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Note


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Since the passage of the Hatch-Waxman Act (the Act) in 1984,1 patent litigation in the pharmaceutical industry has generated a troubling breed of settlement agreements wherein the payment goes from patentee plaintiffs to allegedly infringing defendants, resulting in anticompetitive effects.2 The provisions of the Act, though intended to promote innovation and lower drug prices while expediting infringement litigation, tend to incentivize reverse payments, or pay-for-delay settlements.3 The settlements are often challenged by the

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3. 12 AREEDA & HOVENKAMP, supra note 2, at 340–41; Cotter, supra note
Federal Trade Commission (FTC) and by private parties for violation of antitrust law. Thus, pay-for-delay settlements illustrate a tension between patent law and antitrust law. Since the adoption of the Act, courts have struggled to harmonize the two bodies of law with regard to pay-for-delay settlements, as evidenced by the widely divergent rulings on the legality of these settlements among regional circuit courts. In December 2012, the Supreme Court granted a writ of certiorari to review Federal Trade Commission v. Watson Pharmaceuticals, Inc., an Eleventh Circuit case favoring the pharmaceutical companies, and should enunciate the proper legal standard to apply to pay-for-delay settlements.

2, at 1797–802.
4. See Paula L. Blizzard et al., Antitrust, in AM. BAR ASS’N SECTION OF INTELLECTUAL PROP. LAW, ANDA LITIGATION: STRATEGIES AND TACTICS FOR PHARMACEUTICAL PATENT LITIGATORS 293, 304–24 (Kenneth L. Dorsney et al. eds., 2012).
7. FTC v. Watson Pharmaceuticals, Inc., 677 F.3d 1298 (11th Cir. 2012), cert. granted, 133 S. Ct. 787 (2012). The Eleventh Circuit held that the appropriate test for pay-for-delay settlements is “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.” Id. at 1312.
Whether a court finds a pay-for-delay settlement illegal often reflects the extent to which the court defers to federal patent law—the greater the deference to patent law, the more likely a finding of legality. Challenges to pay-for-delay settlements have thus far been adjudicated almost exclusively in federal court, but these challenges are brought under both federal and state antitrust laws, and one challenge is currently awaiting rehearing by the Supreme Court of California. Should pay-for-delay settlements be challenged in state courts in the future, the doctrine of preemption may pose an obstacle for state antitrust claims confronting the legality of patent infringement settlements.

This Note explores the applicability of the doctrine of preemption to state antitrust claims challenging pay-for-delay settlements. Part I of this Note outlines the history and current status of pay-for-delay settlements, draws attention to potential areas of conflict between antitrust law and patent law, and reviews principles of preemption as enunciated by the Supreme Court. Part II explores the applicability of the doctrine of preemption to state antitrust challenges to pay-for-delay settlements and proposes a framework for determining whether state antitrust law is preempted by federal patent law. This Note concludes that state antitrust claims are likely not preempted by federal patent law in the context of pay-for-delay settlements, nor should they be in light of policy concerns.

9. See Carrier, supra note 6, at 1–2 (“Courts have analyzed [pay-for-delay settlements] by relying on a test that asks if the settlement falls within the ‘scope of the patent.’ They have found, in nearly all of these cases, that it does. And, as a result, they have concluded that the agreements do not violate the antitrust laws.”). Cf. 1 HOVENKAMP ET AL., supra note 6, at 15-36 (“The Eleventh Circuit reasoned from the premise that a valid patent gives its owner a right to exclude to the conclusion that the payment for exclusion was not an unwarranted extension of the patent.”).

10. One exception, and the inspiration for this Note, is discussed in note 12, infra.


12. The Supreme Court made many preemption decisions in the first decade of the twenty-first century, and though these decisions have not been entirely consistent or clear, they have demonstrated that the Court considers preemption a valuable instrument in assessing the balance of state and federal power in various fields. See Ernest A. Young, “The Ordinary Diet of the Law”: The Presumption Against Preemption in the Robert’s Court, 2011 SUP. CT. REV. 253, 253–57 (2012).
I. A PARALLEL HISTORY OF PAY-FOR-DELAY SETTLEMENTS AND PREEMPTION OF FEDERAL PATENT LAW

A. ANDA LITIGATION AND PAY-FOR-DELAY SETTLEMENTS

The Act creates a series of incentives that make settlement an attractive option to both pioneering and generic pharmaceutical companies involved in Abbreviated New Drug Applications (ANDA) litigation.\textsuperscript{13} The settlement agreements have been challenged for violating antitrust laws, with disparate results among federal circuit courts.\textsuperscript{14} The status of these settlements is contested and uncertain.\textsuperscript{15}

1. The Hatch-Waxman Act

Before the Act was passed, there was a significant gap between the time that a patent expired on a pioneer's drug and the time that a generic manufacturer was able to market its version of the drug.\textsuperscript{16} In response to the need to promote pioneering in the pharmaceutical industry and to introduce low-cost generic versions of new drugs at the expiration of the pioneer's patent, Congress passed the Act in 1984.\textsuperscript{17} The Act made changes to patent law and to the United States Food and Drug Administration (FDA) approval process for new drug products in an effort to both protect the exclusive patent rights of pioneering drug companies and encourage the entry of lower-

\textsuperscript{13} See supra text accompanying note 3. “Pioneer” will be used to refer to a drug company that is the first to patent and market a drug.

\textsuperscript{14} See ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 1330 (5th ed. 2011).

\textsuperscript{15} See 1 HOVENKAMP ET AL., supra note 6, at 15-48 to 15-49.

\textsuperscript{16} See MERGES & DUFFY, supra note 14, at 1329.

\textsuperscript{17} See, e.g., Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (“To amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications, to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes.”); 12 AREEDA & HOVENKAMP, supra note 2, at 338 (“The 1984 Hatch-Waxman legislation attempted to balance the pioneer drug manufacturers' innovation incentives against the need to facilitate market entry by manufacturers of equivalent generic products.”); James M. Lennon et al., Statutory and Regulatory Scheme, in AM. BAR ASS’N SECTION OF INTELLECTUAL PROP. LAW, supra note 4, at 1. The Act was also a response to the 1962 amendments to the Food, Drug and Cosmetic Act (FDCA); these amendments created the requirement that new products be proven safe and effective by the FDA, which discouraged market-entry of generic companies. Lennon et al., supra, at 2.
cost generic drugs into the market. First, the Act created the ANDA. The ANDA process is a means for expediting FDA approval of a generic drug that is the bioequivalent of a patented brand-name drug. When a generic company files an ANDA, it must certify either that no patent was filed for the listed drug (a “paragraph I” certification), that the patent has expired (a “paragraph II” certification), that the patent will expire on a specified date and the ANDA filer will not market the drug until that date (a “paragraph III” certification), or that the patent is invalid or would not be infringed by the manufacture, use, or sale of the new drug (a “paragraph IV” certification).

The Act also amended the Patent Act of 1980 to extend the patent term for new pharmaceuticals. The extension of the patent term for new pharmaceuticals.

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18. See 1 HOVENKAMP ET AL., supra note 6, at 15–24 to 15–25.
19. 98 Stat. at 1585; Kenneth L. Dorsney, Preface to AM. BAR ASS’N SECTION OF INTELLECTUAL PROP. LAW, supra note 4, at xxi.
20. The ANDA applicant must present evidence in its application that its generic drug has the same active ingredient as the patent-holder’s drug. Lennon et al., supra note 17, at 18–19. (“[B]ioequivalence is established by showing that the generic drug does not significantly differ in the rate and extent to which the active ingredient becomes available in the body or at the site of action as compared to the NDA drug.”). “Bioequivalence” is statutorily defined as follows:

(B) A drug shall be considered to be bioequivalent to a listed drug if—
(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or
(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

21. Dorsney, supra note 19, at xxi.
The patent term benefits patentee companies that seek to file a New Drug Application (NDA); these filers have drugs which may be delayed from entering the market due to the FDA review process. The extension benefits NDA filers because it allows NDA filers to recover up to five years on the life of their patent for administrative delays. The patent term extension applies to patents claiming “products, methods of manufacturing, and methods of use for human and veterinary drugs, medical devices, and food additives.”

Perhaps most importantly, the Act created a framework for resolving patent disputes in the pharmaceutical industry. This framework consists of several critical innovations. First, the Act created a “listing” requirement for the pioneering drug companies. This provision requires NDA filers to list “any patent which claims the drug for which the applicant submitted the application or which claimed the method of using such a product covering [New Drug Application] inventions can be extended to make up for patent life lost during the approval process for the patented drug.”). The patent term was extended for products or methods of use of manufacture of products if:

1. The term of the patent has not expired before an application is submitted under subsection (d) for its extension;
2. The term of the patent has never been extended;
3. An application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of subsection (d);
4. The product has been subject to a regulatory review period before its commercial marketing or use;
5. The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the ‘approved product’.

In the case of a patent which claims a product, the rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—

98 Stat. at 1598.

24. Lennon et al., supra note 17, at 5.
26. Lennon et al., supra note 17, at 5.
27. Id.; see supra note 23.
28. 12 AREEDA & HOVENKAMP, supra note 2, at 338; 1 HOVENKAMP ET AL., supra note 6, at 15-25; Lennon et al., supra note 17, at 4.
29. 12 AREEDA & HOVENKAMP, supra note 2, at 338; 1 HOVENKAMP ET AL., supra note 6, at 15-25.
drug and with respect to which a claim of patent infringement
could reasonably be asserted . . . .”30 Second, the Act provided
for a thirty-month stay of FDA approval of the generic drug,
upon filing of an infringement suit by the pioneer.31 When a
generic drug company files an ANDA, the pioneer has forty-five
days to sue for infringement, or else the ANDA approval
becomes effective immediately thereafter.32 However, if the
pioneer drug company brings suit, ANDA approval will not be
effective until the end of a thirty-month stay period (with some
exceptions).33 Finally, the Act gives the first generic to file an
ANDA a 180-day exclusivity period in the market upon
expiration (or finding of invalidity) of the pioneer’s patent.34
This provision gives the first generic manufacturer to file an
ANDA the exclusive right to commercialize the product for 180
days upon the expiration of the pioneer’s patent, or, if
the pioneer’s patent is found invalid, 180 days from the court
decision, whichever comes first.35

2. The Origins of ANDA Litigation

The pay-for-delay settlements encouraged by the Act follow
a basic pattern in which the plaintiff in a patent infringement
suit (the pioneering drug company) pays a settlement to the
defendant (the generic company) upon agreement that
defendant will delay commercialization of its product.36 These
pay-for-delay settlements may appeal to both parties under the

30. 21 U.S.C. § 355(b)(1) (2006); see also 12 AREEDA & HOVENKAMP, supra

31. 21 U.S.C. § 355(j)(5)(B)(ii); 12 AREEDA & HOVENKAMP, supra note 2,
at 338–39; 1 HOVENKAMP ET AL., supra note 6, at 15-25.

