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IN THE SUPREME COURT OF CALIFORNIA

IN RE CIPRO CASES I & II.	)	S198616
	)	Ct.App. 4/1 D056361
	)	San Diego County
	)	Super. Ct. Nos.
	)	JCCP 4154/4220

To protect competition in the marketplace, antitrust law prohibits agreements that create or perpetuate monopolies. Patent law, in contrast, grants temporary monopolies to inventors to encourage the development of useful innovations. We consider here a crucial question at the intersection of these two bodies of law: what limits, if any, does antitrust law place on the ability of a patent holder to make agreements restricting competition during the life of its patent? In particular, when another entity tries to invalidate a patent and enter the marketplace, can the patentee pay the would-be competitor to withdraw its challenge and refrain from competing until at or near the natural expiration of the potentially invalid patent's life?

The answer to this is of special moment to the pharmaceutical industry, which has seen a raft of suits in which generic drug manufacturers (generics), seeking to introduce lower priced alternatives to patented brand-name drugs, raise patent invalidity as a defense to claims of infringement. With increasing frequency these cases have settled, with the plaintiff brand-name drug manufacturer (brand) making a "reverse payment" to the defendant generic in

exchange for the generic dropping its patent challenge and consenting to stay out of the market. This case involves just such a settlement agreement.

Under federal antitrust law, these settlements are not immune from scrutiny, even if they limit competition no more than a valid patent would have. (*Federal Trade Commission v. Actavis, Inc.* (2013) 570 U.S. ___, ___ [186 L.Ed.2d 343, 356, 133 S.Ct. 2223, 2230] (*Actavis*).) We conclude the same is true under state antitrust law. Some patents are valid; some are not. Sometimes competition would infringe; sometimes it would not. Parties illegally restrain trade when they privately agree to substitute consensual monopoly in place of potential competition that would have followed a finding of invalidity or noninfringement. The Court of Appeal ruled to the contrary; we reverse.

FACTUAL AND PROCEDURAL BACKGROUND

Bayer AG and Bayer Corporation (collectively Bayer) market Cipro, an antibiotic that has been among the most-prescribed and best-selling drugs in the world. (*Arkansas Carpenters Health and Welfare Fund v. Bayer AG* (2d Cir. 2010) 604 F.3d 98, 100; *In re Ciprofloxacin Hydrochloride Antitrust Lit.* (E.D.N.Y. 2003) 261 F.Supp.2d 188, 194; *In re Ciprofloxacin Hydrochloride Antitrust Lit.* (E.D.N.Y. 2001) 166 F.Supp.2d 740, 743.) In 1987, Bayer was issued a United States patent on the active ingredient in Cipro, ciprofloxacin hydrochloride, a patent that expired in December 2003. (U.S. Patent No. 4,670,444, col. 22, ll. 32-34, claim 12 (the '444 patent); see *In re Ciprofloxacin Hydrochloride Antitrust Lit.* (Fed. Cir. 2008) 544 F.3d 1323, 1327–1328.) A subsidiary and licensee of Bayer obtained Food and Drug Administration (FDA) approval to market Cipro in the United States. (*In re Ciprofloxacin Hydrochloride Antitrust Lit.*, *supra*, 544 F.3d at p. 1328; *In re Ciprofloxacin Hydrochloride Antitrust Lit.*, *supra*, 166 F.Supp.2d at p. 743.) Between 1987 and 2003, Bayer

was the sole producer of Cipro in the United States and, between 1997 and 2003 alone, Cipro generated more than $6 billion in gross sales.

At one time, pioneer drugs like Cipro and the generic drugs that followed them were governed by the same FDA approval process.[1] Subjecting generic drugs to the same "cumbersome drug approval process [as pioneer drugs] delayed the entry of relatively inexpensive generic drugs into the market place," at substantial cost to consumers and the government. (*Mylan Pharmaceuticals, Inc. v. Shalala* (D.D.C. 2000) 81 F.Supp.2d 30, 32; see H.R.Rep. No. 98-857, 2d Sess., pt. 1, p. 17 (1984), reprinted in 1984 U.S. Code Cong. & Admin. News, at p. 2650.) To expedite the availability of low cost generic drugs, Congress authorized an abbreviated approval process for drugs whose active ingredients had already been proven safe and effective in earlier clinical trials. (Drug Price Competition & Patent Term Restoration Act of 1984, Pub.L. No. 98-417, tit. I, §§ 101-106 (Sept. 24, 1984) 98 Stat. 1585, 1585–1597, codified as amended at 21 U.S.C. § 355 (the Hatch-Waxman Act); see H.R.Rep. No. 98-857, 2d Sess., pt. 1, pp. 14, 16–17 (1984), reprinted in 1984 U.S. Code Cong. & Admin. News, pp. 2647, 2649–2650.)

Under the Hatch-Waxman Act, a prospective generic drug manufacturer may file a streamlined application asserting the generic drug's bioequivalence with an existing pioneer drug, thus piggybacking on the safety and efficacy data already submitted to the FDA in connection with its approval of the original drug. (21 U.S.C. § 355(j)(2)(A)(ii), (iv); see *Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d

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[1] A generic drug is a drug designed to be identical to an already-FDA-approved pioneer drug in active ingredients, safety, and efficacy, and thus therapeutically equivalent to its brand-name counterpart. (See *PLIVA, Inc. v. Mensing* (2011) 564 U.S. ___, ___, fn. 2 [180 L.Ed.2d 580, 588, fn. 2; 131 S.Ct. 2567, 2574, fn. 2].)

at p. 354, 133 S.Ct. at p. 2228].) With respect to the patent implications of the application, the generic drug manufacturer must make one of four certifications: There is no patent for the underlying drug, the patent is expired, the patent will expire, or (relevant here) the patent is invalid or will not be infringed by the proposed manufacture and sale of the generic drug. (21 U.S.C. § 355(j)(2)(A)(vii); *Actavis*, at p. ___ [186 L.Ed.2d at pp. 353–354, 133 S.Ct. at p. 2228].) An applicant that certifies the affected patent is invalid or will not be infringed (a "paragraph IV" certification) must give notice to all affected patent owners. (21 U.S.C. § 355(j)(2)(B).) Submission of an application to manufacture a generic version of a drug covered by a patent is a technical act of infringement (35 U.S.C. § 271(e)(2)(A); *Actavis*, at p. ___ [186 L.Ed.2d at p. 354, 133 S.Ct. at p. 2228]); to stay approval of the generic version, a patent owner must file an infringement lawsuit against the generic drug manufacturer within 45 days (21 U.S.C. § 355(j)(5)(B)(iii)). To provide an incentive to assume the risks of exposure to such litigation, the first generic manufacturer to file an application and prevail is granted a potentially lucrative 180-day exclusivity window in which to market its drug without competition from any other generic manufacturer. (21 U.S.C. § 355(j)(5)(B)(iv); *Actavis*, at p. ___ [186 L.Ed.2d at p. 354, 133 S.Ct. at pp. 2228–2229.)

In 1991, twelve years before the scheduled expiration of the '444 patent, defendant Barr Laboratories, Inc., filed an application to market a generic version of Cipro. (*In re Ciprofloxacin Hydrochloride Antitrust Lit.*, *supra*, 544 F.3d at p. 1328.) Barr's application included a paragraph IV certification that the '444 patent was invalid and unenforceable. (*Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, *supra*, 604 F.3d at pp. 101–102; see 21 U.S.C. § 355(j)(2)(A)(vii)(IV).) Barr's statutory notice to Bayer contended Cipro's derivation was obvious in light of prior art, the '444 patent was an invalid double

patent, and the patent was the product of inequitable conduct based on Bayer's withholding of information about preexisting patents from the patent examiner. (See 35 U.S.C. §§ 102, 103; *In re Longi* (Fed. Cir. 1985) 759 F.2d 887, 892–893.) Bayer responded with a patent infringement suit, staying FDA approval, and Barr counterclaimed for a declaratory judgment that the '444 patent was invalid.[2]

In early 1997, Bayer and Barr settled. Under the terms of the settlement, Barr agreed to postpone marketing a generic version of Cipro until the '444 patent expired. It also agreed to a consent judgment affirming the patent's validity and to modification of the certification in its FDA application from a paragraph IV certification, alleging invalidity, to a "paragraph III" certification, seeking to market a generic drug upon patent expiration. (*Arkansas Carpenters Health and Welfare Fund v. Bayer AG, supra*, 604 F.3d at p. 102; see 21 U.S.C. § 355(j)(2)(A)(vii)(III); 21 C.F.R. § 314.94(a)(12)(i)(A)(3) (2014).) In return, Bayer agreed to make payments to Barr and to supply it with Cipro for licensed resale beginning six months before patent expiration. (See *In re Ciprofloxacin Hydrochloride Antitrust Lit.*, *supra*, 544 F.3d at pp. 1328–1329.) This head start mirrored the 180-day duopoly the Hatch-Waxman Act would have provided Barr if it had succeeded in showing invalidity or noninfringement of Bayer's patent.

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[2] While the litigation was ongoing, Barr agreed to accept contribution to its litigation costs from another generic drug manufacturer, defendant The Rugby Group, Inc., a then-subsidiary of defendant Hoechst Marion Roussel, Inc., in exchange for a share of the benefits of any settlement, judgment, or sale of generic ciprofloxacin hydrochloride. (*In re Ciprofloxacin Hydrochloride Antitrust Lit.*, *supra*, 544 F.3d at p. 1328.) In 1998, The Rugby Group, Inc. was acquired by defendant Watson Pharmaceuticals, Inc. Generic defendants Barr Laboratories, Inc., The Rugby Group, Inc., Watson, and Hoechst Marion Roussel, Inc., are referred to collectively as Barr.

(21 U.S.C. § 355(j)(5)(B)(iv).) Barr was to receive Cipro from Bayer at 85 percent of current price.

Pursuant to the settlement, between 1997 and 2003, Bayer paid Barr $398.1 million. In that same period, Bayer's profits from sales of Cipro exceeded $1 billion. (*In re Ciprofloxacin Hydrochloride Antitrust Lit., supra*, 261 F.Supp.2d at p. 194.)

The 1997 settlement between Bayer and Barr produced a wave of state and federal antitrust suits. (*Arkansas Carpenters Health and Welfare Fund v. Bayer AG, supra*, 604 F.3d at p. 102.) This case arises from nine such coordinated class action suits brought by indirect purchasers of Cipro in California against Bayer and Barr. (See *In re Cipro Cases I & II* (2004) 121 Cal.App.4th 402, fn. *, 406–407.) The operative complaint in these coordinated proceedings alleges the Bayer-Barr reverse payment settlement violated the Cartwright Act (Bus. & Prof. Code, § 16700 et seq.), unfair competition law (*id.*, § 17200 et seq.), and common law prohibition against monopolies. The gravamen of the complaint is that the 1997 agreement preserved Bayer's monopoly and ability to charge supracompetitive prices at the expense of consumers, and Bayer in turn split these monopoly profits with Barr. Class certification was granted and upheld on appeal. (*In re Cipro Cases I & II*, at p. 418.) Thereafter, the parties stayed this action pending resolution of consolidated federal challenges to the Bayer-Barr settlement.

