none of the evidence plaintiffs cite is sufficient to prove inequitable conduct. The Federal Circuit recently clarified that the standard for inequitable conduct now requires that the plaintiff show "but for" materiality, *i.e.*, that no valid patent would have issued but for the misrepresentations. (*Therasense, Inc. v. Becton, Dickinson & Co.* (Fed.Cir. 2011) 649 F.3d 1279, 1291 [en banc].) Plaintiffs' evidence made no attempt to meet that standard here. Since the PTO affirmed the patent's Cipro claims not once but twice, and Bayer defeated three validity challenges in court, plaintiffs' failure is not surprising.[7]

VI. PLAINTIFFS HAVE WAIVED ANY ARGUMENT BASED UPON THE UCL OR EVIDENTIARY RULINGS

Plaintiffs' opening brief presents no substantive argument concerning the UCL or the Superior Court's evidentiary rulings. Indeed, plaintiffs made the conscious choice, despite Rule 8.520(b)(2)(B), to omit both topics from the brief's statement of issues presented. (OB 1.) Where "[n]o substantial argument is advanced in support of [a] contention," the

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regulatory regime in the shadow of 50 States' tort regimes" would impose "burdens not contemplated by Congress"].)

[7] Although legally irrelevant, plaintiffs' assertion that Bayer's response to the inequitable conduct claim was a so-called "insanity defense" is groundless. Plaintiffs' inequitable conduct contention is that Bayer withheld two prior art German patent applications. (OB 9.) But *the first page* of the '444 patent confirms that the original PTO examiner reviewed the U.S. counterparts to those applications. (10AA 2340.) These facts explain why the Federal Circuit found no fraud, (see *Cipro-III*, *supra*, 544 F.3d at p.1337), and why *four* later generic challengers—who remained free after the reexamination to raise the same inequitable conduct defense, (Opn. 11)—considered the defense too weak to pursue. (*Cipro-II*, *supra*, 363 F.Supp.2d at p.530.)

"contention has been abandoned." (*Jersey Maid Milk Products Co. v. Brock* (1939) 13 Cal.2d 620, 641.) The Rules now codify this principle, requiring a brief to "[s]tate each point under a separate heading or subheading summarizing the point, and support each point by argument and, if possible, by citation of authority." (Cal. Rules of Court, Rule 8.204(a)(1)(B).)

Plaintiffs have thus waived any argument that their UCL claim does not fall with the Cartwright Act claim. The sole overt reference to the UCL in the opening brief occurs in a footnote, with no argument, in a section entitled "*The Cartwright Act* Prohibits Payments Not to Compete, Like Those at Issue Here." (OB 18 [emphasis added], 23 fn.12.) Plaintiffs also did not present argument concerning the UCL in their opening brief to the Court of Appeal, nor any substantive argument in their Petition.

Any independent theory of liability under the UCL would fail for multiple reasons. First, federal patent law would preempt liability under the UCL for the reasons explained in Part III concerning substantive preemption. Second, plaintiffs have not identified any conduct under the UCL's "unfairness" prong that would be distinct from the alleged "unlawfulness" of the Cartwright Act violation. (See *Chavez v. Whirlpool Corp.* (2001) 93 Cal.App.4th 363, 375.) Third, the UCL claim is also moot because the plaintiff class did not buy Cipro directly from Bayer, rendering restitutionary damages unavailable. (See *Korea Supply Co. v. Lockheed Martin Corp.* (2003) 29 Cal.4th 1134, 1144.) Fourth, this Court should abstain from fashioning an ad hoc equitable remedy in an area of highly-

regulated economic policy determinations made by Congress and the FDA. (*Harris v. Capital Growth Investors XIV* (1991) 52 Cal.3d 1142, 1168, fn.15.) Finally, the 'parallel' Federal Trade Commission Act jurisprudence that this Court found persuasive under the UCL in *Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.* (1999) 20 Cal.4th 163, 185, holds defendants' conduct to be lawful. (*Watson, supra,* 2012 WL 1427789 at *10-13; *Schering-Plough, supra,* 402 F.3d 1056.) Due to plaintiffs' waiver, the UCL issues remain unaddressed by the briefs and unanalyzed by the Court of Appeal.

As to the evidentiary rulings, plaintiffs made no showing here or below "that the admission of any specific evidence constituted prejudicial error." (Opn. 52; see *Reid v. Google* (2010) 50 Cal.4th 512, 534-535 [no reversible error, absent prejudice].) In addition, the evidence of Bayer's subsequent victories against three generic challengers was admissible to show that Bayer's patent was valid at the time of the Bayer-Barr settlement. (*Blank v. Coffin* (1942) 20 Cal.2d 457, 463.)

