

2013

The Preemptive Power of Federal Patent Law: A Framework for Analyzing State Antitrust Challenges to Pay-for-Delay Settlements

Caroline Marsili

Follow this and additional works at: <https://scholarship.law.umn.edu/mjlst>

Recommended Citation

Caroline Marsili, *The Preemptive Power of Federal Patent Law: A Framework for Analyzing State Antitrust Challenges to Pay-for-Delay Settlements*, 14 MINN. J.L. SCI. & TECH. 849 (2013).

Available at: <https://scholarship.law.umn.edu/mjlst/vol14/iss2/9>

Note

The Preemptive Power of Federal Patent Law: A Framework for Analyzing State Antitrust Challenges to Pay-for-Delay Settlements

Caroline Marsili*

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

© 2013 Caroline Marsili

* J.D. Candidate (2014), University of Minnesota Law School. The author would like to thank Professor Thomas F. Cotter for inspiring the topic of this note and for providing invaluable guidance throughout the note-writing process, Emily Puchalski for her excellent feedback on every draft, and the editors and staff of *MJLST* for their hard work and dedication. The author also thanks friends and family for their patience and support.

1. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984); Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281, 286 (2011).

2. See, e.g., *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 204 (3d Cir. 2012) (“[I]n the years after the passage of Hatch-Waxman, some of the patent infringement suits occurring under the Hatch-Waxman framework were resolved through settlement agreements in which the patent holder paid the would-be generic manufacturer to drop its patent challenge and refrain from producing a generic drug for a specified period. These agreements are known as ‘reverse payment agreements’ or ‘exclusion agreements.’”); 12 PHILLIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION* 337 (3d ed. 2006); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 37 (2009); Thomas F. Cotter, *Refining the “Presumptive Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1789, 1797 (2003).

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.⁴ Thus, pay-for-delay settlements illustrate a tension between patent law and antitrust law.⁵ 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.⁶ In December 2012, the Supreme Court granted a writ of certiorari to review *Federal Trade Commission v. Watson Pharmaceuticals, Inc.*,⁷ an Eleventh Circuit case favoring the pharmaceutical companies,⁸ 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).

5. For a detailed analysis of the tension between antitrust law and patent law in the context of pay-for-delay settlements, see, for example, 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., INTELLECTUAL PROPERTY ANTITRUST 387, 393 (2006). For a summary of the tension between antitrust law and intellectual property law in general, see CHRISTOPHER R. LESLIE, ANTITRUST LAW AND INTELLECTUAL PROPERTY RIGHTS: CASES AND MATERIALS 39–86 (2011).

6. *In re K-Dur*, 686 F.3d at 209–14; 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW, at 15-30 to 15-49 (2d ed. Supp. 2012); Michael A. Carrier, *Why the “Scope of the Patent” Test Cannot Solve the Drug Patent Settlement Problem*, 16 STAN. TECH. L. REV. 1, 1–5 (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.

8. *Id.* at 1315. The Supreme Court chose to hear *Watson* in lieu of another case with a certiorari petition, *In re K-Dur*, 686 F.3d at 197, where the Third Circuit found pay-for-delay settlements “presumptively anticompetitive.” See Kevin E. Noonan, *FTC Asks Supreme Court to Play Favorites in Reverse Payment Settlement Agreement Cases*, PATENTDOCS.ORG (Oct. 16, 2012), <http://www.patentdocs.org/2012/10/ftc-asks-supreme-court-to-play-favorites-in-reverse-payment-settlement-agreement-cases.html>; Kevin E. Noonan, *Supreme Court to Review Reverse Payment Settlement Agreements*, PATENTDOCS.ORG (Dec. 9, 2012), <http://www.patentdocs.org/2012/12/supreme-court-to-review-reverse-payment-settlement-agreements.html>.

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.⁹ Challenges to pay-for-delay settlements have thus far been adjudicated almost exclusively in federal court,¹⁰ 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.¹¹ 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.¹²

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*.

11. *In re Cipro Cases I & II*, 200 Cal. App. 4th 442 (2011), *rev. granted*, 269 P.3d 653 (Cal. 2012); Bernice Yeung, *State Court to Examine “Pay-for-Delay” Deals by Drugmakers*, CAL. WATCH (Mar. 2, 2012), <http://california-watch.org/dailyreport/state-court-examine-pay-delay-deals-drugmakers-15133>.