Following a Federal Circuit ruling in favor of Bayer and Barr on federal antitrust claims (*In re Ciprofloxacin Hydrochloride Antitrust Lit., supra*, 544 F.3d 1323),[3] the trial court granted a defense summary judgment. It found decisional

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[3] As discussed below, both *In re Ciprofloxacin Hydrochloride Antitrust Lit., supra*, 544 F.3d 1323 and a second decision rejecting a federal antitrust challenge to the Cipro settlement, *Arkansas Carpenters Health and Welfare Fund v. Bayer*

(footnote continued on next page)

law under the federal Sherman Act (15 U.S.C. § 1 et seq.) dispositive and held that because the settlement agreement did not restrain competition longer than the exclusionary scope of the '444 patent, it did not violate the Cartwright Act. The Court of Appeal affirmed, holding that agreements restraining competition within the scope of a patent are lawful unless the patent was procured by fraud or the suit to enforce it was objectively baseless. The court held further that, even if there were a disputed issue of material fact as to whether Bayer's suit to enforce the '444 patent was objectively baseless, litigation of that theory would be foreclosed by exclusive federal court patent jurisdiction.

We granted review to resolve important unsettled issues of state antitrust law. While the case was pending before this court, we entered an order formalizing Bayer's dismissal from the proceedings pursuant to an approved settlement. Barr remains as respondent.

DISCUSSION

I. *Reverse Payment Settlements Under the Hatch-Waxman Act*

The Hatch-Waxman Act illustrates the law of unintended consequences. Congress wrote into the act a substantial incentive for generics to enter markets earlier by offering a 180-day exclusivity period to the first generic filer, and only that filer, to challenge a patent. (21 U.S.C. § 355(j)(5)(B)(iv); see Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem* (2006) 81 N.Y.U. L.Rev. 1553, 1566, 1578–1579, 1583.) The theory was that a generic would be more likely to challenge dubious patents if offered the

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AG, *supra*, 604 F.3d 98, were decided under principles later rejected by the United States Supreme Court in *Actavis*, *supra*, 570 U.S. ___ [186 L.Ed.2d 343, 133 S.Ct. 2223].

carrot of an enormously valuable six-month period in which only it and the brand could produce a drug. (Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality* (2009) 108 Mich. L.Rev. 37, 47; Bulow, *The Gaming of Pharmaceutical Patents* in 4 Innovation Policy and the Economy (Jaffe et al. edits., 2004) 145, 163; Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition* (2009) 109 Colum. L.Rev. 629, 651.) Otherwise, "free rider" problems might arise: every generic would have an incentive to hold back and let some other generic be the one to shoulder the risk and litigation costs associated with challenging a patent. (Lemley & Shapiro, *Probabilistic Patents* (2005) 19 J. Econ. Perspectives 75, 88; Hemphill, *Paying for Delay*, at p. 1605.)

This solution may well have encouraged more generics to file patent challenges, but not without creating a series of new problems. In other settings, a patentee might have little incentive to buy off a challenger in order to preserve its monopoly and continue reaping monopoly profits, for the simple reason that paying off the first challenger would simply encourage another challenger, and then another. (See *Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at pp. 361–362, 133 S.Ct. at p. 2235].) Two features of the Hatch-Waxman Act change this dynamic. First, the 180-day exclusivity period created a bottleneck; no one else could receive FDA approval until after its expiration. (21 U.S.C. § 355(j)(5)(B)(iv)(I); Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, *supra*, 81 N.Y.U. L.Rev. at pp. 1560–1561, 1586–1587.) Second, other generics tempted to challenge a patent in the wake of a settlement with the first-filing generic would have to wait out an automatic 30-month stay the brand could obtain just by opposing their requests for FDA approval. (21 U.S.C. § 355(j)(5)(B)(iii); *Actavis*, at p. ___ [186 L.Ed.2d at pp. 361–362, 133 S.Ct. at p. 2235]; Bulow, *The Gaming of Pharmaceutical*

Patents in 4 Innovation Policy and the Economy, *supra*, at p. 164.) As a result, the brand could effectively pick off " 'the most motivated challenger, and the one closest to introducing competition' " (*Actavis*, at p. ___ [186 L.Ed.2d at pp. 361–362, 133 S.Ct. at p. 2235], quoting Hemphill, *Paying for Delay*, at p. 1586), with all others stuck in line behind that generic (Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley* (2003) 87 Minn. L.Rev. 1789, 1801).[4]

This legal regime means that, regardless of the degree of likely validity of a patent, the brand and first-filing generic have an incentive to effectively establish a cartel through a reverse payment settlement. (12 Areeda & Hovenkamp, Antitrust Law, *supra*, ¶ 2046, pp. 341–345; Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's* Actavis *Decision* (2014) 15 Minn. J. L. Sci. & Tech. 3, 8–13; see Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, *supra*, 108 Mich. L.Rev. at p. 73 [under Hatch-Waxman, "[g]enerics have powerful incentives to file the first patent challenge but little incentive to pursue the litigation"].) Rather than expend litigation costs on either side, the brand and generic can reach a settlement that reflects the likely validity or invalidity of the patent (stronger patent, smaller settlement; weaker patent, bigger settlement), grants the generic a share of monopoly profits, and leaves the brand

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[4] Amendments to the Hatch-Waxman Act postdating the settlement in this case may have partially alleviated the complete bottleneck problem (Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, *supra*, 81 N.Y.U. L.Rev. at p. 1587), although not issues arising from the 30-month stay or the reduced incentives for other generics, without the carrot of 180 days of duopoly, to bring patent challenges (12 Areeda & Hovenkamp, Antitrust Law (3d ed. 2012) ¶ 2046, p. 341).

the sole manufacturer of the product. (Hovenkamp, *Anticompetitive Patent Settlements*, at pp. 12–13.)

It is likely for this reason that reverse payment settlements, practically unheard of before the Hatch-Waxman Act, have proliferated in the years since its enactment. (*Actavis, supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 362, 133 S.Ct. at p. 2235]; Hovenkamp, *Anticompetitive Patent Settlements, supra*, 15 Minn. J. L. Sci. & Tech. at pp. 13–16; Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, *supra*, 109 Colum. L.Rev. at pp. 647–656.) This is probably not what Congress intended. (*Actavis*, at p. ___ [186 L.Ed.2d at p. 362, 133 S.Ct. at p. 2235] [the Hatch-Waxman Act's provisions have "no doubt unintentionally . . . created special incentives for collusion"]); *id.* at p. ___ [186 L.Ed.2d at p. 360, 133 S.Ct. at p. 2234] [quoting remarks of Sen. Hatch and Rep. Waxman decrying as an unintended consequence of their legislation collusive agreements to delay competition].) The issue for us is what, if anything, state antitrust law has to say about these problems.

II. *The Intersection Between Antitrust and Patent Law*

A. *The Cartwright Act*

The Legislature enacted the state's principal antitrust law, the Cartwright Act, to rein in the burgeoning power of monopolies and cartels. (*Clayworth v. Pfizer, Inc.* (2010) 49 Cal.4th 758, 772.) The act's principal goal is the preservation of consumer welfare. (*Cianci v. Superior Court* (1985) 40 Cal.3d 903, 918; *Marin County Bd. of Realtors, Inc. v. Palsson* (1976) 16 Cal.3d 920, 935.) The act, like antitrust law in general, "rest[s] 'on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress, while at the same time providing an environment conducive to the preservation of our democratic political and social institutions.' " (*Marin County*

Bd., at p. 935; see *National Soc. of Professional Engineers v. United States* (1978) 435 U.S. 679, 695.) At its heart is a prohibition against agreements that prevent the growth of healthy, competitive markets for goods and services and the establishment of prices through market forces. (See *Speegle v. Board of Fire Underwriters* (1946) 29 Cal.2d 34, 44.) "The act 'generally outlaws any combinations or agreements which restrain trade or competition or which fix or control prices' [citation], and declares that, with certain exceptions, 'every trust is unlawful, against public policy and void.' " (*Pacific Gas & Electric Co. v. County of Stanislaus* (1997) 16 Cal.4th 1143, 1147.)

The "trust[s]" the act prohibits include any "combination . . . by two or more persons" to "create or carry out restrictions in trade or commerce" (Bus. & Prof. Code, § 16720, subd. (a)) or to "prevent competition in manufacturing, making, transportation, sale or purchase of merchandise, produce or any commodity" (*id.*, subd. (c)). Also prohibited is any contract by which two or more entities "[a]gree to pool, combine or directly or indirectly unite any interests that they may have connected with the sale . . . of any such article or commodity, that its price might in any manner be affected." (*Id.*, subd. (e)(4).) Agreements in violation of the act are "absolutely void and . . . not enforceable at law or in equity." (*Id.*, § 16722; see *id.*, § 16726.)

Though the Cartwright Act is written in absolute terms, in practice not every agreement within the four corners of its prohibitions has been deemed illegal. (*Morrison v. Viacom, Inc.* (1998) 66 Cal.App.4th 534, 540.) Business and Professions Code sections 16720, 16722, and 16726 draw upon the common law prohibition against restraints of trade. (*Corwin v. Los Angeles Newspaper Service Bureau, Inc.* (1971) 4 Cal.3d 842, 852; *People v. Building Maintenance etc. Assn.* (1953) 41 Cal.2d 719, 727; *Speegle v. Board of Fire Underwriters*, *supra*, 29 Cal.2d at p. 44.) The earliest common law decisions imposed an absolute rule,

voiding "all contracts . . . which in any degree tended to the restraint of trade." (*Wright v. Ryder* (1868) 36 Cal. 342, 357.) But the common law rule was soon modified and "as relaxed, tolerated such [restraints of trade] as were restricted in their operations within reasonable limits." (*Ibid.*; see *Vulcan Powder Co. v. Hercules Powder Co.* (1892) 96 Cal. 510, 512.) The United States Supreme Court looked to the common law in embracing a rule of reason for determining which agreements violate federal antitrust law (see *Standard Oil Co. v. United States* (1911) 221 U.S. 1, 60), and this court thereafter followed suit: "[I]t may be assumed that the broad prohibitions of the Cartwright Act are subject to an implied exception similar to the one that validates reasonable restraints of trade under the federal Sherman Antitrust Act." (*Building Maintenance etc. Assn.*, at p. 727; see *Marin County Bd. of Realtors, Inc. v. Palsson*, *supra*, 16 Cal.3d at p. 930; *Corwin*, at p. 853.)[5] What was true under the common law, however, is true today: "the difficulty lies in determining what are reasonable and what unreasonable restrictions." (*Wright*, at p. 358.)