CONCLUSION

For the reasons stated above and in the brief of Bayer's co-respondents (Cal. Rules of Court, Rule 8.504(e)(3)), the decision of the Court of Appeal should be affirmed.

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Respectfully submitted,

Dated: May 29, 2012

MCKENNA LONG & ALDRIDGE LLP

By: 
Charles A. Bird

Charles A. Bird, *SBN: 056566*
Christopher J. Healey, *SBN: 105798*
Todd R. Kinnear, *SBN: 208831*
MCKENNA LONG & ALDRIGE LLP
600 West Broadway, Suite 2600
San Diego, CA 92101-3391
Telephone: (619) 236-1414
Facsimile: (619) 645-5321

Peter B. Bensinger, Jr*
BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP
54 West Hubbard Street, Suite 300
Chicago, IL 60654
Telephone: (312) 494-4400
Facsimile: (312) 494-4440

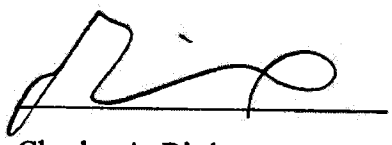
Kevin D. McDonald*
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
Telephone: (202) 879-3939
Facsimile: (202) 626-1700

**Admitted Pro Hac Vice*

Attorneys for Defendant-Respondent Bayer Corporation.

CERTIFICATE OF WORD COUNT

I, Charles A. Bird, counsel for respondent Bayer Corporation, certify that the foregoing brief is prepared in proportionally spaced Times New Roman 13 point type and, based on the word count of the word processing system used to prepare this brief, the brief is 13,997 words long.



Charles A. Bird

PROOF OF SERVICE

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

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

On May 29, 2012, I served true copies of the following document(s) described as: **RESPONDENT BAYER CORPORATION'S ANSWER** on the interested parties in this action as follows:

SEE ATTACHED SERVICE LIST

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

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

Executed on May 29, 2012, at San Diego, California.

Leisa Bitting

SERVICE LIST	
Attorney	**Party**
Dan Drachler ZWERLING, SCHACTER & ZWERLING 1904 Third Avenue, Suite 1030 Seattle, WA 98101 Ralph Botros Kalfayan KRAUSE, KALFAYAN, BENINK & SLAVENS, LLP 550 West C Street, Suite 530 San Diego, CA 92101 Joseph Richard Saveri Dean Michael Harvey Eric Barmon Fastiff Brendan Patrick Glackin Jordan S. Elias LIEFF CABRASER HEIMANN & BERNSTEIN LLP 275 Battery Street, 29th Floor San Francisco, CA 94111	Plaintiff and Appellant: Kayrn McGaughey, Barbara Hymes Cohen, Deborah Patane, Donna Moore, IUOE Stationary Engineers Local 39 Health & Welfare Plan, Sheet Metal Workers Health Plan of Southern California **By U.S. Mail** **(1 copy of brief to each)**
David E. Everson Heather S. Woodson Victoria L. Smith STINSON MORRISON HECKER LLP 1201 Walnut, Suite 2900 Kansas City, MO 64106 Kathryn E. Karcher 401 B Street, Suite 2450 San Diego, CA 92101 Joann F. Rezzo EDELSON & REZZO 402 West Broadway, Suite 2700 San Diego, CA 92101	Defendant and Respondent: Hoechst Marion Roussel, Inc., The Rugby Group, Inc., Watson Pharmaceuticals, Inc. **By U.S. Mail** **(1 copy of brief to each)**
Edwin John U Gregory Skidmore Karen N. Walker KIRKLAND & ELLIS LLP 655 15th Street NW Washington, DC 20005	Defendant and Respondent: Barr Laboratories, Inc. **By U.S. Mail** **(1 copy of brief to each)**

SERVICE LIST	
Jay P. Lefkowitz KIRKLAND & ELLIS LLP 601 Lexington Avenue New York, NY 10022 Kathryn E. Karcher 401 B Street, Suite 2450 San Diego, CA 92101 Joann F. Rezzo EDELSON & REZZO 402 West Broadway, Suite 2700 San Diego, CA 92101	
Judicial Council of California 455 Golden Gate Avenue, 6th Floor San Francisco, CA 94102 Attn: Carlotta Tillman	Judicial Council: **By U.S. Mail** **(1 copy of brief)**
Office of The District Attorney San Diego County 330 W. Broadway San Diego, CA 92101 Office of the Attorney General San Diego Office 110 West "A" Street, Suite 1100 San Diego, CA 92101	The People: **By U.S. Mail** **(1 copy of brief to each)**
Superior Court of California Clerk of the San Diego Superior Court 330 W. Broadway San Diego, CA 92101	**By U.S. Mail** **(1 copy of brief)**