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.¹³ The settlement agreements have been challenged for violating antitrust laws, with disparate results among federal circuit courts.¹⁴ The status of these settlements is contested and uncertain.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.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 1984.¹⁷ 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-

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.

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

15. See 1 HOVENKAMP ET AL., *supra* note 6, at 15-48 to 15-49.

16. See MERGES & DUFFY, *supra* note 14, at 1329.

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.¹⁸ First, the Act created the ANDA.¹⁹ The ANDA process is a means for expediting FDA approval of a generic drug that is the bioequivalent²⁰ of a patented brand-name drug.²¹ When a generic company files an ANDA, it must certify

[e]ither 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).²²

The Act also amended the Patent Act of 1980 to extend the patent term for new pharmaceuticals.²³ The extension of the

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 U.S.C. § 355(j)(8)(B) (2006).

21. Dorsney, *supra* note 19, at xxi.

22. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 191 (2d Cir. 2006) (citing 21 U.S.C. § 355(j)(2)(A)(vii) (2006)). See, e.g., Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491, 505–06 (2002); Lennon et al., *supra* note 17, at 12. The “paragraph IV certification constitutes a technical act of patent infringement,” *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 204 (3d Cir. 2012) (citing 35 U.S.C. § 271(e)(2)(A) (2006)), in which the ANDA applicant asserts that the existing patent is either invalid or not infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2006).

23. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, 98 Stat. 1585, 1598 (1984); see also Lennon et al., *supra* note 17, at 5 (“The Hatch-Waxman Act specifies that the term of a

patent term benefits patentee companies that seek to file a New Drug Application (NDA);²⁴ these filers have drugs which may be delayed from entering the market due to the FDA review process.²⁵ 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.²⁶ 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.”²⁷

Perhaps most importantly, the Act created a framework for resolving patent disputes in the pharmaceutical industry.²⁸ This framework consists of several critical innovations. First, the Act created a “listing” requirement for the pioneering drug companies.²⁹ 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

patent 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)(A) except as provided in subparagraph (B), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the ‘approved product’. (b) 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—(1) in the case of a patent which claims a product, be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred

98 Stat. at 1598.

24. Lennon et al., *supra* note 17, at 5.

25. See Blair & Cotter, *supra* note 22, at 502–04.

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* note 2, at 339 n.66 (citing 21 U.S.C. § 355(b)(1) (2006)).

31. 21 U.S.C. § 355(j)(5)(B)(iii); 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)(iii); 1 HOVENKAMP ET AL., *supra* note 6, at 15–27 (citing 21 U.S.C. § 355(j)(5)(B)(iii) (2006)).

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 decision.” (citing 21 U.S.C. § 355(j)(5)(B)(iii)(I) (2006))).

34. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, 98 Stat. 1585, 1589 (1984); *see* 12 AREEDA & 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 15–28 (citing 21 U.S.C. § 355(j)(5)(B)(iv) (2006)).

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.³⁷ The generic company may accept a settlement payment and in return agree to delay entry into the market for some time.³⁸ This delays the generic company's 180-day exclusivity period and thereby keeps other generic companies from entering the market.³⁹

To illustrate the incentives for settlement, consider *In re Cardizem CD Antitrust Litigation*,⁴⁰ 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.⁴¹ 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.⁴² 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.⁴³

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.⁴⁴

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.

40. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

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.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.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”⁴⁷ The FTC suggests that these settlements cost American consumers \$3.5 billion annually.⁴⁸

3. The IP/Antitrust Interface

Patent law and antitrust law can clash with regards to their underlying policy considerations.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.⁵⁰ Pay-for-delay settlements illustrate this tension, as they may produce anticompetitive effects that harm consumers.⁵¹ However, in those cases where patent settlements may produce anticompetitive effects, the settlements are susceptible to antitrust analysis.⁵²

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

45. 1 HOVENKAMP ET AL., *supra* note 6, at 15-30.

46. *Id.*

47. *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*, FED. TRADE COMMISSION (Jan. 17, 2013), <http://www.ftc.gov/opa/2013/01/mmarpt.shtm>.