B. *Patent Law*

That difficulty is all the greater because antitrust law does not exist in a vacuum. The patent laws "are in *pari materia* with the antitrust laws and modify them *pro tanto* [to that extent]." (*Simpson v. Union Oil Co.* (1964) 377 U.S. 13, 24.) To promote investment in invention and the public disclosure of new discoveries, Congress has seen fit to grant inventors limited statutory monopolies

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[5] As we noted in *People v. Building Maintenance etc. Assn.*, *supra*, 41 Cal.2d at pages 726–727, a separate section of the Cartwright Act effectively codifies this principle: "It is not unlawful to enter into agreements or form associations or combinations, the purpose and effect of which is to promote, encourage or increase competition in any trade or industry, or which are in furtherance of trade." (Bus. & Prof. Code, § 16725.)

and the right to exclude competition in the manufacture, use, or sale of the patent's subject. (35 U.S.C. § 154(a); see *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.* (1989) 489 U.S. 141, 150–151; *Dawson Chemical Co. v. Rohm & Haas Co.* (1980) 448 U.S. 176, 215; *Sears, Roebuck & Co. v. Stiffel Co.* (1964) 376 U.S. 225, 229.) Accordingly, the issuance of a federal patent creates "an exception to the general rule against monopolies and to the right of access to a free and open market." (*Precision Co. v. Automotive Co.* (1945) 324 U.S. 806, 816.) While "[t]he limited monopolies granted to patent owners do not exempt them from the prohibitions" of antitrust law (*Standard Oil Co. v. United States* (1931) 283 U.S. 163, 169; see *United Shoe Mach. Co. v. United States* (1922) 258 U.S. 451, 463–464 ["the rights secured by a patent do not protect the making of contracts in restraint of trade"]), in a given case possession of a patent may provide a defense to liability (*United States v. Gen. Elec. Co.* (1926) 272 U.S. 476, 488–490; *Valley Drug Co. v. Geneva Pharmaceuticals* (11th Cir. 2003) 344 F.3d 1294, 1307). Courts thus must reconcile the two bodies of law, making "an adjustment between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by" antitrust law. (*United States v. Line Material Co.* (1948) 333 U.S. 287, 310.)

At the extremes, this is easy. If a patent were known to be invalid, a private agreement nevertheless giving it effect would be plainly illegal. (See Bus. & Prof. Code, §§ 16720, 16722, 16726.) Conversely, if a patent were known to be valid, an agreement foreclosing competition no more than the statutory monopoly would not restrain trade beyond what federal law permitted, and the rights patent law affords the patentee would supersede any state law prohibition. Difficulties emerge when we move from a hypothetical patent known to be determinately valid or invalid to the real world, where validity may be unclear. When assessing the antitrust implications of an agreement arising from a patent, the truth about the

patent's validity cannot always be known. The issue is how antitrust and patent law should accommodate each other under these conditions of uncertainty.

III. *The Scope of the Patent Test*

A. *The Court of Appeal and the Scope of the Patent Approach*

The particular accommodation this case calls for arises from an issue of virtual first impression under the Cartwright Act: how to apply the statutory bar against restraints of trade to patent settlement agreements that limit competition, but no more broadly than an injunction enforcing the patent would have, had one been obtained. (Cf. *In re Cardizem CD Antitrust Litigation* (6th Cir. 2003) 332 F.3d 896, 904, fn. 8, 906–909 [deciding the issue under both federal law and the Cartwright Act, but without independently analyzing state law].) Rejecting plaintiffs' argument that agreements of this sort should be deemed uniformly illegal, the Court of Appeal resolved the issue by adopting one of several competing approaches courts had developed to solve the problem under federal antitrust law, the scope of the patent test.[6] Under that test, the Court of Appeal held, "a settlement of a lawsuit to enforce a patent does not violate the Cartwright Act if the settlement restrains competition only within the scope of the patent, unless the patent was procured by fraud or the suit for its enforcement was objectively baseless." The scope of the patent test thus gives wide effect to patents by essentially presuming their validity in most cases. We conclude, as more recent United States Supreme Court authority has now made clear, that this

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[6] See *In re Tamoxifen Citrate Antitrust Litigation* (2d Cir. 2006) 466 F.3d 187; cf. *In re Cardizem CD Antitrust Litigation*, *supra*, 332 F.3d at pp. 907–909 (adopting per se rule); *In re K-Dur Antitrust Litigation* (3d Cir. 2012) 686 F.3d 197 (adopting quick look rule of reason analysis).

test accords excess weight to the policies motivating patent law, gives insufficient consideration to the concerns animating antitrust law, and must be rejected.

The federal cases the Court of Appeal followed identify three core rationales for concluding a patent litigation settlement restricting competition no more than a valid patent would is generally lawful. First, patents are presumed valid. (35 U.S.C. § 282(a).) Given this presumption, many lower federal courts reasoned, an agreement that does not extend monopoly beyond what a patent grants imposes no additional injury to competition and, in the absence of anti-competitive effects, generally survives antitrust scrutiny. (See *In re Ciprofloxacin Hydrochloride Antitrust Lit.*, *supra*, 544 F.3d at p. 1337; *In re Tamoxifen Citrate Antitrust Litigation*, *supra*, 466 F.3d at pp. 212–213; *Schering-Plough Corp. v. FTC* (11th Cir. 2005) 402 F.3d 1056, 1066–1068.)

Second, the fundamental purpose of patent law is to promote innovation and the disclosure of inventions so that ultimately new discoveries may benefit the public at large. (*Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, *supra*, 489 U.S. at pp. 150–151.) To subject exclusions within the scope of a patent to scrutiny and potential liability would, lower courts feared, chill innovation and give inventors pause in deciding whether to share their creations with the public. (See *In re Tamoxifen Citrate Antitrust Litigation*, *supra*, 466 F.3d at p. 203; *Schering-Plough Corp. v. FTC*, *supra*, 402 F.3d at p. 1075; *Valley Drug Co. v. Geneva Pharmaceuticals*, *supra*, 344 F.3d at p. 1308.)

Third, there is a general policy in favor of settlement, perhaps more so in patent litigation. (*In re Ciprofloxacin Hydrochloride Antitrust Lit.*, *supra*, 544 F.3d at p. 1333; *In re Tamoxifen Citrate Antitrust Litigation*, *supra*, 466 F.3d at p. 202; *Schering-Plough Corp. v. FTC*, *supra*, 402 F.3d at pp. 1072–1073.) Patent litigation settlements "may benefit the public by introducing a new rival into the market, facilitating competitive production, and encouraging further innovation."

(*Schering-Plough Corp.*, at p. 1075.) Conversely, a legal regime that hampers settlement "may actually decrease product innovation by amplifying the period of uncertainty around a drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product." (*Ibid.*; see *In re Tamoxifen Citrate Antitrust Litigation*, at p. 203.)

B. Federal Trade Commission v. Actavis

The Court of Appeal's adoption of the scope of the patent test was the product not of an analysis of the Cartwright Act's text, policy, or history, but of an assessment of procedural and policy-based aspects of patent law. The soundness of its choice of test thus depends on the extent to which that patent law assessment was sound. In *Actavis, supra*, 570 U.S. ___ [186 L.Ed.2d 343, 133 S.Ct. 2223], issued after the Court of Appeal's decision and after our grant of review, the Supreme Court reversed a federal decision holding Hatch-Waxman reverse payment settlement agreements " 'immune from antitrust attack so long as [their] anticompetitive effects fall within the scope of the exclusionary potential of the patent.' " (*Id.* at p. ___ [186 L.Ed.2d at p. 353, 133 S.Ct. at p. 2227].) In the course of its opinion, the Supreme Court dismantled the underpinning of each of the cases the Court of Appeal had found persuasive.

First, the Supreme Court rejected the scope of the patent test's foundational presumption that the holder of a challenged patent enjoys all the rights attendant to ownership of a valid patent: "to refer . . . simply to what the holder of a valid patent could do does not by itself answer the antitrust question. The patent here may or may not be valid, and may or may not be infringed." (*Actavis, supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 356, 133 S.Ct. at pp. 2230–2231].) To be sure, a valid patent allows the patentee to exclude others from the market, "[b]ut an *invalidated* patent carries with it no such right." (*Id.* at p. ___ [186 L.Ed.2d at p. 356, 133 S.Ct. at p. 2231].) Patent litigation "put[s] the patent's validity at

issue, as well as its actual preclusive scope"; simply because a settlement curtails testing and ultimate resolution of that issue, courts should not thereafter treat patent law and its presumptions as conclusively establishing the challenged patent's legitimate scope. (*Id.* at p. ___ [186 L.Ed.2d at p. 357, 133 S.Ct. at p. 2231].)

Second, the core policies underlying patent law are more nuanced than the cases applying a scope of the patent test had recognized, and the incentives to innovate far sturdier than those courts had feared. Patents carry with them a frequent cost—monopoly premiums the public must bear. (See *Lear, Inc. v. Adkins* (1969) 395 U.S. 653, 670.) The willingness to pay that cost depends upon a quid pro quo: " 'the public interest in granting patent monopolies' exists only to the extent that 'the public is given a novel and useful invention' in 'consideration for its grant.' " (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 358, 133 S.Ct. at p. 2232].) Accordingly, patent policy does not support unquestioned protection of every inventor's rights, but instead favors "eliminating unwarranted patent grants so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification.' " (*Id.* at p. ___ [186 L.Ed.2d at p. 359, 133 S.Ct. at p. 2233].) Vigorous testing for validity is thus desirable in order to weed out patents that shield a monopoly without offering corresponding public benefits. (See *Aronson v. Quick Point Pencil Co.* (1979) 440 U.S. 257, 264; *United States v. Glaxo Group Ltd.* (1973) 410 U.S. 52, 58; *Edward Katzinger Co. v. Chicago Mfg. Co.* (1947) 329 U.S. 394, 400–401.)[7]

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[7] As commentators have noted, an excess of invalid patents is one of the principal problems in modern patent law. (See Ford, *Patent Invalidity Versus Noninfringement* (2013) 99 Cornell L.Rev. 71, 74 & fn. 11 [discussing substantial scholarship on the point].) The pro-patent-challenge policy is particularly strong in the Hatch-Waxman Act setting, given the 180-day exclusivity bounty Congress

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Third, the Supreme Court explained that while the policy favoring settlement of patent litigation offers some support for limiting scrutiny of agreements restraining competition only within the scope of a patent, it ultimately is not dispositive. (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at pp. 360, 364, 133 S.Ct. at pp. 2234, 2238].) Settlements are generally a positive good, but not always; settlements of the sort challenged in *Actavis*, the court observed, can amount to "payment in return for staying out of the market" and permit monopoly premiums still to be charged and simply divided up between the patent holder and patent challenger; "[t]he patentee and the challenger gain; the consumer loses." (*Id.* at p. ___ [186 L.Ed.2d at p. 361, 133 S.Ct. at pp. 2234, 2235].) Such anti-competitive effects will not always be justified, and an antitrust action to test a settlement's legality may be warranted and feasible. (*Id.* at p. ___ [186 L.Ed.2d at pp. 361–364, 133 S.Ct. at pp. 2235–2237].) Fears of chilling even legitimate settlements are overstated; all that allowing antitrust scrutiny does is remove the incentive to settle as a way to split monopoly profits. (*Id.* at p. ___ [186 L.Ed.2d at p. 363, 133 S.Ct. at p. 2237].) Because the scope of the patent test overvalues the policies underlying patent law at the expense of the equally relevant policies underlying antitrust law, the court concluded, it cannot stand under federal law. (*Id.* at p. ___ [186 L.Ed.2d at p. 357, 133 S.Ct. at p. 2231].)