32. 21 U.S.C. § 355(j)(5)(B)(ii); 1 HOVENKAMP ET AL., supra note 6, at 15-

33. 1 HOVENKAMP ET AL., supra note 6, at 15-27 (“If a court concludes in a
final decision that the patent is invalid or not infringed prior to the expiration
of the 30-month stay, ANDA approval is effective as of the date of that court

34. Drug Price Competition and Patent Term Restoration (Hatch-
HOVENKAMP, supra note 2, at 339; 1 HOVENKAMP ET AL., supra note 6, at 15-
25; Lennon et al., supra note 17, at 22.

35. 21 U.S.C. § 355(j)(5)(B)(iv); 1 HOVENKAMP ET AL., supra note 6, at 15-

36. See, e.g., 12 AREEDA & HOVENKAMP, supra note 2, at 338; 1
HOVENKAMP ET AL., supra note 6, at 15-24; Alden F. Abbott & Susan T.
Michel, The Right Balance of Competition Policy and Intellectual Property
Law: A Perspective on Settlements of Pharmaceutical Patent Litigation, in
PRACTISING LAW INST., supra note 5, at 387, 393 (2006).
Act’s framework. The generic company may accept a settlement payment and in return agree to delay entry into the market for some time. This delays the generic company’s 180-day exclusivity period and thereby keeps other generic companies from entering the market.

To illustrate the incentives for settlement, consider In re Cardizem CD Antitrust Litigation, in which a pioneer drug company had a patent on a drug, a generic drug company filed an ANDA with a paragraph IV certification for their version of that drug, and the pioneer drug company filed suit. During litigation over infringement of the pioneer company’s drug patent, the parties entered an agreement in which the pioneer company paid the generic company $10 million per quarter to delay entry into the market. Litigation was prolonged, the 180-day exclusivity period for the generic company was postponed, and other generic companies were barred from entering the market for this time.

Under this agreement, both parties were better off than they would have been if they had litigated the case to completion. Both would have spent time and money on litigating the case, the pioneer drug company was able to extend its monopoly, and the generic got paid, perhaps more than it would have profited from actually manufacturing the drug.

Because of incentives for collusive settlements, the FTC requires disclosure of pay-for-delay settlements, to screen for

37. For an explanation of how the provisions of the Act incentivize sham litigation, see Blair & Cotter, supra note 22, at 506–10.
38. See, e.g., Carrier, supra note 2, at 39.
39. HOVENKAMP ET AL., supra note 6, at 15–29.
41. Id. at 901–02.
42. Id. at 903.
43. Id. at 904.
44. Cf. Carrier, supra note 2, at 39–40. See also Abbott & Michel, supra note 5, at 414–15. Under the Hatch-Waxman framework, generic drugs sell for less than their branded counterparts, [so] generic entry causes the branded company to lose more in profits than the generic company earns, with the difference accruing as consumer savings . . . . A brand company could pay a generic to delay market entry more than it would earn by entering, and still be better off than if it faced competition . . . . [T]he brand firm and its generic rival are always better off eliminating their expected competition and sharing the brand’s monopoly profits.

Id. at 414.
anticompetitive effects.\footnote{\textsuperscript{45}} FTC studies on these settlements reveal that settlement payments often pass from pioneer to generic manufacturer, and range in the tens of millions of dollars.\footnote{\textsuperscript{46}} The FTC has recognized the severity of this problem, noting that “[i]n Fiscal Year (FY) 2012, the number of potentially anticompetitive patent dispute settlements between branded and generic drug companies increased significantly compared with FY 2011, jumping from 28 to 40 . . . .”\footnote{\textsuperscript{47}} The FTC suggests that these settlements cost American consumers \$3.5 billion annually.\footnote{\textsuperscript{48}}

3. The IP/Antitrust Interface

Patent law and antitrust law can clash with regards to their underlying policy considerations.\footnote{\textsuperscript{49}} Patent law protects individual property rights of inventors in order to promote innovation and competition, while antitrust seeks to prevent monopoly power and anticompetitive behavior.\footnote{\textsuperscript{50}} Pay-for-delay settlements illustrate this tension, as they may produce anticompetitive effects that harm consumers.\footnote{\textsuperscript{51}} However, in those cases where patent settlements may produce anticompetitive effects, the settlements are susceptible to antitrust analysis.\footnote{\textsuperscript{52}}

In considering the purposes of the antitrust laws, it seems Congress intended to protect competition and prevent monopoly.\footnote{\textsuperscript{53}} However, as Areeda and Hovenkamp describe in

\footnote{\textsuperscript{45}} 1 HOVENKAMP ET AL., \textit{supra} note 6, at 15-30.
\footnote{\textsuperscript{46}} \textit{Id.}
\footnote{\textsuperscript{47}} \textit{FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market}, \textsc{fed. trade commission} (Jan. 17, 2013), http://www.ftc.gov/opa/2013/01/mmarpt.shtm.
\footnote{\textsuperscript{48}} \textit{Id.}
\footnote{\textsuperscript{49}} See generally Mark A. Lemley, \textit{A New Balance Between IP and Antitrust}, 13 \textsc{sw. j.l. \\& trade americas} 237, 238–45, 253–56 (2007) (discussing the nature and purposes of IP and antitrust law and arguing for an equal balance between the two bodies of law).
\footnote{\textsuperscript{50}} See Abbott & Michel, \textit{supra} note 5, at 391–92. But see Lemley, \textit{supra} note 49, at 1–9. Lemley acknowledges the tension exists in some situations, but finds the goals of the two systems are not really in conflict. \textit{Id.} at 9–17.
\footnote{\textsuperscript{51}} See \textit{supra} notes 47–48 and accompanying text. It should be noted that settlements of patent disputes \textit{in general} have the potential to produce procompetitive effects, through both benefit to consumers and judicial efficiency. See Abbott & Michel, \textit{supra} note 5, at 392–93.
\footnote{\textsuperscript{52}} See MERGES \\& DUFFY, \textit{supra} note 14, at 1330; \textit{infra} Part I.A.4.
\footnote{\textsuperscript{53}} See, \textit{e.g.}, 1 PHILLIP E. AREEDA \\& HERBERT HOVENKAMP, \textit{ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION} 3 (3d
their treatise, “the principle objective of antitrust policy is to maximize consumer welfare by encouraging firms to behave competitively while yet permitting them to take advantage of every available economy that comes from internal or jointly created production efficiencies, or from innovation producing new processes or new or improved products.”

However, the authors note that the antitrust laws are specifically designed to protect competition, and not to address the detrimental outcomes that may result. The Sherman Act was the first federal statement of the antitrust laws, which was meant to codify the pre-existing state competition laws, and the drafters of the Sherman Act were concerned with injury to competitors caused by monopoly pricing.

States have their own antitrust laws that largely overlap with the regulations of the Sherman Act, though states may impose stricter or more lenient regulations than federal antitrust laws. These state laws may be preempted in situations where they allow something that federal law prohibits, or they prohibit something that federal law permits, the latter being the more usual case.

Antitrust challenges to the legality of pay-for-delay settlements generally arise under section 1 of the Sherman Act, which states that “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.” However, “the Supreme Court has long

ed. 2006) (quoting Standard Oil Co. v. FTC, 340 U.S. 231, 249 (1951)).

54. Id. at 4.

55. The laws do not purport to remedy the negative results of competition, including increased income inequality, losses due to failed risks, and displaced human capital and infrastructure. See id. at 6.

56. See id. at 9–10. Though it should be noted that the framers of the Act did not necessarily distinguish between these two injured parties. See id. at 52–53. For a thorough discussion of the legislative history of the Sherman Act, see id. at 42–63. Areeda and Hovenkamp ultimately conclude that the legislative history should be given little weight in crafting policy implications of the Sherman Act. Id. at 59.


58. See 1 AREEDA & HOVENKAMP, supra note 53, at 339.

59. Id. at 347.

60. 15 U.S.C. § 1 (2006); see also In re K-Dur Antitrust Litig., 686 F.3d 197, 208 (3d Cir. 2012) (listing section 1 of the Sherman Act as the “general antitrust standard”).
construed [section 1] to prohibit only unreasonable restraints.”61 Courts may take one of several different approaches in determining whether an unreasonable restraint on trade exists, namely the per se rule, the rule of reason analysis, and the quick look approach.62 Usually, a court will apply the rule of reason approach, in which the fact finder determines whether a practice restrains competition in light of relevant market factors.63 Courts treat some conduct as per se illegal if the conduct is very likely to result in anticompetitive effects.64 Courts may apply the intermediate “quick look” approach in cases where the conduct is similar to that which requires the per se treatment.65

In the case of pay-for-delay settlements, the contested conduct may be actions of the pioneer drug company plaintiff, or the pioneer and generic drug company defendant together, that results in the delayed entry of the generic competitor into the market.66 However, patent law allows the pioneer patentee to exclude others from making, using, and selling the patented drug.67 Therefore, under patent law, the plaintiff should be able

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61. In re K-Dur, 686 F.3d at 209.
62. See LESLIE, supra note 5, at 26–27.
63. See State Oil Co. v. Khan, 522 U.S. 3, 10 (1997). The fact-finder decides “whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.” Id. Further, under this approach, the plaintiff has the initial burden of proving that the activity has anticompetitive market effects, the defendant then must show that the activity promotes a pro-competitive goal, and lastly, the plaintiff then has a chance to show that the activity is not necessary to promote the pro-competitive goal. See In re K-Dur, 686 F.3d at 209.
64. See, e.g., In re K-Dur, 686 F.3d at 209; LESLIE, supra note 5, at 26 (“The per se rule is categorical; if an agreement falls in a per se category, then the agreement violates Section One, without any analysis of the agreement’s actual effect on competitive conditions.”). California’s Cartwright Act follows the Sherman Act in this respect, categorizing certain agreements as illegal per se if they “have a pernicious effect on competition and lack any redeeming virtue.” In re Cipro Cases I & II, 200 Cal. App. 4th 442, 467 (2011), rev. granted, 269 P.3d 653 (Cal. 2012).
65. See, e.g., In re K-Dur, 686 F.3d at 209. In the context of pay-for-delay settlements, the plaintiff shifts the burden to the defendant by showing that the payment went to the generic company and caused delay of the generic product’s entry to the market, after which the defendant must prove the settlement was pro-competitive or competitively neutral. See Blair & Cotter, supra note 22, at 534.
66. See, e.g., Blizzard et al., supra note 4, at 293.
to enter into agreements that do not extend its exclusionary power beyond the protection of the patent.68