48. *Id.*

49. See generally Mark A. Lemley, *A New Balance Between IP and Antitrust*, 13 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).

50. See Abbott & Michel, *supra* note 5, at 391-92. But see Lemley, *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. *Id.* at 9-17.

51. See *supra* notes 47-48 and accompanying text. It should be noted that settlements of patent disputes *in general* have the potential to produce procompetitive effects, through both benefit to consumers and judicial efficiency. See Abbott & Michel, *supra* note 5, at 392-93.

52. See MERGES & DUFFY, *supra* note 14, at 1330; *infra* Part I.A.4.

53. See, e.g., 1 PHILLIP E. AREEDA & HERBERT HOVENKAMP, 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.”⁵⁴ However, the authors note that the antitrust laws are specifically designed to protect competition, and not to address the detrimental outcomes that may result.⁵⁵ 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.⁵⁶

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.⁵⁷ These state laws may be preempted in situations where they allow something that federal law prohibits, or they prohibit something that federal law permits,⁵⁸ the latter being the more usual case.⁵⁹

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.”⁶⁰ 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.

57. *See* 1 AREEDA & HOVENKAMP, *supra* note 53, at 339; *cf.* *California v. ARC Am. Corp.*, 490 U.S. 93, 102 (1989) (“Congress intended the federal antitrust laws to supplement, not displace, state antitrust remedies.”).

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

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.

67. E.g., 35 U.S.C. § 154(a)(1) (2006).

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.

73. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907–08 (6th Cir. 2003).

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).

76. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1249 (11th Cir. 2003).

77. *Id.* at 1306.

78. *Id.*

The Eleventh Circuit later announced what became known as the “scope of the patent” test⁷⁹ 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

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*,⁹¹ concluding that "[t]he 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."⁹²

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*.⁹³ The court enunciated the test as follows:

[W]e 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.⁹⁴

The court reasoned that:

[T]he 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.⁹⁵

cases. The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent. But the law allows the settlement even of suits involving weak patents with the presumption that the patent is valid and that settlement is merely an extension of the valid patent monopoly. So long as the law encourages settlement, weak patent cases will likely be settled even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved.

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.

93. *In re K-Dur Antitrust Litig.*, 686 F.3d 196, 218 (3d Cir. 2012).

94. *Id.*

95. *Id.* at 217.

Finally, in *FTC v. Watson Pharmaceuticals, Inc.*,⁹⁶ 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.”⁹⁷ 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.⁹⁸ Preemption stands for the idea that, “under

96. *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir.), *cert. granted*, 133 S. Ct. 787 (2012).

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,

[p]atent 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).

98. *See* U.S. CONST. art. VI, cl. 2 (“[T]he Laws of the United States . . . shall be the Supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the . . . Laws of any State to the Contrary notwithstanding.”); Richard A. Epstein & Michael S. Greve, *Introduction: Preemption in Context*, in *FEDERAL PREEMPTION: STATES’ POWERS, NATIONAL INTERESTS* 1, 3 (Richard A. Epstein & Michael S. Greve eds., 2007).

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

99. William W. Buzbee, *Introduction*, in *PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION 1* (William W. Buzbee ed., 2008).

100. See, e.g., Ralph F. Hall & Michelle Mercer, *Rethinking Lohr: Does "SE" Mean Safe and Effective, Substantially Equivalent, or Both?*, 13 MINN. J. L. SCI. & TECH. 737, 755 (2012); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 226 (2000). Preemption may be divided into taxonomies different than the one given above. See Epstein & Greve, *supra* note 98, at 18; KENNETH STARR ET AL., *THE LAW OF PREEMPTION: A REPORT OF THE APPELLATE JUDGES CONFERENCE, AMERICAN BAR ASSOCIATION* 14–34 (1991).

101. See Nelson, *supra* note 100, at 227.

102. *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1332 (Fed. Cir. 1998) (“[F]ederal patent law plainly does not provide for explicit preemption . . .”); 1 HOVENKAMP ET AL., *supra* note 6, at 5-41.

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

106. *Rice v. Santa Fe Elevator*, 331 U.S. 218 (1947).

107. *Id.* at 230.