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adopted as an incentive to bring such challenges. (See 21 U.S.C. § 355(j)(5)(B)(iv); 12 Areeda & Hovenkamp, Antitrust Law, *supra*, ¶ 2046, p. 340; Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, *supra*, 108 Mich. L.Rev. at pp. 43, 64; *ante*, pp. 7–8.)

C. *The Scope of the Patent Test's Validity Under State Law*

Barr contends *Actavis* is distinguishable because it involved a public prosecution under the Federal Trade Commission Act (15 U.S.C. § 45 et seq.), not a private antitrust suit, and this court should embrace the scope of the patent test as a matter of state antitrust law.

We agree *Actavis* is not dispositive on matters of state law. Indeed, even if *Actavis* had been a private Sherman Act case, its conclusions would not dictate how the Cartwright Act must be read. "Interpretations of federal antitrust law are at most instructive, not conclusive, when construing the Cartwright Act, given that the Cartwright Act was modeled not on federal antitrust statutes but instead on statutes enacted by California's sister states around the turn of the 20th century." (*Aryeh v. Canon Business Solutions, Inc.* (2013) 55 Cal.4th 1185, 1195; see *State of California ex rel. Van de Kamp v. Texaco, Inc.* (1988) 46 Cal.3d 1147, 1164.) That said, nothing in the United States Supreme Court's discussion of the legal rules at the boundary between antitrust and patent law hinged on the happenstance that the case under review involved a public prosecutor. Accordingly, that circumstance neither adds to nor detracts from the persuasive force the discussion would otherwise have.

What does affect the weight to be accorded *Actavis* is the extent to which its analysis establishes the metes and bounds of patent law and policy. Patent law is federal law. (U.S. Const., art. I, § 8, cl. 8; see *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, *supra*, 489 U.S. at pp. 146–157.) The United States Supreme Court is the final arbiter of questions of patent law and the extent to which interpretations of antitrust law—whether state or federal—must accommodate patent law's requirements, and *Actavis* is its latest word on the subject. If under *Actavis* patent law demands extensive deference to patents' presumed validity and the consecration of a broad range of agreements otherwise facially illegal under

state law, we must abide by that judgment. Conversely, if the accommodation necessitated by patent policy is somewhat narrower than previously understood, we again must treat that determination as conclusive and reconsider the proper domain of state antitrust law in light of that cession of territory.

Barr asserts *Actavis* is alternatively distinguishable on the ground the underlying patent there was far weaker than the underlying patent here.[8] But *Actavis*'s analysis was not contingent on a particular level of uncertainty surrounding the patent before it. Instead, the court simply recognized that any patent might, or might not, be valid. (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 356, 133 S.Ct. at p. 2231]; see *id.* at p. ___ [186 L.Ed.2d at p. 367, 133 S.Ct. at p. 2240] (dis. opn. of Roberts, C.J.) [recognizing the problem "that we're not quite certain if the patent is actually valid, or if the competitor is infringing it," a problem "that is always the case" in patent disputes].) Indeed, a critical insight undergirding *Actavis* is that patents are in a sense probabilistic, rather than ironclad: they grant their holders a potential but not certain right to exclude.

The uncertainty concerning a patent's validity is a by-product of the realities surrounding patent issuance and the legal regime Congress and the courts have established for patent enforcement. In the first instance, a patent "simply represents a legal conclusion reached by the Patent Office. Moreover, the legal conclusion is predicated on factors as to which reasonable men can differ widely. Yet the Patent Office is often obliged to reach its decision in an *ex parte*

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8 After the settlement, Bayer submitted the '444 patent to the Patent and Trademark Office for reexamination and obtained reaffirmation that it was not invalid. (See 35 U.S.C. § 302.) Later patent challenges by litigants other than Barr were unsuccessful. (See *In re Ciprofloxacin Hydrochloride Antitrust Lit.* (E.D.N.Y. 2005) 363 F.Supp.2d 514, 519–520.)

proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity." (*Lear, Inc. v. Adkins, supra,* 395 U.S. at p. 670.) That decision is constrained by time and resource pressures; facing an enormous backlog, patent examiners may average less than 20 hours spent on each application. (Ford, *Patent Invalidity Versus Noninfringement*, *supra*, 99 Cornell L.Rev. at pp. 87–89; Lemley & Shapiro, *Probabilistic Patents*, *supra*, 19 J. Econ. Perspectives at p. 79; Lemley, *Rational Ignorance at the Patent Office* (2001) 95 Nw.U. L.Rev. 1495, 1499–1500.) Given this underlying reality, Congress has elected not to make the issuance of a patent conclusive but, rather, subject to validation or invalidation in court proceedings. (35 U.S.C. § 282; see, e.g., *Alice Corp. Pty. Ltd. v. CLS Bank Int'l* (2014) 573 U.S. ___ [189 L.Ed.2d 296, 134 S.Ct. 2347]; *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.* (1965) 382 U.S. 172, 176.) A patent is, in effect, a right to ask the government to exercise its power to keep others from using an invention without consent. (*Zenith Corp. v. Hazeltine* (1969) 395 U.S. 100, 135.) Whether a court will do so—whether it will issue an injunction—will depend on actual proof of validity.

The differential application of collateral estoppel adds another layer of uncertainty. A finding that a patent is invalid operates in rem and estops the patentee from asserting validity against the world. (*Blonder-Tongue v. University Foundation* (1971) 402 U.S. 313, 349–350.) In contrast, a finding that a patent is valid operates only on the parties and does not extend from one infringement case to the next. A future challenger with new or better information may subsequently raise, and succeed on, an invalidity defense to a charge of infringement. (*In re Swanson* (Fed. Cir. 2008) 540 F.3d 1368, 1377; *Ethicon, Inc. v. Quigg* (Fed. Cir. 1988) 849 F.2d 1422, 1429, fn. 3 [" 'A patent is not held valid for all purposes but, rather, not invalid on the record before the court' " and " 'simply remains valid

until another challenger carries' " the burden of showing invalidity].) Each case may show only that a patent has not been invalidated, yet.

If the assertion of patent rights leads to a court injunction excluding a competitor from the marketplace, there is no antitrust problem. If instead the assertion leads to a private settlement agreement, there is a potential antitrust problem. With a settlement, any restraint arises directly from the private agreement and only indirectly from the patent, which remains in the background, motivating the parties' actions according to their assessments of its strength. That a patent has not (yet) been invalidated may allow some confidence about its fundamental enforceability, but does not allow a court to skip entirely an antitrust analysis of competitive restraints within the patent's scope on the assumption that its validity has been established. The scope of the patent test is flawed precisely because it assumes away whatever level of uncertainty a given patent—the '444 patent here, no less than the one at issue in *Actavis*—may be subject to.[9]

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[9] The *Actavis* treatment of patents as in some sense probabilistic rests on a substantial body of scholarship suggesting patents are best understood this way. (See, e.g., Lemley & Shapiro, *Probabilistic Patents*, *supra*, 19 J. Econ. Perspectives at pp. 75–76, 95; Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals* (Summer 2003) 17 Antitrust 70, 75; Leffler & Leffler, *The Probabilistic Nature of Patent Rights* (Summer 2003) 17 Antitrust 77; Shapiro, *Antitrust Limits to Patent Settlements* (2003) 34 RAND J. Econ. 391, 395.) Others, including the *Actavis* dissenters, have disagreed, insisting a patent ultimately is always only valid or invalid, whether we know it yet or not. (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 372, 133 S.Ct. at p. 2244] (dis. opn. of Roberts, C.J.); Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy* (2004) 71 Antitrust L.J. 1033; McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives* (Spring 2003) 17 Antitrust 68.) The Supreme Court majority's views are conclusive as to which side of this philosophical divide over the proper treatment of patents is correct, and we follow them.

Aside from its attempts to distinguish *Actavis*, Barr argues a 1953 California decision predating the recent federal Hatch-Waxman Act decisions favors the scope of the patent test for Cartwright Act challenges to patent settlements. (See *Fruit Machinery Co. v. F.M. Ball & Co.* (1953) 118 Cal.App.2d 748, 758.) We do not read that opinion so broadly.

In *Fruit Machinery*, six canning companies formed a corporation and licensed to it rights under a fruit pitter patent owned by one of the companies. In turn, the licensee contracted with each of the six, sublicensing to them the right to build and own a specified number of pitters and to lease additional pitters in exchange for payment of royalties. A dispute over nonpayment of royalties arose between the licensee and one of the six companies. The company raised as a defense to payment that the contractual arrangements gave the six companies an unlawful monopoly on pitter ownership and were thus unenforceable. The Court of Appeal found no antitrust violation, explaining: "Defendant has not shown that the parties, in executing and carrying out the sublicense agreement in suit, exercised rights or powers not accorded them by the patent law *or abused any rights or powers accorded them by that law*." (*Fruit Machinery Co. v. F.M. Ball & Co.*, *supra*, 118 Cal.App.2d at p. 762, italics added.) The Court of Appeal distinguished other cases involving antitrust violations as involving a "patentee or his assignee [who] went beyond that which was necessary or incidental to the scope of his patent and brought himself within the proscription of the antitrust laws." (*Id.* at p. 763.)

Fruit Machinery does not stand for the proposition that any restraints of trade within the scope of a patent are valid. Rather, it recognizes trade restraints that exceed those authorized by a patent may be invalid and, moreover, that the "abuse[]" of patent rights may *also* run afoul of antitrust law. (*Fruit Machinery Co. v. F.M. Ball & Co.*, *supra*, 118 Cal.App.2d at p. 762.) The court responded to

the concern that the corporate licensee might use its exclusive patent rights to charge far higher royalties for leased than owned pitters not by saying such a differential would automatically be lawful, as within the scope of any patent rights, but by saying only "that such has not happened yet" and it would not presume a "[f]uture violation . . . of the antitrust laws." (*Ibid.*)

No other California authority Barr has cited, nor any we have found, establishes the scope of the patent test is applicable under the Cartwright Act. Even if such precedent existed, we would be forced to reexamine it in light of *Actavis*. The scope of the patent test insulates from antitrust scrutiny virtually any agreement that restrains trade no more than the patent itself would have, if valid. State law must yield to federal, but we cannot under the guise of patent law carve into the Legislature's enactments a larger exception than federal law dictates, and *Actavis* shows such a broad exemption is not required. Accordingly, we conclude the scope of the patent test is inapplicable to Cartwright Act claims.