Though these antitrust claims contesting the legality of pay-for-delay settlements are brought under the Sherman Act, federal law only allows monetary damages for direct purchasers of the patented drug.69 This means that end consumers and other indirect purchasers may not recover damages in antitrust challenges brought under the Sherman Act, though they do have the option of injunctive relief.70 However, many state antitrust statutes reward damages to indirect purchasers.71 Therefore, in many pay-for-delay

68. See, e.g., Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1304 (11th Cir. 2003).
69. See 15 U.S.C. § 15 (2006); Illinois Brick Co. v. Illinois, 431 U.S. 720, 734–35 (1977); Blizzard et al., supra note 4, at 303. In order for a private plaintiff (any plaintiff other than the U.S. government) to be eligible for damage awards, they must meet stringent standing requirements including showing that the conduct in question caused an injury-in-fact to the plaintiff’s business or property, that the recovery is not duplicative of that of a more directly injured person, that the injury is one that the antitrust laws were intended to prevent, and that the damages claimed are a reasonable measure of the injury. See, e.g., 2A PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION 61–62 (3d ed. 2007).
70. See 15 U.S.C. § 26 (2006) (“Any person, firm, corporation, or association shall be entitled to sue for and have injunctive relief, in any court of the United States having jurisdiction over the parties, against threatened loss or damage by a violation of the antitrust laws . . . .”); see also ABA SECTION OF ANTITRUST LAW, STATE ANTITRUST PRACTICE AND STATUTES at 6-51 (4th ed. 2009) (explaining that California’s Cartwright Act was amended in 1978 to allow indirect purchasers to bring claims under the Act).
71. See Blizzard et al., supra note 4, at 304. For example, California’s Cartwright Act includes a damages provision which states that an action may be brought under the Act “by any person who is injured in his or her business or property by reason of anything forbidden or declared unlawful by this chapter, regardless of whether such injured person dealt directly or indirectly with the defendant.” CAL. BUS. & PROF. CODE § 16750 (West 2012). “Indirect purchasers” are purchasers who did not buy the product or service directly from one of the defendants in an antitrust action, but bought from a prior purchaser of the product or service. Cf. California v. ARC Am. Corp., 490 U.S. 93, 97 (1989) (“The State and the local governments were all indirect purchasers of concrete block—that is, they did not purchase concrete block directly from the price-fixing defendants but rather purchased products or contracted for construction into which the concrete block was incorporated by a prior purchaser.”).
challenges, courts apply state law to the contested settlement in concert with federal antitrust law. 72

4. The Legality of Pay-for-Delay Settlements

The Federal Circuit Courts have taken different approaches to the legality of pay-for-delay settlements. In the In re Cardizem example outlined in Part I.A.2, the Sixth Circuit found that the settlement agreement was “a classic example of a per se illegal restraint on trade.” 73 The court’s conclusion derived from the anticompetitive nature of the agreement to eliminate competition. 74

Some courts have been more deferential to the pharmaceutical companies, applying a rule of reason analysis. 75 In Valley Drug Co. v. Geneva Pharmaceuticals, Inc. 76 the Eleventh Circuit refused to find the reverse payment settlement per se illegal, concluding that “[u]nlike some kinds of agreements that are per se illegal whether engaged in by patentees or anyone else, such as tying or price-fixing, the exclusion of infringing competition is the essence of the patent grant.” 77 The court further found that the fact that the patent at issue was later determined to be invalid did not subject the settlement agreement to per se treatment; the agreement should be judged by its reasonableness at the time it was formed. 78

72. See Blizzard et al., supra note 4, at 323 (“State laws often contain equivalent, or even broader claims than federal law, allowing indirect purchasers to pursue the state law equivalents of Walker Process claims, sham patent litigation claims, and sham citizen petitions claims.”). The Supreme Court has ruled that state antitrust laws that allow indirect purchasers to sue for damages are not preempted by federal antitrust law. See ARC Am. Corp., 490 U.S. at 101.


74. Id. at 908; see also Carrier, supra note 6, at 2 (“The court found that the brand paid ‘the only potential competitor $40 million per year to stay out of the market.’” (quoting In re Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003))).

75. See generally supra notes 67–68 and accompanying text (describing how patentees should be able to make agreements that do not exceed the scope of their patent).


77. Id. at 1306.

78. Id.
The Eleventh Circuit later announced what became known as the “scope of the patent” test\(^79\) in *Schering Plough Corp. v. FTC*,\(^80\) evaluating “(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.”\(^81\) Using this test, the court applied a presumption of patent validity,\(^82\) and accordingly found no expansion beyond the scope of the patent in the settlement agreement.\(^83\) In reference to *Valley Drug* and *Schering Plough*, the Eleventh Circuit later “clarified that its prior opinions did not call for an evaluation of the strength of the patent but rather only a determination whether, absent sham litigation or fraud in obtaining the patent, the settlement agreement exceeded the scope of the patent.”\(^84\) In *Andrx Pharmaceuticals, Inc. v. Elan Corp.*,\(^85\) the Eleventh Circuit applied its three-part test, finding that plaintiff Andrx had sufficiently alleged a violation of section 1 of the Sherman Act;\(^86\) if Andrx’s allegation that the defendant generic drug company agreed *never* to market its product were true, then the agreement would exceed the exclusionary scope of the patent.\(^87\)

Taking the “scope of the patent” test one step further, the Second Circuit has characterized the settlements as essentially *per se* legal.\(^88\) *In re Tamoxifen Citrate Antitrust Litigation*\(^89\) did not examine the validity of the patent, but drew the presumption that as long as the patent litigation is not a sham and the patentee has not exceeded the scope of the patent, the settlement is legal.\(^90\) The Court of Appeals for the Federal

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79. *See Carrier, supra note 6, at 1.*
80. *Schering Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).
81. *Id.* at 1066.
82. *Id.*
83. *Id.* at 1075–76.
84. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 212 (3d Cir. 2012).
85. *Andrx Pharm., Inc., v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005).
86. *Id.* at 1235.
87. *Id.*
88. *See Carrier, supra note 6, at 3* (“Courts then imperceptibly shifted from punishing conduct ‘outside the scope’ of the patent to immunizing conduct ‘within the scope’ of the patent. In doing so, the test took a dramatic turn toward deference.”).
89. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).
90. *See id.* at 211–13. The Second Circuit made the following observation regarding the possibility that a patent on a brand name drug, which was the object of a contested settlement, was in fact invalid:

*We are not unaware of a troubling dynamic that is at work in these*
Circuit (CAFC) affirmed the district court’s application of the “scope of the patent” test in In re Ciprofloxacin Hydrochloride Antitrust Litigation, concluding that “the essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent.”

The Third Circuit further complicated the circuit split in July 2012 when it applied a “quick look rule of reason analysis” in deciding In re K-Dur. The court enunciated the test as follows:

[We] will direct the District Court to apply a quick look rule of reason analysis based on the economic realities of the reverse payment settlement rather than the labels applied by the settling parties. Specifically, the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.

The court reasoned that:

[The] judicial preference for settlement, while generally laudable, should not displace countervailing public policy objectives or, in this case, Congress’s determination—which is evident from the structure of the Hatch-Waxman Act and the statements in the legislative record—that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers.

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Id. at 211.

91. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); see id. at 1333. CAFC was created primarily to interpret patent law and stand as a specialized court for national unity of patent regulation. See MERGES & DUFFY, supra note 14, at 10.

92. *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1336.


94. Id.

95. Id. at 217.
Finally, in *FTC v. Watson Pharmaceuticals, Inc.* the Eleventh Circuit stuck to its precedent, stating, “Our Valley Drug, Schering-Plough, and Andrx decisions establish the rule that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.” This series of cases illustrates the uncertainty and inconsistency of pay-for-delay challenge jurisprudence, though the courts have generally embraced a more deferential approach in recent years.

**B. FEDERAL PATENT LAW PREEMPTION**

1. Federal Preemption

   The Supremacy Clause of the United States Constitution, which declares that the “Laws of the United States” are “the Supreme Law of the Land,” provides the basis for the doctrine of preemption. Preemption stands for the idea that, “under

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97. Id. at 1312 (citation omitted). The Eleventh Circuit gave a pointed rejection of the FTC’s argument to “adopt a rule that an exclusion payment is unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date.” Id. By analyzing the defendants’ probability-based anticipation of success, patent litigation can also be a high stakes, spin-the-chambers, all or nothing undertaking. For the company with a patented drug, it obviously makes sense to settle the infringement action if it is “not likely to prevail,” even though that company may have a substantial (up to 49%) chance of winning. On the other side of the settlement equation is the generic drug company that is only “likely to prevail” in the action; with a substantial (up to 49%) chance of losing, that company also has a legitimate motive for settling. When both sides of a dispute have a substantial chance of winning and losing, especially when their chances may be 49% to 51%, it is reasonable for them to settle. That companies with conflicting claims settle drug patent litigation in these circumstances is not a violation of the antitrust laws.