IV. *Analysis of Reverse Payment Patent Settlements*

Having joined the United States Supreme Court in rejecting the scope of the patent test, we consider what rubric courts should instead apply under state law to reverse payment patent settlements.

A. *Antitrust Analysis Under the Cartwright Act*

As discussed, although the prohibitions of the Cartwright Act are framed in superficially absolute language, deciding antitrust illegality is not as simple as identifying whether a challenged agreement involves a restraint of trade. (See *Chicago Board of Trade v. United States* (1918) 246 U.S. 231, 238 [pointing out that "[*e*]*very* agreement concerning trade . . . restrains" (italics added)].) Instead, the Cartwright Act and Sherman Act carry forward the common law

understanding that "only unreasonable restraints of trade are prohibited." (*Marin County Bd. of Realtors, Inc. v. Palsson*, *supra*, 16 Cal.3d at p. 930.)

Under the traditional rule of reason, "inquiry is limited to whether the challenged conduct promotes or suppresses competition." (*Fisher v. City of Berkeley* (1984) 37 Cal.3d 644, 672, affd. *sub nom. Fisher v. Berkeley* (1986) 475 U.S. 260.) To determine whether an agreement harms competition more than it helps, a court may consider "the facts peculiar to the business in which the restraint is applied, the nature of the restraint and its effects, and the history of the restraint and the reasons for its adoption." (*United States v. Topco Associates, Inc.* (1972) 405 U.S. 596, 607; see *Corwin v. Los Angeles Newspaper Service Bureau, Inc.*, *supra*, 4 Cal.3d at p. 854.) In a typical case, this may entail expert testimony on such matters as the definition of the relevant market (*Corwin*, at p. 855) and the extent of a defendant's market power (*Fisherman's Wharf Bay Cruise Corp. v. Superior Court* (2003) 114 Cal.App.4th 309, 334–339; *Roth v. Rhodes* (1994) 25 Cal.App.4th 530, 542–543).

Rule of reason inquiry is not required in every case; we and the United States Supreme Court have partially simplified the analysis by identifying categories of agreements or practices that can be said to always lack redeeming value and thus qualify as per se illegal. (See *Northern Pac. R. Co. v. United States* (1958) 356 U.S. 1, 5; *Marin County Bd. of Realtors, Inc. v. Palsson*, *supra*, 16 Cal.3d at pp. 930–931; *Oakland-Alameda County Builders' Exchange v. F. P. Lathrop Constr. Co.* (1971) 4 Cal.3d 354, 360–362.) "The per se rule reflects an irrebuttable presumption that, if the court were to subject the conduct in question to a full-blown inquiry, a violation would be found under the traditional rule of reason." (*Fisher v. City of Berkeley*, *supra*, 37 Cal.3d at p. 666.)

More recently, a third category, quick look rule of reason analysis, has emerged. (*California Dental Assn. v. FTC* (1999) 526 U.S. 756, 769–770; see

FTC v. Indiana Federation of Dentists (1986) 476 U.S. 447, 459–460; *NCAA v. Board of Regents of Univ. of Okla*. (1984) 468 U.S. 85, 109–110.) Under the quick look approach, applicable to cases where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets," a defendant may be asked to come forward with procompetitive justifications for a challenged restraint without the plaintiff having to introduce elaborate market analysis first. (*California Dental Assn.*, at p. 770.)

There was a time when this court and the United States Supreme Court treated the choice between per se and rule of reason analysis as a necessary threshold inquiry involving rigidly distinct analytic boxes. In more recent years, however, the Supreme Court has explained, "[t]he truth is that our categories of analysis of anticompetitive effect are less fixed than terms like '*per se*,' 'quick look,' and 'rule of reason' tend to make them appear." (*California Dental Assn. v. FTC*, *supra*, 526 U.S. at p. 779.) "[T]here is generally no categorical line to be drawn between restraints that give rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment. What is required, rather, is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint." (*Id.* at pp. 780–781.) The emergence of quick look rule of reason analysis did not signal the supplanting of the traditional per se/rule of reason dichotomy with a new trichotomy (*Polygram Holding, Inc. v. FTC* (D.C. Cir. 2005) 416 F.3d 29, 35), but rather a shift to " ' "something of a sliding scale" ' " in antitrust analysis. (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 364, 133 S.Ct. at p. 2237].)

This more nuanced approach makes equal sense for claims under the Cartwright Act. Like the federal antitrust statutes, nothing in the text of the Cartwright Act dictates the precise details of the per se and rule of reason

approaches; these are but useful tools the courts have developed over time to carry out the broad purposes and give meaning to the general phrases of the antitrust statutes. (See *National Soc. of Professional Engineers v. United States*, *supra*, 435 U.S. at p. 688.) It is consistent with the common law tradition at the root of our antitrust laws to describe, as the United States Supreme Court now has, the analytic approach as involving a continuum, with the "the circumstances, details, and logic" of a particular restraint (*California Dental Assn. v. FTC*, *supra*, 526 U.S. at p. 781) dictating how the courts that confront the restraint should analyze it. In lieu of an undifferentiated one-size-fits-all rule of reason, courts may "devise rules . . . for offering proof, or even presumptions where justified, to make the rule of reason a fair and efficient way to prohibit anticompetitive restraints and to promote procompetitive ones." (*Leegin Creative Leather Products, Inc. v. PSKS, Inc.* (2007) 551 U.S. 877, 898–899; see *Fisher v. City of Berkeley*, *supra*, 37 Cal.3d at pp. 671–677 [tailoring the rule of reason to account for differences between private and municipal government actions].)

It follows that we must consider not simply whether per se or rule of reason analysis applies to reverse payment patent settlements. To the extent rule of reason analysis applies, as we will conclude it does, we must also consider how the analysis should be structured to most efficiently differentiate between reasonable and unreasonable restraints of trade in this context. (See *California Dental Assn. v. FTC*, *supra*, 526 U.S. at p. 781.)

B. *The Competitive Harm from Purchasing an Extension of Monopoly*

We begin with the proposition that agreements to establish or maintain a monopoly are restraints of trade made unlawful by the Cartwright Act. (*Lowell v. Mother's Cake & Cookie Co.* (1978) 79 Cal.App.3d 13, 23; *Dimidowich v. Bell & Howell* (9th Cir. 1986) 803 F.2d 1473, 1478.) Under general antitrust principles, a

business may permissibly develop monopoly power, i.e., "the power to control prices or exclude competition" (*United States v. DuPont & Co.* (1956) 351 U.S. 377, 391), through the superiority of its product or business acumen. To acquire or maintain that power through agreement and combination with others, however, is quite a different matter. (*United States v. Grinnell Corp.* (1966) 384 U.S. 563, 570–571.)

Pursuant to this rule, businesses may not engage in a horizontal allocation of markets, with would-be competitors dividing up territories or customers. (*United States v. Topco Associates, Inc.*, *supra*, 405 U.S. at pp. 608, 612; *Vulcan Powder Co. v. Hercules Powder Co.*, *supra*, 96 Cal. at pp. 514–515; *Guild Wineries & Distilleries v. J. Sosnick & Son* (1980) 102 Cal.App.3d 627, 633–635.) Such allocations afford each participant an "enclave . . . , free from the danger of outside incursions," in which to exercise monopoly power and extract monopoly premiums. (*United States v. Sealy, Inc.* (1967) 388 U.S. 350, 356.)

Similarly, a firm may not "pay[] its only potential competitor not to compete in return for a share of the profits that firm can obtain by being a monopolist." (*Valley Drug Co. v. Geneva Pharmaceuticals*, *supra*, 344 F.3d at p. 1304.) In *Palmer v. BRG of Ga., Inc.* (1990) 498 U.S. 46, for example, two competing bar review course providers did just that. One provider agreed to withdraw from a particular state market in exchange for the second provider paying the withdrawing provider a share of subsequent profits and agreeing in return not to compete outside that state market. In a per curiam opinion, the United States Supreme Court summarily declared the agreement unlawful on its face. (*Id.* at pp. 49–50; see *Getz Bros. & Co. v. Federal Salt Co.* (1905) 147 Cal. 115, 119 [payment for agreement not to compete and to discourage others from competing is illegal]; *Wright v. Ryder*, *supra*, 36 Cal. at p. 359 [agreement not to

compete in California market violates common law prohibition on restraints of trade].)

Second, these principles extend into the patent arena to prohibit a patentee's purchase of a potential competitor's consent to stay out of the market. Antitrust law condemns a patentee's payment "to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 363, 133 S.Ct. at p. 2236].) This is so even when the patent is likely valid: "The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm." (*Ibid.*)

Actavis embraces the insights of Professor Carl Shapiro and others that the relevant benchmark in evaluating reverse payment patent settlements should be no different from the benchmark in evaluating any other challenged agreement: What would the state of competition have been without the agreement? In the case of a reverse payment settlement, the relevant comparison is with the average level of competition that would have obtained absent settlement, i.e., if the parties had litigated validity/invalidity and infringement/noninfringement to a judicial determination. (Shapiro, *Antitrust Limits to Patent Settlements*, *supra*, 34 RAND J. Econ. at p. 396; see Addanki & Butler, *Activating* Actavis*: Economic Issues in Applying the Rule of Reason to Reverse Payment Settlements* (2014) 15 Minn. J. L. Sci. & Tech. 77, 93; Lemley & Shapiro, *Probabilistic Patents*, *supra*, 19 J. Econ. Perspectives at p. 94; Willig & Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation* (2004) 49 Antitrust Bull. 655, 664, 677–679.) Consider a patent with a 50 percent chance of being upheld. After litigation, on average, consumers would be subject to a monopoly for half the remaining life of the

patent. A settlement that allowed a generic market entry at the midpoint of the time remaining until expiration would replicate the expected level of competition; the period of exclusion would reflect the patent's strength. But a settlement that delayed entry still longer would extend the elimination of competition beyond what the patent's strength warranted; to the extent it did, the additional elimination of the possibility of competition would constitute cognizable anticompetitive harm. (See *Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 363, 133 S.Ct. at p. 2236].)

Barr argues that the procompetitive or anticompetitive effects of a settlement must be measured by comparison to the entire remaining life of a patent. We disagree. *Actavis* makes clear that for antitrust purposes patents are no longer to be treated as presumptively ironclad. This means the period of exclusion attributable to a patent is not its full life, but its expected life had enforcement been sought. This expected life represents the baseline against which the competitive effects of any agreement must be measured.[10] If an agreement only replicates the likely average result of litigation, any exclusion is a function of the underlying patent strength; if it extends exclusion beyond that point, this further exclusion from the marketplace—and the attendant anticompetitive effect—is attributable to the agreement. *Actavis* thus represents an application of the settled principle that "[t]he owner of a patent cannot extend his statutory grant by contract or agreement. A patent affords no immunity for a monopoly not fairly or plainly

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10 To be clear, because the relevant baseline is the result that would have occurred in the absence of any agreement, it is not a cognizable harm simply to show that the parties might have elected a different settlement agreement more favorable to competition and consumers. There is no statutory right to have parties enter the agreement most favorable to competition, only a prohibition against entering agreements that harm competition.

within the grant." (*U.S. v. Masonite Corp.* (1942) 316 U.S. 265, 277.) The measure of the statutory grant, and the limit on the monopoly that may be preserved by agreement, is the average expected duration that would have resulted from judicial testing.