Id. at 1313 (citations omitted).

the U.S. Constitution’s Supremacy Clause, federal law reigns supreme and hence preempts any conflicting law or law that federal legislation deems preempted.99 The doctrine may be understood as encompassing three basic types of preemption: express, field, and conflict or obstacle.100

Express preemption exists where Congress has included a provision in legislation stipulating that states may not exercise a given power.101 The Patent Act does not contain an express preemption provision,102 unlike other areas of intellectual property (IP) law.103

Field preemption refers to an implicit intent of Congress that federal regulation has completely occupied an area of law, such that state regulation of the same area is impermissible.104 Though the history and current status of the doctrine has been convoluted,105 perhaps the clearest statement of the doctrine

101. See Nelson, supra note 100, at 227.
103. The Copyright Act does include an express preemption provision, 17 U.S.C. § 301 (2006). 1 HOVENKAMP ET AL., supra note 6, at 5-43. The provision states that “all legal or equitable rights that are equivalent to any of the exclusive rights within the general scope of copyright . . . are governed exclusively by this title. Thereafter, no person is entitled to any such right or equivalent right in any such work under the common law or statutes of any State.” 17 U.S.C. § 301(a) (2006). For an analysis of conflicting interpretations of this statute, see Thomas F. Cotter & Irina Y. Dmitrieva, Integrating the Right of Publicity with First Amendment and Copyright Preemption Analysis, 33 COLUM. J.L. & ARTS 165, 181–88 (2010).
104. See Nelson, supra note 100, at 227. Both field preemption and conflict preemption can be considered to fall under a broader category of “implied” preemption, where, in the absence of an explicit provision in a statute, Congress’s intent that federal law displaces state law is implied. Cf. STARR ET AL., supra note 100, at 18–30 (classifying “occupation of the field” and “obstacle preemption” as types of “implied preemption”).
105. Cf. Young, supra note 12, at 255 (“Most observers consider the law in this area to be, in the words of a leading practitioner, ‘a muddle.’”).
came from the 1947 case, *Rice v. Santa Fe Elevator*.\(^{106}\) In *Rice*, Justice Douglas suggested state law is preempted where federal law is “so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it” or it may “touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.”\(^{107}\) Field preemption may also be described as “jurisdictional” preemption, the idea that jurisdictional rules exist that prohibit states from regulating certain fields.\(^{108}\)

Finally, conflict preemption arises when the state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”\(^{109}\) Justice Douglas classified conflict preemption as two separate categories: obstacle preemption, where “the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose,” and conflict preemption, where “the state policy may produce a result inconsistent with the objective of the federal statute.”\(^{110}\) One scholar characterizes the test courts should apply as follows: “Courts are required to disregard state law if, but only if, it contradicts a rule validly established by federal law.”\(^{111}\)

The Supreme Court has frustrated courts and scholars through its inconsistent application and interpretation of the preemption doctrine.\(^{112}\) Further, the Court has decided only a handful of decisions regarding preemption of federal patent law.\(^{113}\) These decisions provide the only Supreme Court

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107. *Id.* at 230.
111. *Nelson*, *supra* note 100, at 260. Nelson refers to this as the “logical-contradiction” test. *Id.*
112. *Cf. id.* at 262; *Young*, *supra* note 12, at 255.
guidance on the preemptive effect of patent law, which are outlined in Part I.B.2 below, along with relevant case law from the CAFC. Though these decisions concern whether patent law preempts various state laws, it is important to note that the Court has not considered whether federal patent law preempts state antitrust law. CAFC had the opportunity in *Zenith Electronics Corp. v. Exzec, Inc.* to decide if federal antitrust law may be “preempted” by federal patent laws. There is a basic argument that “a given federal antitrust challenge to the exercise of federally-created intellectual property rights cannot be countenanced because the antitrust challenge conflicts with, and should be deemed ‘preempted’ by, the intellectual property rights regime.” Yet CAFC declined to find any preemption among federal intellectual property and antitrust law, instead finding that when two federal laws conflict, a court must “interpret and apply them ‘in a way that preserves the purposes of both and fosters harmony between them.’”

2. Supreme Court and CAFC Case Law Addressing Preemption of Federal Patent Law

The Supreme Court has decided a few cases which address the question of preemption of federal patent law over various state laws. In an early pair of cases, the Court found that state competition laws are preempted when they attempt to create patent-like rights for products in the public domain. In *Sears, Roebuck & Co. v. Stiffel Co.*, the Court held that state unfair competition law could not impose liability for copying of the design of a lamp that was not protected by federal patent law. The Court reasoned that a state could not evade the requirements of federal patent law by using unfair competition law to provide protection to an unpatented

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114. See *Zenith Electronics Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1342 (Fed. Cir. 1999); 1 HOVENKAMP ET AL., *supra* note 6, at 5-48.

115. 1 HOVENKAMP ET AL., *supra* note 6, at 5-48.

116. *Zenith*, 182 F.3d at 1347 (quoting *Vornado Air Circulation Sys., Inc. v. Duracraft Corp.*, 58 F.3d 1498, 1507 (10th Cir. 1995)).


120. *Id.* at 232–33.
product. In *Compco Corp. v. Day-Brite Lighting, Inc.*, the Court held that though state laws may not prohibit copying and selling of unpatented products, states may enforce laws that require proper identification of the source of the copied products.

After *Sears* and *Compco*, the Court decided a case involving preemption of federal copyright law, *Goldstein v. California*, and found that a state statute criminalizing piracy of sound recordings (which was not a protected work under the Copyright Act at that time) was not preempted by federal copyright law. The Court reasoned that, whereas in *Sears* and *Compco* the state laws were “to prevent the copying of articles which did not meet the requirements for federal protection,” a similar conflict didn’t exist in this case because “[i]n regard to this category of ‘Writings,’ Congress has drawn no balance; rather, it has left the area unattended, and no reason exists why the State should not be free to act.”

The Court again deferred to state law in a case involving a claim of preemption of state trade secret law. In *Kewanee Oil Co. v. Bicron Corp.*, the Court found that state trade secret laws are not preempted by federal patent law, reasoning that the important question in determining federal patent preemption is whether the state law in question conflicts with the operation of the Patent Act. Significantly, the Court announced a test for determining whether a given state law conflicts with the purposes of federal patent law:

First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions, to stimulate further innovation and to permit the public to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to assure

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121. *Id.* at 231–32 (“To allow a State by use of its law of unfair competition to prevent the copying of an article which represents too slight an advance to be patented would be to permit the State to block off from the public something which federal law has said belongs to the public.”).


123. *Id.* at 238.

124. *Goldstein v. California*, 412 U.S. 546, 571 (1973) (“We conclude that the State of California has exercised a power which it retained under the Constitution, and that the challenged statute, as applied in this case, does not intrude into an area which Congress has, up to now, pre-empted.”).

125. *Id.* at 569–70.


127. *Id.* at 491–92.

128. *Id.* at 479.
that ideas in the public domain remain there for the free use of the public.\textsuperscript{129}

The Court noted that trade secret law protects items which would not be proper subjects for consideration for patent protection,\textsuperscript{130} that having two systems that both support innovation will not be in conflict,\textsuperscript{131} and that in cases where a product is patentable, it is unlikely that an inventor would opt for the lesser protections provided by trade secret laws just to avoid disclosure.\textsuperscript{132}

Finally, in \textit{Bonito Boats, Inc. v. Thunder Draft Boats, Inc.},\textsuperscript{133} the Court held that a state law may not restrict the public’s ability to exploit an unpatented design,\textsuperscript{134} and that the state had, in effect, created a monopoly, which encroached on Congress’s power to regulate patent law.\textsuperscript{135} In finding the state law to be preempted,\textsuperscript{136} the court distinguished \textit{Kewanee Oil} based on the differences in protection offered by trade secret law, versus the “patent like” rights awarded by the state law in \textit{Bonito Boats}.\textsuperscript{137}

In the late nineties, the CAFC decided a series of cases regarding federal patent preemption of state business tort and unfair competition claims.\textsuperscript{138} In \textit{Dow Chemical Co. v. Exxon Corp.}, the CAFC held that a state unfair competition claim alleging intentional interference with contractual relations, based on a patentee’s inequitable conduct before the United States Patent and Trademark Office (PTO),\textsuperscript{139} was not preempted by federal patent law.\textsuperscript{140} The court reasoned that

\begin{itemize}
\item \textsuperscript{129}Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979) (interpreting \textit{Kewanee Oil Co. v. Bicron Corp.}, 416 U.S. 470 (1974)).
\item \textsuperscript{130}\textit{Kewanee Oil}, 416 U.S. at 482.
\item \textsuperscript{131}Id. at 484.
\item \textsuperscript{132}Id. at 490.
\item \textsuperscript{133}Bonito Boats, Inc. v. Thunder Draft Boats, 489 U.S. 141 (1989).
\item \textsuperscript{134}Id. at 168.
\item \textsuperscript{135}Id. at 167 (“The Florida law substantially restricts the public’s ability to exploit an unpatented design in general circulation, raising the specter of state-created monopolies in a host of useful shapes and processes for which patent protection has been denied or is otherwise unobtainable.”).
\item \textsuperscript{136}Id. at 168.
\item \textsuperscript{137}Id. at 156–57 (“[S]tates may not offer patent-like protection to intellectual creations which would otherwise remain unprotected as a matter of federal law.”).
\item \textsuperscript{138}Zenith Electronics Corp. v. Exzec, Inc., 182 F.3d 1340 (Fed. Cir. 1999); Dow Chemical Co. v. Exxon Corp., 139 F.3d 1470 (Fed. Cir. 1998); Hunter Douglas, Inc. v. Harmonic Design, Inc., 150 F.3d 1318 (Fed. Cir. 1998).
\item \textsuperscript{139}Dow Chemical, 139 F.3d at 1472.
\item \textsuperscript{140}Id. at 1479.
\end{itemize}
the state law wasn’t preempted because it “does not stand as an
impermissible obstacle to the accomplishment and execution of
the patent laws and because the cause of action requires
entirely different elements from the defense of inequitable
conduct under the federal patent laws.”141

However, the CAFC reached a different conclusion in
Hunter Douglas, Inc. v. Harmonic Design when it held that
state commercial disparagement claims are preempted by
federal patent law in cases where the state law claim depends
on the patent holder’s conduct before the PTO and the plaintiff
fails to allege fraud or bad faith in obtaining the patent.142
Since federal patent law already addresses these issues, CAFC
reasoned, a showing of bad faith is required in order to avoid
preemption.143

As mentioned in Part I.B.1, supra, the CAFC declined to
acknowledge a formal preemption between conflicting federal
laws in Zenith Electronics, finding that neither federal
antitrust law nor federal patent law preempted a federal unfair
competition claim.144

The Supreme Court’s and the CAFC’s rulings regarding
preemption of federal patent law, though not expansive, are
instructive and provide guidance as to how courts might apply
the doctrine of preemption to cases where pay-for-delay
settlements are challenged in state courts under state antitrust
laws. One such case is pending hearing in the Supreme Court
of California, and invites the application of preemption
analysis.145

3. Case Study: In re Cipro Cases I & II

In February 2012, the California Supreme Court granted
review for In re Cipro Cases I & II (the Cipro Cases).146 This is
presently the first and only challenge to a pay-for-delay

141. Id. at 1478–79.
142. Hunter Douglas, 153 F.3d at 1336.
143. Id. The CAFC distinguished Dow, suggesting that it “is in harmony
with this conduct-based approach. In that case, because the plaintiff alleged
the bad faith enforcement of a patent, the state law torts were not preempted.”
Id. at 1337 (citations omitted).
Cir. 1999).
269 P.3d 653 (Cal. 2012).
146. Yeung, supra note 11.
settlement brought in a state court. One of the issues to be presented upon review is whether “the facts of this case demonstrating egregious patent misuse in the form of a large cash payment, made to head off likely invalidation, that drove up prescription drug prices in an area critical to social welfare, preclude federal preemption of California law . . . .” Thus, the California Supreme Court may directly decide this issue.