This method of analysis, and of assessing anticompetitive harm, is not materially different from that applied in any other garden-variety antitrust case. Every case involves a comparison of a challenged agreement against a prediction about—a probabilistic assessment of—the expected competition that would have arisen in its absence. (Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, *supra*, 17 Antitrust at p. 70.) Every restraint of trade condemned for suppressing market entry involves uncertainties about the extent to which competition would have come to pass. (Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, *supra*, 109 Colum. L.Rev. at p. 637.) No matter; as the leading antitrust treatise notes, "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." (12 Areeda & Hovenkamp, Antitrust Law, *supra*, ¶ 2030b, p. 220; see *U.S. v. Microsoft Corp.* (D.C. Cir. 2001) 253 F.3d 34, 79 (en banc) ["it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will"].) The antitrust laws foreclose agreements eliminating "the risk of competition"—the competitive market that "might have been." (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 363, 133 S.Ct. at p. 2236].) Purchasing freedom from the possibility of competition, whether done by a patentee or anyone else, is illegal. An agreement to exchange consideration for elimination of any portion of the period of competition that would have been expected had a patent been litigated is a violation of the Cartwright Act.

C. *The Structure of the Rule of Reason as Applied to Patent Settlements*

We consider next how to identify whether the parties' settlement agreement eliminates competition beyond the point at which competition would have been expected in the absence of an agreement. Only if the agreement limits competition beyond that point, the point the strength of the patent would have justified, is there an antitrust issue.

1. Plaintiff's Prima Facie Case

We conclude a third-party plaintiff challenging a reverse payment patent settlement must show four elements: (1) the settlement includes a limit on the settling generic challenger's entry into the market; (2) the settlement includes cash or equivalent financial consideration flowing from the brand to the generic challenger; and the consideration exceeds (3) the value of goods and services *other* than any delay in market entry provided by the generic challenger to the brand, as well as (4) the brand's expected remaining litigation costs absent settlement. We explain these elements in turn.

That a plaintiff challenging a reverse payment settlement must establish the settlement limits the challenging generic's entry is self-evident. If the settlement contains no component of delay and permits the generic to enter the market and compete fully and immediately, there is no restraint of trade and no potential for antitrust concern.

As well, a plaintiff must establish a reverse payment—financial consideration flowing from the brand to the generic challenger.[11] In the absence

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[11] To some extent, the settlement agreement challenged here is a relic. Cash reverse payments were not uncommon in the 1990s, but shortly thereafter brands and generics began using a wide range of other forms of consideration to accomplish reverse payment. (See Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, *supra*,

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of payment, one would expect rational parties that settle to select a market entry point roughly corresponding to their joint expectation as to when entry would have occurred, on average, if the patent's validity and infringement had been fully litigated. (Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes* (2003) 87 Minn. L.Rev. 1719, 1762.) If market entry were substantially later than the generic thought it could obtain through litigation, the generic would be unwilling to settle and forgo the additional profits it thought it could earn from an earlier entry; conversely, if the entry were substantially earlier than the brand thought it could obtain through litigation, the brand would not settle and forgo an additional period of monopoly. Absent payment, one can accept an agreement to postpone market entry as a fair approximation of the expected level of competition that would have obtained had the parties litigated; absent payment, any delay in entry may be attributed to the effective strength of the challenged patent, rather than the settlement agreement. (See *ibid.*; Carrier, *Payment After* Actavis (2014) 100 Iowa L.Rev. 7, 17.)

Third, a plaintiff must establish the consideration to the generic challenger exceeds the value of any other collateral products or services provided by the generic to the brand. As the Supreme Court noted, the concern that a reverse payment raises will depend in part on "its independence from other services for which it might represent payment." (*Actavis, supra*, 570 U.S. at p. ___ [186

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109 Colum. L.Rev. at pp. 647–658.) Because the Cipro settlement involved cash, we need not define precisely what noncash forms of consideration will qualify, but courts considering Cartwright Act claims should not let creative variations in the form of consideration result in the purchase of freedom from competition escaping detection.

L.Ed.2d at p. 364, 133 S.Ct. at p. 2237].) A "payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item." (*Id.* at p. ___ [186 L.Ed.2d at p. 362, 133 S.Ct. at p. 2236.) If payment is no more than would be expected as compensation for additional products or services, then the agreement includes no additional consideration for delay and we can trust that any limit on competition is a legitimate consequence of the patent's strength and the contracting parties' expectations concerning its exclusionary power.

Considerable caution is in order in evaluating settlements that include side agreements for generic products or services. Historically, it appears brands and generics have engaged in business dealings outside the settlement context far less often than in it. (Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, *supra*, 109 Colum. L.Rev. at pp. 663–668.) A side agreement involving difficult-to-value assets might conceivably be added to a patent settlement to provide cover for the purchase of additional freedom from competition. (*Id.* at pp. 632–633, 669; Bulow, *The Gaming of Pharmaceutical Patents* in 4 Innovation Policy and the Economy, *supra*, at pp. 169–171; Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, *supra*, 108 Mich. L.Rev. at p. 79.) This court long ago established that side deals should not be permitted to serve as fig leaves for agreements to eliminate competition. In *Getz Bros. & Co. v. Federal Salt Co.*, *supra*, 147 Cal. 115, the parties entered an agreement to exchange money for (1) an agreement not to compete and to discourage competition in the salt trade and (2) more than 1,000 pounds of salt. Precisely how much of the payment was attributable to the actual provision of salt we could not say, but so long as any portion of the payment was attributable to the covenant not to compete—and we

viewed it as "plain . . . that part of it, at least, was"—the deal as a whole was an illegal restraint of trade. (*Id.* at p. 118.)

Fourth, a plaintiff must establish the amount of the payment, over and above the value of collateral products or services from the generic, also exceeds the brand's anticipated future litigation costs. In some cases, a "reverse payment . . . may amount to no more than a rough approximation of the litigation expenses saved through the settlement. . . . Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement. In such cases, the parties may have provided for a reverse payment without having sought or brought about the anticompetitive consequences we mentioned above." (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 362, 133 S.Ct. at p. 2236].) A rational brand might be indifferent as between (1) actually litigating or (2) settling, with market entry at the point expected, on average, from asserting its patent in litigation and a payment to the generic in an amount up to what would have been spent in that litigation. It is thus necessary to evaluate the reverse payment's "scale in relation to the payor's anticipated future litigation costs." (*Id.* at p. ___ [186 L.Ed.2d at p. 364, 133 S.Ct. at p. 2237].)

We consider briefly the allocation of burdens of proof and production. Unless a challenged settlement agreement includes both a restraint on generic competition and a reverse payment to the generic in excess of both brand litigation costs and generic collateral products and services, there is no reason to assume the settlement includes any element of purchased freedom from competition, as opposed to a limit on competition flowing naturally, and lawfully, from the perceived strength of the brand's patent. Accordingly, the burden of proof as to

these elements rests with the Cartwright Act plaintiff. (See *Aguilar v. Atlantic Richfield Co.* (2001) 25 Cal.4th 826, 861.)

The burden of producing evidence (see Evid. Code, §§ 110, 550) is a slightly different matter. " 'Where the evidence necessary to establish a fact essential to a claim lies peculiarly within the knowledge and competence of one of the parties, that party has the burden of going forward with the evidence on the issue although it is not the party asserting the claim.' " (*Sanchez v. Unemployment Ins. Appeals Bd.* (1977) 20 Cal.3d 55, 71.) This is so with regard to both a settling party's own litigation costs and the existence and value of any collateral products or services provided as part of a patent settlement; these are matters about which the settling parties will necessarily have superior knowledge.[12] Accordingly, once a plaintiff has shown an agreement involving a reverse payment and delay, the defendants have the burden of coming forward with evidence of litigation costs and the value of collateral products and services.[13] If the defendants fail to do so, because, e.g., there was no side agreement or because they do not dispute the collective amounts fall short of any payment to the generic, the plaintiff has satisfied its burden on these points. If instead the defendants do so, the plaintiff must carry the ultimate burden of persuasion that any reverse payment exceeds litigation costs and the value of collateral products or services.

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12 We do not suggest a defendant's testimony concerning the value conveyed in side agreements is entitled to any more weight than the plaintiff's, only that the defendants have the initial burden of introducing evidence of agreements for the purchase of other products or services sufficiently valuable to explain any payment.

13 Here, the brand, Bayer, settled out of the antitrust case, and Barr would not be in a superior position with regard to knowledge of Bayer's future patent litigation costs, so the burden of production on this point would remain with plaintiffs.

We further conclude that a showing of the above elements is not only necessary but also sufficient to make out a prima facie case that the settlement is anticompetitive. If a brand is willing to pay a generic more than the costs of continued litigation, and more than the value of any collateral benefits, in order to settle and keep the generic out of the market, there is cause to believe some portion of the consideration is payment for exclusion beyond the point that would have resulted, on average, from simply litigating the case to its conclusion. Otherwise, the brand would have had little incentive to settle at such a high price. Moreover, the larger the gap, the stronger the inference one can draw.

A wealth of economic scholarship and analysis supports this inference. Because the profit that can be earned under monopoly conditions is greater than the combined profit that can be earned under duopoly conditions,[14] a brand and generic have a substantial incentive to settle at the latest market entry date possible, with the brand paying a portion of monopoly profits to compensate the generic for what it would have earned with an earlier entry.[15] If the parties can

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14 While this is a broadly shared economic tenet, it has also been empirically demonstrated by the FDA in the current context. (See FDA, Center for Drug Evaluation and Research, Generic Competition and Drug Prices (2010) online at <http://www.fda.gov/AboutFDA/CentersOffices/Officeofmedicalproductsandtobacco/CDER/ucm129385.htm> [last visited May 7, 2015].) Indeed, in its briefing Barr effectively concedes this is the case here: "[E]ach day of early entry would have cost Bayer more given the price of its branded product than it would have benefitted Barr given the price of its generic product."

15 *Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at pp. 361–362, 133 S.Ct. at pp. 2234–2235]; see, e.g., Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's* Actavis *Decision*, *supra*, 15 Minn. J. L. Sci. & Tech. at pages 8–13; Mungan, *Reverse Payments, Perverse Incentives* (2013) 27 Harv. J. Law & Tech. 1, 5–6, 27, 34; Elhauge & Krueger, *Solving the Patent Settlement Puzzle* (2012) 91 Tex. L.Rev. 283, 289; Kades, *Whistling Past the Graveyard: The Problem with the Per Se Legality Treatment of Pay-for-Delay Settlements* (2009) 5

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share monopoly profits through a reverse payment from the brand to the generic, the generic no longer has motivation to hold out for its best estimate of the average entry point it could obtain through litigation. Instead, the parties' interests align in favor of maximizing their combined wealth by extending the monopoly for as long as possible. Once payment to the generic exceeds what the brand is otherwise receiving from it in products and services or would have spent to litigate, a court may fairly presume the settling parties have engaged in such conduct and should be put to the burden of coming forward with a procompetitive justification for their settlement. (Elhauge & Krueger, *Solving the Patent Settlement Puzzle*, *supra*, 91 Tex. L.Rev. at pp. 297–304; see Edlin et al., *Activating* Actavis (2013) 28 Antitrust 16, 22, appen.; Lemley & Shapiro, *Probabilistic Patents*, *supra*, 19 J. Econ. Perspectives at p. 93; Shapiro, *Antitrust Limits to Patent Settlements*, *supra*, 34 RAND J. Econ. at p. 408.)

Barr argues this degree of scrutiny will stifle innovation. But Congress was not authorized to, and did not, grant inventors eternal monopolies; instead, it approved a scheme that presumptively represents the appropriate balance between promoting innovation and allowing competition. Reverse payment patent settlements may enable the parties to extend the monopoly beyond that point. (Elhauge & Krueger, *Solving the Patent Settlement Puzzle*, *supra*, 91 Tex. L.Rev.

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Competition Policy Internat. 143, 148–150; Leffler & Leffler, *Settling the Controversy over Patent Settlements* in Antitrust Law and Economics (Kirkwood edit., 2004) 475, 480–484; Willig & Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, *supra*, 49 Antitrust Bull. at page 659; Bulow, *The Gaming of Pharmaceutical Patents* in 4 Innovation Policy and the Economy, *supra*, at page 166; Shapiro, *Antitrust Limits to Patent Settlements*, *supra*, 34 RAND J. Econ. at pages 394–395.

at pp. 295–304; Lemley & Shapiro, *Probabilistic Patents*, *supra*, 19 J. Econ. Perspectives at p. 93; Leffler & Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?* (2004) 39 U.S.F. L.Rev. 33, 37–38; Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, *supra*, 17 Antitrust at p. 73.) Indeed, insufficient scrutiny of such settlements has the potential to hamper innovation by allowing weak patents to offer the exact same exclusionary potential and monopoly possibilities as strong ones,[16] thus steering innovator incentives away from more costly true innovation and toward cheaper, less socially valuable pseudoinnovation. (See Mungan, *Reverse Payments, Perverse Incentives*, *supra*, 27 Harv. J. Law & Tech. at pp. 42–44; Elhauge & Krueger, *Solving the Patent Settlement Puzzle*, at pp. 294–295.)

Relatedly, Barr expresses concern that close scrutiny of reverse payment settlements will chill some generics from challenging patents, to the detriment of consumers. But any challenge that results in the brand simply paying the generic not to compete—a potentially common outcome absent scrutiny—does nothing to enhance competition, and deterring such challenges accordingly represents no loss to consumers. Moreover, standard economic theory suggests reducing unfettered access to reverse payment settlements would chill generic challenges to strong,

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16 See *In re Tamoxifen Citrate Antitrust Litigation*, *supra*, 466 F.3d at page 211 (noting the "troubling dynamic" that "[t]he less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent"); Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, *supra*, 109 Colum. L.Rev. at page 638 (treating patents as conclusively valid until expiration "produces the absurd result that an ironclad patent and a trivial patent have the same exclusionary force"); Bulow, *The Gaming of Pharmaceutical Patents* in Innovation Policy and the Economy, Volume 4, *supra*, at page 167.

likely valid patents more than challenges to weak patents. The effect would be to increase the value of strong patents, while still leaving generics incentives to challenge weak patents. (Mungan, *Reverse Payments, Perverse Incentives*, *supra*, 27 Harv. J. Law & Tech. at p. 7.) This consequence presents no reason to scale back scrutiny of these settlements.

Finally, Barr argues that in some cases only a reverse payment can bridge the differences between the brand and generic challenger and make settlement possible. Perhaps; but as the Supreme Court has made clear, ordinarily "the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit." (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 363, 133 S.Ct. at p. 2237].) Parties can still use financial considerations to bridge small gaps arising from differing subjective perceptions of their probabilities of success in litigation; what they cannot do is use money to bridge their differences over the point when competitive entry is economically desirable, for that gap is not one antitrust law permits would-be competitors to bridge by agreement: "If the basic reason [the parties prefer a reverse payment settlement] is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." (*Ibid.*) That some settlements might no longer be possible absent a payment in excess of litigation costs is no concern if the ones now barred would simply have facilitated the sharing of monopoly profits.

Barr relies on one commentary showing that some theoretically possible settlements involving payments exceeding the sum of expected litigation costs and the value of other products and services might enhance consumer welfare. (Harris et al., *Activating* Actavis*: A More Complete Story* (2014) 28 Antitrust 83.) The principal conclusion is that introducing brand risk aversion into the settlement model opens up a region of possible settlements involving supralitigation cost

payments that nevertheless increase consumer welfare by enabling earlier generic market entry dates.[17] What is not shown is that such settlements are at all likely in practice. Although a brand and generic may through payment of money be able to settle on an earlier entry date than would arise from litigation, their incentive (if left undeterred by the antitrust regime) remains to settle on a far later entry date for still larger sums of money, as even some of the leading economists highlighting the relevance of risk aversion recognize. (Willig & Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, *supra*, 49 Antitrust Bull. at p. 659.) Attempts to quantitatively estimate the frequency with which risk aversion would produce an efficient settlement despite payment in excess of litigation costs suggest such occurrences would be exceedingly rare. (Leffler & Leffler, *The Probabilistic Nature of Patent Rights*, *supra*, 17 Antitrust at pp. 79–80; Leffler & Leffler, *Settling the Controversy over Patent Settlements* in Antitrust Law and Economics, *supra*, at p. 504; see Bulow, *The Gaming of Pharmaceutical Patents* in 4 Innovation Policy and the Economy, *supra*, at p. 167.) Thus, while we do not discount the possibility, it affords no reason to expand plaintiff's prima facie case beyond the elements discussed.

We also observe that the outlined prima facie showing will suffice, without more, to raise a presumption of the patentee's market power. Proving that a restraint has anticompetitive effects often requires the plaintiff to " 'delineate a

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[17] The Harris model also addresses the effects of asymmetric information, but different perspectives on the likelihood of success are unlikely to alone render it possible for a supralitigation-costs reverse payment settlement to be efficient. (Elhauge & Krueger, *Solving the Patent Settlement Puzzle*, *supra*, 91 Tex. L.Rev. at pp. 300–303, 325–329.) Money may be needed to bridge the gap between the parties' expectations, but a rational brand asked to pay more than its litigation costs to persuade a generic with different perceptions would, in the ordinary case, presumably just litigate.

relevant market and show that the defendant plays enough of a role in that market to impair competition significantly,' " i.e., has market power. (*Roth v. Rhodes*, *supra*, 25 Cal.App.4th at p. 542.) Here, proof of a sufficiently large payment is a surrogate: "the 'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power'—namely, the power to charge prices higher than the competitive level." (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 362, 133 S.Ct. at p. 2236].) Logically, a patentee would not pay others to stay out of the market unless it had sufficient market power to recoup its payments through supracompetitive pricing. (*Ibid.*) Consequently, proof of a reverse payment in excess of litigation costs and collateral products and services raises a presumption that the settling patentee has market power sufficient for the settlement to generate significant anticompetitive effects.

2. Defendants' Rebuttal

Once a plaintiff has made out a prima facie case that a reverse payment patent settlement has anticompetitive effects, a court "must weigh these anticompetitive effects against the possible justifications" for the challenged restraint. (*Marin County Bd. of Realtors, Inc. v. Palsson*, *supra*, 16 Cal.3d at p. 937.) At this point, we deem it appropriate to shift the burden to the defendants to offer legitimate justifications and come forward with evidence that the challenged settlement is in fact procompetitive. (See Bus. & Prof. Code, § 16725 ["[i]t is not unlawful to enter" an agreement "to promote, encourage, or increase competition"]; *Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 362, 133 S.Ct.

at p. 2236] ["An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present."].)[18]

Plaintiffs argue we should declare every reverse payment in excess of litigation costs and collateral products and services a per se violation of the Cartwright Act. We are unwilling to declare every settlement payment of a certain size illegal. Like the United States Supreme Court, we cannot say with reasonable certainty—yet—that we have posited every possible justification that might render a particular reverse payment settlement procompetitive. (See *Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 362, 133 S.Ct. at p. 2236].) The theoretical possibility that a settlement in excess of litigation costs and collateral services could be procompetitive, while insufficient to alter the plaintiff's prima facie case, is nevertheless sufficient for us to reject a categorical rule and instead afford defendants the opportunity to demonstrate a given settlement is the exception.

This does not mean any justification will do. An antitrust defendant cannot argue a settlement is procompetitive simply because it allows competition earlier than would have occurred if the brand had won the patent action; as *Actavis* and our previous discussion make clear, the relevant baseline is the average period of competition that would have obtained in the absence of settlement. (See *Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 363, 133 S.Ct. at p. 2236].)[19]

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18 See also *FTC v. Indiana Federation of Dentists*, *supra*, 476 U.S. at pages 459–461; *National Soc. of Professional Engineers v. United States*, *supra*, 435 U.S. at page 693; 7 Areeda & Hovenkamp, Antitrust Law (3d ed. 2010) ¶¶ 1504b, 1507c, pages 402–403, 430.

19 This point also addresses Barr's argument that causation is lacking in reverse payment cases because absent a settlement, the parties would have litigated, the patentee would likely or surely have won, and consumers would have been no better off. At the time of settlement, the outcome of future litigation is uncertain, and an agreement that "seeks to prevent the risk of competition" causes,

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Likewise, consideration of whether the agreement is justified as procompetitive will not turn on whether the patent would ultimately have been proved valid or invalid. Agreements must be assessed as of the time they are made (*Valley Drug Co. v. Geneva Pharmaceuticals*, *supra*, 344 F.3d at p. 1306), at which point the patent's validity is unknown and unknowable. Just as later invalidation of a patent does not prove an agreement when made was anticompetitive (*id.* at pp. 1306–1307), later evidence of validity will not automatically demonstrate an agreement was procompetitive.[20] Antitrust law condemns the purchase of freedom from competition; what matters is whether a settlement postpones market entry beyond the average point that would have been expected at the time in the absence of agreement. (See *In re Aggrenox Antitrust Lit.* (D. Conn., Mar. 23, 2015, No. 3:14-md-2516 (SRU)) __ F.Supp.3d __ [2015 U.S.Dist. Lexis 35634, *38] ["The salient question is not whether the fully-litigated patent would ultimately be found valid or invalid—that may never be known—but whether the settlement included a large and unjustified reverse payment leading to the inference of profit-sharing to avoid the risk of competition."].)