The court will be reviewing the decision of the California Court of Appeal for the Fourth District. The case, like pay-for-delay challenges brought in federal courts, involves a pioneering company, Bayer, which concluded settlement agreements with several generic companies stipulating that the generics would delay entry to the market, and requiring payments to one of the generics, Barr, amounting to nearly $400 million. Bayer’s patent for the ciprofloxacin hydrochloride molecule, the active ingredient in Cipro, was confirmed to be valid upon reexamination and in further ANDA challenges subsequent to the initial settlements. Direct and indirect purchasers initiated federal litigation challenging the settlements in 2000 and 2001; all the litigation ultimately favored the pharmaceutical companies, finding that the agreements were within the exclusionary scope of the

147. Id.
148. Petition for Review at 1, In re Cipro Cases I & II, 200 Cal. App. 4th 442 (Dec. 18, 2011) (No. S198616). The petitioner argues that the California Court of Appeal wrongly decided that federal patent law preempts California antitrust law and that this ruling will completely prevent state courts from hearing patent disputes. Id. at 20.
150. Id. at 451.
151. Cipro is “an antibiotic prescribed for the treatment of infections.” Id. at 448.
152. Reexamination is a process which Congress implemented in 1980, which was meant to improve the quality of patents by allowing the validity of patents to be revisited by the PTO without recourse to litigation. See Merges & Duffy, supra note 14, at 1099. The process was codified in the Patent Act under 35 U.S.C. §§ 301–07 (ex parte reexamination) and 35 U.S.C. §§ 311–18 (inter partes reexamination, added in 1999). Id. However, the reexamination process was revised in the America Invents Act, and now comprises new post-grant and inter partes review proceedings and ex parte reexamination. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011); Matthew C. Phillips & Kevin B. Laurence, Changes to Reexamination Under the America Invents Act, INTELLECTUAL PROP. TODAY, Nov. 2011, at 22, 22–23.
patent and therefore were not in violation of antitrust laws.154 The plaintiffs in this case, state residents and nonprofit organizations, claimed that the settlements were per se illegal under the Cartwright Act as an unreasonable restraint on trade.155 The court analyzed the reasoning of federal challenges to pay-for-delay settlements, and concluded that “unless a patent was procured by fraud, or a suit for its enforcement was objectively baseless, a settlement of the enforcement suit does not violate the Cartwright Act if the settlement restrains competition only within the scope of the patent.”156

The court further employed the doctrine of preemption to analyze plaintiffs’ sham litigation claim.157 The plaintiffs argued that Bayer procured its patent through inequitable conduct, and that Bayer’s infringement suit was therefore objectively baseless.158 The California Court of Appeal concluded that the plaintiffs’ sham litigation claim was preempted by federal patent law, based on a theory of field (or “jurisdictional”) preemption; the court reasoned that federal courts have original jurisdiction when “the plaintiff’s right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims.”159 The California Court of Appeals also rejected plaintiffs’ argument that a state court may decide patent issues that are ancillary to the main

154. Id. at 452–54.
155. Id. at 456.
156. Id. at 467.
157. A sham litigation claim requires a plaintiff to show “(1) ‘the lawsuit [to] be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits,’ and (2) that the litigant’s ‘subjective motivation’ for bringing the action was a sham seeking to conceal a knowing attempt to interfere with a competitor.” Id. at 470 (quoting In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 547 (E.D.N.Y. 2005)). The court looked only at jurisdictional, or field preemption, but the parties addressed the possibility of preemption in their briefs, which is reviewed in detail in Part II, infra. The court declined to address substantive or “conflict” preemption in its opinion. Id. at 470–77.
158. See id. at 470. “Objectively baseless” refers to sham litigation, described in note 157, supra.
159. See id. at 473 (quoting Holiday Matinee, Inc. v. Rambus, Inc., 118 Cal. App. 4th 1413, 1422 (2004)). The Court of Appeal specifically reasoned that, because plaintiffs’ claim of an objectively baseless suit depended on a question of federal patent law (the question of whether Bayer procured its patent through inequitable conduct), the claim was preempted by patent law. See id. at 473.
claim, finding that plaintiffs’ claims in fact depended on an issue of patent law.160

The California Court of Appeal’s conclusion that the plaintiffs’ sham litigation claim “arises from and is preempted by federal law,”161 invited discussion of preemption in the parties’ petitions for review and briefs that followed the opinion.162 Though the Court of Appeal only explicitly addressed field preemption, briefs filed with the Supreme Court of California address substantive preemption (or “obstacle preemption”), as discussed in detail in Part II.

II. THE DOCTRINE OF PREEMPTION APPLIED TO STATE ANTITRUST CHALLENGES TO PAY-FOR-DELAY SETTLEMENTS

A. PREEMPTION IN CONTEXT: IN RE CIPRO I & II

Part I of this Note explored the mechanics of pay-for-delay settlements and their legal treatment to date, as well as the doctrine of preemption as it has been understood by the Supreme Court and scholars. This Part analyzes the applicability of the doctrine of preemption to a state law challenge to a pay-for-delay settlement, using the Cipro Cases as an illustration. That analysis is informed by a general framework adapted from the limited case law in this area.163 Finally, Part II.B, infra, explores policy ramifications of finding state antitrust law to be preempted by federal patent law, concluding that preemption is inappropriate in this context.

1. The Doctrine of Preemption

As described in Part I.B, supra, the doctrine of preemption may be divided into three types: express, field, and conflict or obstacle.164 The Supreme Court’s pronouncements on preemption have tended to lack clarity, and have left room for lower and state courts to interpret the doctrine divergently.165

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160. See id. at 475.
161. Id. at 477.
162. See, e.g., Petition for Review, supra note 148, at 19.
163. See supra Part I.B.2.
164. Again, different taxonomies exist to describe the types of preemption; for the purposes of this analysis, the terms “substantive” and “jurisdictional” may also be employed to refer to conflict/obstacle and field preemption, respectively.
165. See supra note 112 and accompanying text.
Regarding the Cipro Cases, field and conflict preemption are relevant; as noted in Part II.B, infra, there is no provision in the Patent Act requiring preemption, and express preemption does not apply.\textsuperscript{166} However, the text of the relevant patent laws and of the state laws at issue in the Cipro Cases will provide a framework for the preemption analysis.

The plaintiffs in the Cipro Cases brought claims under section 16720 of the Cartwright Act, California's antitrust act, alleging that "Defendants, and their co-conspirators, entered into and engaged in a continuing unlawful trust in restraint of the trade and commerce described above in violation of California Business and Professions Code section 16720."\textsuperscript{167} The Cartwright Act defines a "trust" as: "a combination of capital, skill or acts by two or more persons for any of the following purposes: . . . [t]o create or carry out restrictions in trade or commerce . . . [t]o prevent competition in manufacturing . . . sale or purchase of merchandise, produce or any commodity."\textsuperscript{168} Plaintiffs alleged that defendants violated


\textsuperscript{167} Consolidated Second Amended Complaint at 35, In re Cipro Cases I & II, 200 Cal. App. 4th 442 (2011), rev. granted, 269 P.3d 653 (Cal. 2012) (Nos. 4154, 4220). The plaintiffs also brought claims for violation of state unfair competition law, CAL. BUS. & PROF. CODE § 17200 (West 2012), and common law monopolization, but this analysis will focus only on the antitrust challenges.

\textsuperscript{168} The full text of section 16720 reads as follows:

A trust is a combination of capital, skill or acts by two or more persons for any of the following purposes:
(a) To create or carry out restrictions in trade or commerce.
(b) To limit or reduce the production, or increase the price of merchandise or of any commodity.
(c) To prevent competition in manufacturing, making, transportation, sale or purchase of merchandise, produce or any commodity.
(d) To fix at any standard or figure, whereby its price to the public or consumer shall be in any manner controlled or established, any article or commodity of merchandise, produce or commerce intended for sale, barter, use or consumption in this State.
(e) To make or enter into or execute or carry out any contracts, obligations, or agreements of any kind or description, by which they do all or any or any combination of the following:
(1) Bind themselves not to sell, dispose of or transport any article or any commodity or any article of trade, use, merchandise, commerce or consumption below a common standard figure, or fixed value.
(2) Agree in any manner to keep the price of such article, commodity or transportation at a fixed or graduated figure.
section 16720 through trusts [that] have included concerted action and undertakings among the Defendants with the purpose and effect of: (a) allocating the entire California market for ciprofloxacin to Bayer; (b) permitting Bayer to maintain a monopoly over the California market for ciprofloxacin and to charge supra-competitive prices for Cipro, the proceeds of which it shares in part with Barr and HMR; (c) precluding the introduction of generic ciprofloxacin in California, which would have been available to consumers at a cost much lower than Cipro; and (d) fixing, raising, maintaining or stabilizing the price of ciprofloxacin.169

The patent laws themselves are not explicit regarding the extent of rights that they bestow. But several provisions seem relevant to the “scope of the patent” referred to in federal circuit court decisions.170 The Patent Act grants patent holders a negative property right to “exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.”171 The patent holder is entitled to a twenty-year term, subject to adjustments (including those granted under the Hatch-Waxman Act mentioned in Part I.A),172 and the patent is entitled to a presumption of validity.173 As noted in Kewanee Oil, there is nothing explicit in the text of these laws indicating

(3) Establish or settle the price of any article, commodity or transportation between them or themselves and others, so as directly or indirectly to preclude a free and unrestricted competition among themselves, or any purchasers or consumers in the sale or transportation of any such article or commodity.

(4) Agree to pool, combine or directly or indirectly unite any interests that they may have connected with the sale or transportation of any such article or commodity, that its price might in any manner be affected.

CAL. BUS. & PROF. CODE § 16720 (West 2012).

169. Consolidated Second Amended Complaint, supra note 167, at 37.
173. 35 U.S.C. § 282(a) (2006). The full text of the section reads as follows: A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

Id.
preemption. The question, then, turns to Congress’ purpose for enacting the Patent Act, whether it can be implied that the Patent Act was meant to foreclose the states’ ability to adjudicate matters touching on the patent law, and whether the Cartwright Act conflicts with the purposes and objectives of the Patent Act. Since the taxonomy of preemption is often neither clear nor consistent, analysis of “field” and “conflict” preemption may overlap, as the ultimate inquiry relates to congressional intent.

2. Field Preemption

The doctrine of field preemption and Supreme Court jurisprudence suggest that state courts are competent to adjudicate antitrust challenges to pay-for-delay settlements, and that state antitrust claims are not preempted by the federal patent laws. As mentioned in Part I.B.1, supra, field preemption exists where state law “regulates conduct in a field that Congress intends the federal government to occupy exclusively.” In the Cipro Cases, the California Court of Appeal reached the issue of preemption, but focused its analysis narrowly on jurisdiction, failing to address congressional intent. As an amicus request for review of the Cipro Cases points out, the Court of Appeal used a rule for determining exclusive federal jurisdiction rather than applying the doctrine of field preemption when it determined that plaintiffs’ claims depended on a question of patent law and therefore were preempted. Questions of jurisdiction may


175. Nelson, supra note 100, at 263 (“The [Supreme] Court itself has . . . conceded that field pre-emption may be understood as a species of conflict pre-emption.” (internal quotation marks omitted)).


177. See supra text accompanying note 159.

evidence a congressional intent that certain matters of federal law ought not be determined in state court, but that conclusion merely indicates that state court is the improper venue to try the question. The preemption inquiry asks whether Congress has the constitutional power to occupy a particular field entirely, such that a state law cannot stand. Proper jurisdiction is a threshold matter to adjudicating state law claims that relate to issues of patent law that are brought in state court, so it merits discussion.

As mentioned in Part II.A.1, supra, even though a jurisdiction question is not an identical inquiry to field preemption, there could be overlap in Congress's intent that certain federal questions are not to be adjudicated in state court. With that in mind, the court in the Cipro Cases could have considered case law that indicates an expansive right of the state to adjudicate issues concerning patent law. The Supreme Court has made it clear that state courts are separate from its preemption analysis, and did not involve an inquiry into Congress's intent regarding the reach of federal patent law. Hunter Douglas, 153 F.3d at 1324–25. The U.S. District Court for the Eastern District of New York similarly applied 28 U.S.C. § 1338(a) to find a state Walker Process claim preempted by federal patent law. See In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 543 (E.D.N.Y. 2005). The court referenced the Supreme Court’s interpretation of “what it means for a claim to ‘arise under’ patent law,” id. (quoting Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 809–11 (1988)), and concluded that the claims arose under patent law since they required a showing of misconduct before the PTO. Id. This argument fails for the same reason the Cipro Cases court’s argument fails, as discussed below.

179. Cf. Gunn v. Minton, 133 S. Ct. 1059, 1062 (2013) (stating that “[t]he question presented is whether a state law claim alleging legal malpractice in the handling of a patent case must be brought in federal court[,]” and concluding that the state law malpractice claim did not arise under federal patent law for purposes of § 1338(a)); id. at 1068.
182. Cf. Hunter Douglas, 153 F.3d at 1329–30 (concluding that a state law claim whose outcome turned on the validity and enforceability of a patent raised issues of federal patent law that were sufficiently “substantial” to confer federal jurisdiction under 28 U.S.C. § 1338(a)).
183. Cf. id. at 1334 (determining the possibility of field preemption of state unfair competition claims by federal patent law, and finding that precedent showed “the substantial difference between the two fields” and demonstrated “that the regulation of business affairs is traditionally a matter for state regulation”).
competent to decide patent law issues, though the state court may not invalidate the issued patent.\(^{184}\)

Perhaps cementing the argument that state courts have jurisdiction to hear antitrust claims that involve issues of patent law, the Supreme Court’s February 2013 opinion in *Gunn v. Minton* held that 28 U.S.C. § 1338(a) “does not deprive the state courts of subject matter jurisdiction” in cases where the court must answer a question of federal patent law to resolve the state claim, but “their answer will have no broader effects.”\(^{185}\) The Court adopted the *Grable* test for determining when claims “arise under” federal patent law and must be brought in federal court: “federal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress.”\(^{186}\) The Court focused its inquiry on the third factor and concluded that, though resolution of a patent issue in assessing a state claim may matter to the specific parties involved, “something more, demonstrating that the question is significant to the federal system as a whole, is needed” to preclude state jurisdiction.\(^{187}\) In light of this decision, state courts have wide authority to hear state claims that depend on resolution of a patent issue—even a “substantial” issue like whether plaintiff Minton’s infringement claim would have prevailed\(^{188}\)—where such resolution lacks importance to the federal system as a whole.

Beyond the question of jurisdiction, further considerations could have informed the California Court of Appeal’s field preemption determination, and may inform state antitrust challenges to pay-for-delay settlements generally. First, the Supreme Court’s recent decision in *Arizona v. United States* implies that the doctrine of field preemption may be inapposite where the potentially conflicting state and federal law regulate

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186. *Id.* at 1065.

187. *Id.* at 1068.

188. See *id.*
different fields. The Court found that “the Federal Government has occupied the field of alien registration” and held that “[w]here Congress occupies an entire field, as it has in the field of alien registration, even complementary state regulation is impermissible. Field preemption reflects a congressional decision to foreclose any state regulation in the area, even if it is parallel to federal standards.” In the case of pay-for-delay, the area of state regulation is antitrust, a field which Congress does not occupy exclusively. In California v. ARC America Corp., the Supreme Court held that, in the antitrust field, state law will not be preempted by concurrent federal antitrust law. Further, the Supreme Court has evaluated the extent of similarity between the Cartwright Act and the Sherman Act, and concluded that the Cartwright Act was not, in fact, modeled after the Sherman Act, nor after common law, so Sherman Act cases are not dispositive in interpreting the Cartwright Act. This holding is echoed in the reasoning of another court filing for the impending Supreme Court of California hearing, which submits that defendants depended on federal decisions that interpreted the Sherman Act, but that they failed to explain how limitations on the Sherman Act would preempt the Cartwright Act. This illustrates the key point that, though federal antitrust and patent laws are formally considered to co-exist, state antitrust laws predated their federal counterparts, and may create a

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190. Id. The Court further defined the premise of field preemption as the idea “that States may not enter, in any respect, an area the Federal Government has reserved for itself.” Id.

191. Specifically, the Supreme Court held that California’s indirect purchaser remedy is not preempted by the Sherman Act, and that “Congress intended the federal antitrust laws to supplement, not displace, state antitrust remedies.” California v. ARC Am. Corp., 490 U.S. 93, 102 (1989).

192. See ABA SECTION OF ANTITRUST LAW, supra note 70, at 6-4. California law has notable differences from Sherman Act cases in the analytical rules it applies; for example, the state does recognize a set of practices as per se restraints on trade, but its rule of reason differs from federal law in that it sparsely applies the “quick look” approach. See id. at 6-9 to 6-10. Further, case law has shown that certain provisions of the Cartwright Act may stand where they prohibit something that is permitted by the Sherman Act, and the Cartwright Act is not preempted by the Sherman Act in such cases. See id. at 6-32 (citing Turnbull & Turnbull v. ARA Transp., 219 Cal. App. 3d 811 (1990)).

more palpable conflict with federal patent law. This consideration is applicable in determining the extent to which state antitrust laws conflict with federal patent law discussed in Part II.A.3, infra, as they may not be substantively the same as federal antitrust law.

Next, should a state court adopt the California Court of Appeal's approach by adopting the "scope of the patent" test and following its approach to "preemption," and if a court could apply that approach to the question of federal jurisdiction, a plaintiff's claim would always be preempted. In the Cipro Cases, the court concluded that plaintiffs' sham litigation claim required a determination of a substantial question of patent law and therefore could not be adjudicated in state court. In its rejection of plaintiffs' argument that their claims were premised on the defendant's conduct in the settlement agreement and not in the procurement of the patent itself, the court's reasoning is somewhat circular. It first determined

194. See ABA SECTION OF ANTITRUST LAW, supra note 70, at 6-1 ("The California antitrust laws provide a potent alternative to their federal counterparts. They often have been accorded broader interpretation by the courts . . . .").

195. As mentioned in Part I.B.1, supra, the categories of preemption often blur and overlap. In addressing the government's argument of field preemption in Hines v. Davidowitz, Justice Black wrote: Little aid can be derived from the vague and illusory but often repeated formula that Congress "by occupying the field" has excluded from it all state legislation. Every Act of Congress occupies some field, but we must know the boundaries of that field before we can say that it has precluded a state from the exercise of any power reserved to it by the Constitution. To discover the boundaries we look to the federal statute itself, read in the light of its constitutional setting and its legislative history.

Hines v. Davidowitz, 312 U.S. 52, 78–79 (1941). The analysis then turned to (traditional) conflict preemption. See id. at 79–81. The Court concluded that "compliance with the state law does not preclude or even interfere with compliance with the act of Congress." Id. at 81.


197. Note that even under the district court's approach in In re Ciprofloxacin Hydrochloride Antitrust Litigation, this argument may still have teeth, as the allegations focus on conduct in settling a patent dispute, not conduct in procurement of the patent. In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514 (E.D.N.Y. 2005). Under Minton, this claim should not be precluded from state court; even if the claim required the court to pass on the question of patent validity, like in Minton, a state court's resolution of a claim involving such a question would not affect the validity of the patent. See Gunn v. Minton, 133 S. Ct. 1059, 1068 (2013).
that the “scope of the patent test” is the correct test to apply and that the defendants could only be subject to liability if plaintiffs could prove sham litigation, and then concluded that the plaintiffs were foreclosed from proving sham litigation because such inquiry would require answering substantial questions of patent law that cannot be decided in state courts.\textsuperscript{198} Thus, the court has used an incorrect interpretation of § 1338(a) to prevent a state claim from prevailing under its own test for legality of pay-for-delay settlements.