To determine whether such a settlement has occurred under state law, as under federal law, "it is normally not necessary to litigate patent validity." (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 363, 133 S.Ct. at p. 2236].)

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i.e., has as a "consequence . . . the relevant anticompetitive harm." (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 363, 133 S.Ct. at p. 2236].)

20 Some kinds of evidence may also be suspect: once a brand and generic challenger settle, their incentives align in favor of arguing that the patent was stronger and more clearly infringed than it may have appeared at the time.

"An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness. . . . In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." (*Id.* at p. ___ [186 L.Ed.2d at p. 363, 133 S.Ct. at pp. 2236–2237].)

3. The Plaintiff's Ultimate Burden

The ultimate burden throughout rests with the plaintiff to show that a challenged settlement agreement is anticompetitive. (*Bert G. Gianelli Distributing Co. v. Beck & Co.* (1985) 172 Cal.App.3d 1020, 1048.) Once the plaintiff has made out a prima facie case that a reverse payment patent settlement is anticompetitive, however, the plaintiff thereafter need only show that any procompetitive justifications proffered by the defendants are unsupportable. (See *Polygram Holding, Inc. v. FTC*, *supra*, 416 F.3d at pp. 37–38.)

The ultimate question in reverse payment settlement cases is whether an agreement involves "significant unjustified anticompetitive consequences." (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 364, 133 S.Ct. at p. 2238].) The prima facie case requires the plaintiff to eliminate the possibility that litigation costs or other products or services could explain the consideration paid the generic. If a plaintiff does so and thereafter can dispel each additional justification the defendants put forward to explain the consideration, the conclusion follows that the settlement payment must include, in part, consideration for additional delay in entering the market. That payment for delay is condemned by the

Cartwright Act, as by federal antitrust law, and its purchase as part of a settlement agreement is an unlawful restraint of trade.

* * *

We summarize the structure of the rule of reason applicable to reverse payment patent settlements. To make out a prima facie case that a challenged agreement is an unlawful restraint of trade, a plaintiff must show the agreement contains both a limit on the generic challenger's entry into the market and compensation from the patentee to the challenger. The defendants bear the burden of coming forward with evidence of litigation costs or valuable collateral products or services that might explain the compensation; if the defendants do so, the plaintiff has the burden of demonstrating the compensation exceeds the reasonable value of these. If a prima facie case has been made out, the defendants may come forward with additional justifications to demonstrate the settlement agreement nevertheless is procompetitive. A plaintiff who can dispel these justifications has carried the burden of demonstrating the settlement agreement is an unreasonable restraint of trade under the Cartwright Act.

D. *Preemption*

Barr argues federal preemption concerns narrowly constrain how reverse payment patent settlements must be analyzed under state law. According to Barr, any rule more stringent than the traditional, unstructured rule of reason would fall prey to obstacle preemption, which "arises when ' "under the circumstances of [a] particular case, [the challenged state law] stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." ' " (*Viva! Internat. Voice for Animals v. Adidas Promotional Retail Operations, Inc.* (2007) 41 Cal.4th 929, 936.) We disagree; the rule we adopt is in harmony with *Actavis*, which offered only broad outlines and explicitly left to

other courts the task of developing a framework for analyzing the anticompetitive effects of reverse payment patent settlements. (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 364, 133 S.Ct. at p. 2238].)

State antitrust law ordinarily is fully compatible with federal law. States have regulated against monopolies and unfair competition for longer than the federal government, and federal law is intended only "to supplement, not displace, state antitrust remedies." (*California v. ARC America Corp.* (1989) 490 U.S. 93, 102; see *id.* at pp. 101–102 & fn. 4; *Partee v. San Diego Chargers Football Co.* (1983) 34 Cal.3d 378, 382.) "[T]he Cartwright Act is broader in range and deeper in reach than the Sherman Act" (*Cianci v. Superior Court, supra,* 40 Cal.3d at p. 920); this greater domain has never been thought to pose supremacy clause problems. To the contrary, in light of the established state role, a presumption against preemption applies. (*ARC America Corp.*, at p. 101.)

Barr argues that to avoid conflicting with federal patent law, state antitrust law must cohere with the federal rule that patents are presumed valid. (See 35 U.S.C. § 282.) But as we have discussed, the Patent Act's allocation of a burden of proof is no more than a procedural device. It does not insulate settlements of patent disputes from federal antitrust scrutiny (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 356, 133 S.Ct. at pp. 2230–2231]), nor does it insulate them from state antitrust scrutiny. The agnostic stance toward patent validity our structured rule of reason adopts is identical to that embraced by the United States Supreme Court under federal antitrust law: a patent may or may not be valid or infringed. (*Ibid.*) What matters instead is simply whether a payoff to eliminate the possibility of competition has occurred. (*Id.* at p. ___ [186 L.Ed.2d at p. 363, 133 S.Ct. at p. 2236.) If federal antitrust law can conduct that inquiry without offense to patent law, so too can the state antitrust law it was designed to supplement.

Additionally, Barr argues the rule we adopt must be no more favorable to reverse payment patent settlement challenges than would be the case under *Actavis*. The supposed rationale is that *Actavis* identifies precisely the accommodation patent law requires of antitrust law, such that deviation would pose an obstacle to congressional patent objectives.

If *Actavis* had established a special rule limiting antitrust scrutiny of reverse payment settlements in order to preserve the incentives created by the patent system, we might agree. But the lesson of *Actavis* is that nothing in the patent laws or the Hatch-Waxman Act dictates such a special rule; that a settlement resolves a patent dispute does not "immunize the agreement from antitrust attack." (*Actavis*, *supra*, 570 U.S. at p. ___ [186 L.Ed.2d at p. 356, 133 S.Ct. at p. 2230].) Instead, such agreements may, like any other form of agreement restraining trade, be examined for unjustified anticompetitive effects. (*Id.* at p. ___ [186 L.Ed.2d at p. 364, 133 S.Ct. at p. 2238].) As for how such an examination is to be conducted, *Actavis* reverts solely to antitrust considerations. (*Id.* at p. ___ [186 L.Ed.2d at p. 364, 133 S.Ct. at pp. 2237–2238].) In selecting a test to apply—to the extent the Supreme Court does, as opposed to "leav[ing] to the lower courts the structuring of the present rule-of-reason antitrust litigation" (*id.* at p. ___ [186 L.Ed.2d at p. 364, 133 S.Ct. at p. 2238])—the Court looks to whether its experience with the economics of reverse payment settlements is sufficient to allow it, yet, to require particular modifications to rule-of-reason analysis (*id.* at p. ___ [186 L.Ed.2d at p. 363, 133 S.Ct. at p. 2237]).

Where the choice of a test rests solely on economic analysis, no patent law preemption concerns arise. Instead, the issue reduces to a problem in the relation between federal and state antitrust law, and there the Supreme Court has been quite clear that states may depart from federal rules—or, here, accept an invitation to develop a gap in the law explicitly left by the Supreme Court—absent evidence

of a clear congressional purpose to the contrary. (*California v. ARC America Corp.*, *supra*, 490 U.S. at p. 103.)

We note as well that the structured rule of reason we adopt is consistent with, not an obstacle to, congressional patent and health care goals in two specific ways. First, considerable research and analysis suggests the broad availability of reverse payment settlements favors weak patents and channels investment resources toward suboptimal innovation prospects. (See *ante*, pp. 38–39.) To the extent careful scrutiny of such settlements promotes the very innovation the patent laws were intended to promote, it cannot stand as an obstacle to congressional objectives.

Second, a fundamental goal of the Hatch-Waxman Act is to enhance generic competition and thereby lower prices. Congress rued the "serious anti-competitive effects" of existing rules for generic drug approval, rules that resulted in "the practical extension of the monopoly position of the patent holder beyond the expiration of the patent." (H.R.Rep. No. 98-857, 2d Sess., pt. 2, p. 4 (1984), reprinted in 1984 U.S. Code Cong. & Admin. News, p. 2688.) The substantial reworking of those rules to ease generic approval was designed to "make available more low cost generic drugs" (*Id.*, pt. 1, p. 14, reprinted in 1984 U.S. Code Cong. & Admin. News, p. 2647) and reduce costs for consumers and government-funded health care alike (*id.* at p. 17, reprinted in 1984 U.S. Code Cong. & Admin. News, p. 2650). By ferreting out anticompetitive agreements that limit generic market entry and sustain costly monopolies, a structured rule of reason serves those goals and poses no obstacle to congressional objectives.[21]

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[21] A second federalism concern raised by the Court of Appeal, that state antitrust scrutiny would intrude on the exclusivity of federal court patent jurisdiction (see 28 U.S.C. § 1338(a)), likewise presents no issue. This exclusive

(footnote continued on next page)

E. *Application*

The trial court and Court of Appeal treated the '444 patent as ironclad and used the entire period until its expiration as the relevant benchmark in order to assess whether the parties' settlement agreement had anticompetitive effects. This was error.

Barr argues we nevertheless should affirm because in the course of their respective opinions the trial court and Court of Appeal purported to apply the rule of reason in addition to the scope of the patent test. But the rule of reason these courts applied is not the structured rule of reason for reverse payment patent settlements we articulate today to effectuate the purposes of the Cartwright Act. Rather, in each instance the courts simply concluded that because the agreement did not exclude competition beyond what the '444 patent would have permitted (assuming it were valid), the agreement necessarily had no anticompetitive effect and was not unlawful under the rule of reason. The same misapprehension underlying the lower courts' scope of the patent analysis, that for antitrust purposes patents are ironclad, also underlay their rule of reason analysis. Accordingly, we must reverse.

(footnote continued from previous page)

jurisdiction does not prevent state courts from deciding state law claims incidentally touching on the validity of a patent. (*Caldera Pharmaceuticals, Inc. v. Regents of University of California* (2012) 205 Cal.App.4th 338, 353–356.) Moreover, the "slim category" of state law claims subject to exclusive federal patent jurisdiction includes only those that " 'necessarily raise' " a federal patent issue. (*Gunn v. Minton* (2013) 568 U.S. ___, ___ [185 L.Ed.2d 72, 79, 133 S.Ct. 1059, 1065].) As we have discussed, it is entirely possible to resolve an antitrust challenge to a reverse payment patent settlement without adjudicating the patent's validity.

V. *Unfair Competition Law and Common Law Monopoly Claims*

The trial court entered judgment against plaintiffs on their unfair competition and common law monopoly claims using the same reasoning it applied to the Cartwright Act claim. Because that reasoning was erroneous, we reverse on these claims as well.

DISPOSITION

We reverse the Court of Appeal's judgment and remand for further proceedings consistent with this opinion.

WERDEGAR, J.

WE CONCUR:

CANTIL-SAKAUYE, C. J.
CHIN, J.
CORRIGAN, J.
LIU, J.
CUÉLLAR, J.
KRUGER, J.

See last page for addresses and telephone numbers for counsel who argued in Supreme Court.

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