Further, the California Court of Appeal did not address the presumption against preemption applied by the Supreme Court and adopted by California.\textsuperscript{199} Though the Court’s application of the doctrine of preemption has not been incredibly consistent in recent years, and it is unclear whether the Court considers Rice good law, the Court continues to apply the presumption in some cases.\textsuperscript{200} For example, in a 2008 decision, the majority opinion favorably reiterated Rice, stating that “[w]hen addressing questions of express or implied pre-emption, we begin our analysis with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”\textsuperscript{201} The basis of the presumption against preemption in preserving “historic police powers” of states is consistent with the above discussion of the reach of state antitrust laws.

Thus, a field preemption approach to state antitrust law challenges to pay-for-delay settlements should take account of the jurisdiction question as a threshold issue (when pay-for-delay settlements are challenged in state court), though Minton strongly suggests that state court jurisdiction is permitted. Arizona suggests field preemption may be irrelevant when the state law is not acting collaterally to federal law, while California v. ARC America Corp. teaches that the Sherman Act does not preempt the field of antitrust law. In further consideration of the presumption against preemption and state police powers, it is not clear that Congress intended the federal

\textsuperscript{198} Cf. Cipro Cases, 200 Cal. App. 4th at 473–74 (discussing how the plaintiff’s claim under state law depended on proving sham litigation, but the sham litigation claim was preempted).

\textsuperscript{199} See Petition for Review, supra note 148, at 22.

\textsuperscript{200} See Young, supra note 12, at 309; see also Nelson, supra note 100, at 262 (discussing how the Supreme Court has not treated the categories of preemption separately).

patent law to so dominate the field that there is neither room
for the states to decide cases that involve the patent law, nor
room for states to supplement it.202

3. Conflict Preemption

Conflict preemption inquiry requires a determination of
whether the relevant state law “stands as an obstacle to the
accomplishment and execution of the full purposes and
objectives of Congress,”203 and “[t]he purpose of Congress is the
ultimate touchstone” in determining preemption.204 In
determining whether California law is preempted by federal
patent law, it is first necessary to identify the potential area of
conflict, beginning with the language of the statutes
themselves.

The primary purpose of the Patent Act, generally stated, is
to provide inventors with an incentive to innovate and an
incentive to invest in innovation, by granting a temporary
monopoly on the specific invention of the patentee.205 The
Patent Act is founded upon the “IP Clause” of the Constitution,
which gives Congress the power “[t]o promote the Progress of
Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.”206
With this basic premise in place, the question of conflict
preemption turns on whether laws that challenge pay-for-delay
settlements conflict with Congress’s objectives for the patent
laws.207

The Supreme Court has provided guidance on the question,
though not in the context of pay-for-delay settlements. As
illustrated in Part I.B.2, supra, the Supreme Court’s patent
(and copyright) preemption cases all involved state laws that
attempted to provide protection for Intellectual Property (IP).208

202. See supra notes 182-84 and accompanying text.
205. See Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974); see
also R. CARL MOY, MOY’S WALKER ON PATENTS, at 1-79 (4th ed. 2012)
suggesting that the “increased incentive to invent that the expectation of
patenting creates” is the primary benefit of the patent system).
207. See Kewanee Oil, 416 U.S. at 479 (“The only limitation on the States is
that in regulating the area of patents and copyrights they do not conflict with
the operation of the laws in this area passed by Congress . . . .”)
208. See Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 145
In the cases where the court found preemption, the state law was protecting conduct that created monopolies in manufacture, use, or sale of IP—conduct that is regulated by the Patent Act but which, in these cases, failed to meet the requirements of the Patent Act. Where the Court found state laws could stand, the laws were offering protection for IP that was alternative or collateral to federal law.\(^{209}\) In contrast, antitrust laws protect competition and consumer welfare by regulating monopoly power, with the exception of legal monopolies that are provided by IP law.\(^{210}\) Though the Supreme Court's preemption cases provide an imperfect analogy, the Court's reasoning should extend to substantive conflict with federal patent law generally.\(^{211}\)

In *Kewanee Oil*, the Court identified three purposes of the patent law that must be considered in determining whether the state law "clashes with the objectives of the federal patent laws":\(^{212}\) creating an incentive for inventors, ensuring that the invention is disclosed to the public, and ensuring that inventions that enter the public domain cannot leave the public domain.\(^{213}\) The Court in *Bonito Boats* refined this test, determining that a state law is preempted if it "substantially interferes with" or "substantially impedes" one of the *Kewanee Oil* objectives of federal patent law.\(^{214}\) Under this test, the *Cipro* Cases' plaintiffs' claims under the Cartwright Act may be

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211. See Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1333 (Fed. Cir. 1998) (reasoning that, though the Supreme Court IP preemption jurisprudence was not perfectly analogous, "it sets forth the essential criteria for analyzing preemption"); cf. Cotter & Dmitrieva, supra note 103, at 181 n.106 (discussing how the broader principle from *Bonito Boats* should be "that state laws that substantially interfere with the federal patent or copyright scheme are preempted").


213. See *id.* at 480–81.

214. *Bonito Boats*, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 156–57 (1989). In this case the Court focused on the objective of ensuring that inventions unworthy of federal patent protection remain in the public domain for all to use. See *id.* at 156. For analysis of a "substantial interference" standard applied in the context of preemption of state right of publicity law by federal copyright law, see Cotter & Dmitrieva, supra note 103, at 181 n.106, 208–18.
preempted by the federal patent law if the relevant provisions of the Cartwright Act stand as an obstacle to one of the three patent law objectives.

The second two purposes of the Kewanee Oil test are clearer questions. As CAFC stated in Hunter Douglas, “[Patent law] promotes disclosure of inventions to stimulate further innovation and to permit the public to practice the invention once the patent expires.”215 This policy objective is aligned with the purpose of the Hatch-Waxman Act to expedite the entry of generic versions of already-disclosed patented drugs to market upon expiration of the patent.216 A state antitrust challenge to a patent infringement settlement of a patented (and therefore disclosed) drug could only promote this objective by attempting to remedy the harms of delayed availability of generic drugs to the market. The contested litigation itself, in which a generic company has created a bioequivalent version of the patented drug, suggests that the invention has been disclosed and has sufficiently enabled one skilled in the art to recreate the patented drug. Likewise, state law challenges to pay-for-delay settlements create no conceivable threat of removing a patented and publicly disclosed drug from the public domain—these challenges would have the opposite purpose: preventing the extension of the patent monopoly.

More complex is the question whether state antitrust challenges to patent litigation settlements will affect the patent law’s ability to incentivize pharmaceutical innovation. This inquiry could be broken down into two issues: whether patent protection really incentivizes invention of new drugs, and whether challenges to patent litigation settlements have any effect on the patent laws’ ability to incentivize invention of new drugs.

Some scholars of patent reform argue that there is no proof that patents incentivize invention.217 However, the pharmaceutical industry has been considered to be an

216. See supra Part I.A.1.
exceptional case.\footnote{218}{See F.M. Scherer, The Political Economy of Patent Reform in the United States, 7 J. ON TELECOMM. & HIGH TECH. L. 167, 184 (2009) ("[P]atents are of special importance to pharmaceutical (and related biopharmaceutical) companies, in part because they provide strong protection from competitive imitation on products that often have relatively inelastic demands.").}\footnote{219}{See id. at 27.} Pharmaceutical research is hugely expensive and economically risky,\footnote{220}{See CONGRESSIONAL BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 2 (2006).} requiring immense investment, both public and private.\footnote{221}{See id. at 27.} Pharmaceutical innovation is largely dependent on expected revenue, but the extent to which the patent incentive causes innovation is uncertain.\footnote{222}{See CONGRESSIONAL BUDGET OFFICE, PHARMACEUTICAL R&D AND THE EVOLVING MARKET FOR PRESCRIPTION DRUGS 1–2 (2009). The introduction of new drugs has declined since 2000, id. at 2, while pay-for-delay settlements have sharply increased in recent years. See supra notes 47–48 and accompanying text. Though only a correlation, it appears the availability or supposed legality of pay-for-delay settlements is not incentivizing pharmaceutical innovation.} On one hand, without the incentives of the patent system, drug development may still take place, since much drug development research is publicly subsidized because it is in the public’s interest.\footnote{223}{See generally Boldrin & Levine, supra note 217, at 4–5 (discussing the role of patent law in the pharmaceutical industry).} Without patent law as an incentive, new drugs may still be developed, but offered at a lower price to consumers since the drug would not have the exclusionary protection of a patent, yet could still be reverse engineered by competitors.\footnote{224}{See id.} On the other hand, studies have shown that patents do, in fact, play an important role in pharmaceutical innovation.\footnote{225}{See supra Part I.A.4.} Additionally, the structure of pay-for-delay settlements reveals the importance to drug companies of patent protection; the payment avoids the risk of losing patent protection through invalidation.\footnote{226}{See id. at 27.} Thus, it is uncertain whether drug development would be chilled in the absence of the patent laws.

Even assuming that patents incentivize new drug development, it is unlikely that allowing challenges to pay-for-delay settlements would affect the patent laws’ ability to
incentivize new drug development. Some courts have acknowledged the possibility that “exposing patent activity to wider antitrust scrutiny would weaken the incentives underlying the patent system, thereby depriving consumers of beneficial products.”

Commentators have also expressed concern that antitrust liability in the context of pay-for-delay may stifle innovation. However, whatever effect potential antitrust liability for anticompetitive settlements has on incentives to create new drugs, this effect should be viewed on balance with the harmful effects of the settlements on competition and innovation.

Allowing state antitrust challenges to pay-for-delay settlements potentially bears little connection to whether a drug company will invent. As urged in a Reply Brief on the Merits in the Cipro Cases, the belief that pay-for-delay settlements will not be challenged will stifle real innovation by “encouraging drug companies to place more reliance on the least innovative patents.” In Dow Chemical, the CAFC, applied the Kewanee Oil analysis to a state unfair competition claim of contract interference by a patent holder. The CAFC found that the state claims in no way interfered with the objectives of the patent system identified in Kewanee Oil.

[226] Data Gen. Corp. v. Grumman Sys. Support Corp., 36 F.3d 1147, 1186 (1st Cir. 1994); see also C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998) (“[A]ntitrust jurisprudence has well understood that the enforcement of the antitrust laws is self-defeating if it chills or stifles innovation.”).

[227] See Sheila Kadura, Is an Absolute Ban on Reverse Payments the Appropriate Way to Prevent Anticompetitive Agreements Between Branded- and Generic-Pharmaceutical Companies?, 86 Tex. L. Rev. 647, 664–65 (2008) (“Clearly, generic products save consumers money, but it is important to remember that such products cannot exist unless a branded-pharmaceutical product is first developed and shown to be safe and effective, which is an expensive endeavor. The decreased certainty that accompanies increased litigation may be particularly troublesome in the context of pharmaceutical innovation because the pharmaceutical industry relies heavily on a strong patent system to attract investors due to the high cost and risk associated with drug development.” (citations omitted)).


[229] Reply Brief on the Merits, supra note 184, at 49.

declaring, “[I]t seems most improbable that an inventor would choose to forfeit the benefits of patent protection because of fear of the risk of being found tortiously liable based upon attempting to enforce a patent obtained by inequitable conduct.”231 This conveys a sentiment that innovation is unaffected by concerns that any resulting invention may subsequently become the subject of patent litigation which results in a settlement that could potentially raise antitrust questions—such a connection seems too attenuated. Even if innovation were so affected, antitrust liability should be balanced by the potential of pay-for-delay settlements to stifle innovation. The _Kewanee Oil_ test thus appears to weigh on the side of no preemption.

The line of CAFC cases described in Part I.B.2, _supra_, provides a better analogy to state antitrust challenges to pay-for-delay settlements than the Supreme Court preemption cases—the CAFC cases involve state claims that challenge anticompetitive conduct of patent holders,232 as opposed to challenges to state laws that created patent-like (or copyright-like, in the case of _Goldstein_) protection for unpatentable products. In _Hunter Douglas_, the CAFC created a rule for determining whether a state commercial disparagement claim (which, like an antitrust claim, involves the assertion of conduct on the part of a patentee that restricts competition) is preempted by federal patent law:

To determine whether these state law torts are in conflict with federal patent law and accordingly preempted, we assess a defendant’s allegedly tortious conduct. If a plaintiff bases its tort action on conduct that is protected or governed by federal patent law, then the plaintiff may not invoke the state law remedy, which must be preempted for conflict with federal patent law. Conversely, if the conduct is not so protected or governed, then the remedy is not preempted. This approach, which considers whether a state law tort, “as-applied,” conflicts with federal patent law, is consistent with that employed by the Supreme Court in cases involving preemption of state unfair competition law.233

To summarize, a state law claim in this context will be preempted if the challenged conduct is “protected or governed

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231. _Id._ at 1475; _see also_ Reply Brief on the Merits, _supra_ note 184, at 49–50 (quoting Dow Chemical Co. v. Exxon Corp., 139 F.3d 1470, 1475 (Fed. Cir. 1998)).

232. _See supra_ notes 138–44 and accompanying text.

by federal patent law.” 234 Here, the CAFC found that patent law immunizes a patent holder from “imposition of liability for conduct before the PTO unless the plaintiff can show that the patent-holder’s conduct amounted to fraud or rendered the patent application process a sham” and that patent law also “bars the imposition of liability for publicizing a patent in the marketplace unless the plaintiff can show that the patent-holder acted in bad faith.” 235 Unfortunately, in the context of pay-for-delay, this rule serves to return analysis to the debate of whether a reverse payment settlement is “protected or governed by federal patent law.” This essentially amounts to the “scope of the patent” test: whether paying a competitor to delay entry to the market is conduct falling within the exclusionary scope of the patent. 236 On the other hand, Dow Chemical and Hunter Douglas suggest that an allegation of bad faith will at least save a state claim from automatic preemption, and proceed to a determination of the merits of the claim. 237 This element of bad faith may not be relevant to state pay-for-delay challenges. First, early pay-for-delay-challenge defendants failed to convince courts that their settlement agreements should be immune to antitrust scrutiny under the Noerr-Pennington Doctrine. 238 Since the doctrine doesn’t apply,

234. Id.
235. Id. at 1336. The CAFC concluded that when a plaintiff’s claims depend on a patent holder’s “conduct in obtaining and publicizing its patent, if the plaintiff were to fail to allege that the defendant patent-holder was guilty of fraudulent conduct before the PTO or bad faith in the publication of a patent, then the complaint” would be preempted. Id. Similarly, in Zenith Electronics, the CAFC held that “bad faith is a prerequisite to [plaintiff’s] state-law tortious interference claim; without it, the claim is preempted by patent law.” Zenith Electronics Corp. v. Exzec, Inc., 182 F.3d 1340, 1355 (Fed. Cir. 1999).
236. See supra Part I.A.4.
237. See Dow Chemical Co. v. Exxon Corp., 139 F.3d 1470, 1477 (Fed. Cir. 1998) (“Bad faith . . . is only one of three elements that must be established to make out the tort.”); Hunter Douglas, 153 F.3d at 1336; In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 544 (E.D.N.Y. 2005) (“[F]ederal patent law preempts any state antitrust cause of action premised on Bayer’s alleged bad faith conduct before the PTO because Count V does not allege any conduct other than conduct before the PTO. In other words, the state law remedies invoked by indirect plaintiffs are directed to allegedly tortious conduct before the PTO, not tortious conduct in the marketplace.”).
238. See 1 HOVENKAMP ET AL., supra note 6, at 15-31. The Noerr-Pennington Doctrine shields conduct that can be regarded as petitioning the government (and thereby protected by the First Amendment) from antitrust immunity. LESLIE, supra note 5, at 111–13. The doctrine arguably does not
the allegation of bad faith, a requisite of the sham petitioning exception to Noerr immunity, is unnecessary. Further, whatever the CAFC’s reason for requiring an allegation of bad faith to avoid federal preemption in state business tort and commercial disparagement claims, state courts are not obliged to follow suit.

The above analysis provides a basic framework to determine whether state antitrust claims are preempted by federal patent law in pay-for-delay settlements. State courts facing such preemption claims should first consider whether state antitrust challenges to pay-for-delay settlements substantially interfere with or impede Congress’s objective to incentivize innovation in the pharmaceutical industry. Next, state courts should consider whether the challenged conduct is protected or governed by federal patent law—where the “conduct” is a reverse payment settlement, the preemption question would pose merely a threshold inquiry to a court’s consideration of the legality of reverse payment settlements. Dow Chemical and Hunter Douglas teach that a plaintiff must allege bad faith to avoid preemption of a claim “protected or governed” by federal patent law, though this requirement may not be particularly relevant to state antitrust challenges to pay-for-delay settlements. Thus, it appears state antitrust claims are probably not preempted by federal patent law.

B. . . . NOR SHOULD THEY BE

Briefly, there are several reasons state antitrust challenges to pay-for-delay settlements should not be preempted by federal patent law. First, state antitrust laws are the only vehicle for indirect purchaser damage awards. State antitrust claims that approximate a given federal antitrust claim are brought in federal cases to provide an avenue for relief for indirect purchasers. California v. ARC America Corp. suggests that state indirect-purchaser remedies could provide relief only upon success of state antitrust claims, but that they may not

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239. See LESLIE, supra note 5, at 112.
240. The analysis in Part II.A, supra, suggests that it probably would not.
241. See supra notes 70–72 and accompanying text.
242. See supra note 70 and accompanying text.
provide relief under federal antitrust law. If state antitrust claims are preempted by federal patent law in a given case, monetary damages for indirect purchasers are foreclosed.

Perhaps this issue has been overlooked because courts may treat state antitrust claims as counterparts of equivalent scope to federal antitrust claims. However, state and federal antitrust laws are not coextensive, and state antitrust laws may be given a more robust interpretation than a federal counterpart in state court. It follows that state court challenges may be an attractive option for pay-for-delay plaintiffs if state laws are potentially more likely to result in antitrust liability. The presumption against preemption further supports allowing plaintiffs to use the historic police powers in areas like antitrust to challenge anticompetitive conduct in state courts.

Finally, at least under the framework announced in Hunter Douglas, whether state claims can survive federal preemption depends on whether the challenged conduct is “protected or governed” by federal patent law, which virtually mirrors the “scope of the patent” test for legality of pay-for-delay settlements. Apart from the circularity of a standard that would preempt a state claim based on the same legal question the claim is meant to challenge, courts and scholars have


Under federal law, no indirect purchaser is entitled to sue for damages for a Sherman Act violation, and there is no claim here that state law could provide a remedy for the federal violation that federal law forbids. Had these cases gone to trial and a Sherman Act violation been proved, only direct purchasers would have been entitled to damages for that violation, and there is no suggestion by the parties that the same rule should not apply to distributing that part of the fund that was meant to settle the Sherman Act claims. The issue before us is whether this rule limiting recoveries under the Sherman Act also prevents indirect purchasers from recovering damages flowing from violations of state law, despite express state statutory provisions giving such purchasers a damages cause of action.

Id.

244. See supra note 192 and accompanying text.


246. See supra notes 199–201 and accompanying text.

247. See supra note 236 and accompanying text.
renounced the “scope of the patent” test.248 For example, Abbott and Michel argue that the “right to purchase exclusion that could not have been obtained through the strength of the patent at the time of the settlement agreement” is not one of the rights protected by the patent system.249 Critically, the authors argue that

the scope of the patent grant does not include the right to pay potential competitors to stay off the market because the source of the exclusion is the payment, not the exclusionary power of the patent. Because the payment falls outside the scope of the patent grant, antitrust law may judge its legality.250

These rationales further compel a conclusion that federal patent law should not preempt state antitrust law in pay-for-delay settlements.

III. CONCLUSION

Pay-for-delay settlements have posed a legal conundrum since the passage of the Hatch-Waxman Act. There currently exists a stark division among the federal circuit courts as to the legality of these settlements, and the legal field is awaiting a ruling from the Supreme Court to provide guidance. Of the various legal theories applied by the courts thus far, all are influenced by the tension between patent law and antitrust law. This tension is illustrated by the prospect of preemption of state antitrust law by federal patent law. Presently, only one pay-for-delay settlement has been challenged in state court, and the Supreme Court of California is likely to address the issue of preemption when it eventually decides that case. Based on the guidance that the Supreme Court has provided on the preemptive effects of federal patent law and on the doctrine of preemption in general, state antitrust claims should not be preempted by federal patent law. Concluding that they are preempted would not be compatible with Supreme Court precedent, nor would it be good policy.

248. See, e.g., In re K-Dur Antitrust Litig., 686 F.3d 197, 214 (3d Cir. 2012) (“In our view, that test improperly restricts the application of antitrust law and is contrary to the policies underlying the Hatch–Waxman Act and a long line of Supreme Court precedent on patent litigation and competition.”).
249. Abbott & Michel, supra note 5, at 405.
250. Id. at 408.