108. Nelson, *supra* note 100, at 261–62.

109. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). An alternative taxonomy of federal preemption comprises express preemption and implied preemption, wherein implied preemption includes jurisdictional, or field preemption, and obstacle preemption. See, e.g., John E. Mauk, Note, *The Slippery Slope of Secrecy: Why Patent Law Preempts Reverse-Engineering Clauses in Shrink-Wrap Licenses*, 43 WM. & MARY L. REV. 819, 830–31 (2001); *supra* note 104.

110. *Rice*, 331 U.S. 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.

113. See generally *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989); *Kewanee Oil Co. v. Bicorn Corp.*, 416 U.S. 470 (1974); *Compcor Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964).

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.¹¹⁴ 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.”¹¹⁵ 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.’”¹¹⁶

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.¹¹⁷ 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.¹¹⁸ In *Sears, Roebuck & Co. v. Stiffel Co.*,¹¹⁹ 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.¹²⁰ 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

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)).

117. See BARTON BEEBE ET AL., TRADEMARK, UNFAIR COMPETITION, AND BUSINESS TORTS 805–17 (2011).

118. *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 225 (1964); *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 234 (1964); see *infra* notes 119–123 and accompanying text.

119. *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964).

120. *Id.* at 232–33.

product.¹²¹ In *Compco Corp. v. Day-Brite Lighting, Inc.*,¹²² 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.¹²³

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.¹²⁴ 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.”¹²⁵

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.*,¹²⁶ the Court found that state trade secret laws are *not* preempted by federal patent law,¹²⁷ 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.¹²⁸ 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

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.”).

122. *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964).

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.

126. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974).

127. *Id.* at 491–92.

128. *Id.* at 479.

that ideas in the public domain remain there for the free use of the public.¹²⁹

The Court noted that trade secret law protects items which would not be proper subjects for consideration for patent protection,¹³⁰ that having two systems that both support innovation will not be in conflict,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.¹³²

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

In the late nineties, the CAFC decided a series of cases regarding federal patent preemption of state business tort and unfair competition claims.¹³⁸ In *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),¹³⁹ was not preempted by federal patent law.¹⁴⁰ The court reasoned that

129. *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) (interpreting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974)).

130. *Kewanee Oil*, 416 U.S. at 482.

131. *Id.* at 484.

132. *Id.* at 490.

133. *Bonito Boats, Inc. v. Thunder Draft Boats*, 489 U.S. 141 (1989).

134. *Id.* at 168.

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.").

136. *Id.* at 168.

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.").

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.*, 153 F.3d 1318 (Fed. Cir. 1998).

139. *Dow Chemical*, 139 F.3d at 1472.

140. *Id.* at 1479.

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).

144. *Zenith Electronics Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1351–55 (Fed. Cir. 1999).

145. *In re Cipro Cases I & II*, 200 Cal. App. 4th 442 (2011), *rev. granted*, 269 P.3d 653 (Cal. 2012).

146. Yeung, *supra* note 11.

settlement brought in a state court.¹⁴⁷ 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”¹⁴⁸ 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.¹⁴⁹ 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.¹⁵⁰ Bayer’s patent for the ciprofloxacin hydrochloride molecule, the active ingredient in Cipro,¹⁵¹ was confirmed to be valid upon reexamination¹⁵² and in further ANDA challenges subsequent to the initial settlements.¹⁵³ 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.

149. *In re Cipro Cases I & II*, 200 Cal. App. 4th 442 (2011), *rev. granted*, 269 P.3d 653 (Cal. 2012).

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.

153. *Cipro Cases*, 200 Cal. App. 4th at 451–52.

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

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.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."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."¹⁶⁸ Plaintiffs alleged that defendants violated

166. "[F]ederal patent law plainly does not provide for explicit preemption . . ." *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1332 (Fed. Cir. 1998).

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.

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.

170. See, e.g., *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 224 (2d Cir. 2006); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005), *aff'd in part*, 544 F.3d 1323 (Fed. Cir. 2008).

171. 35 U.S.C. § 154(a)(1) (2006).

172. 35 U.S.C. § 154(a)(2) (2006).

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.¹⁷⁴ 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.¹⁷⁵

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."¹⁷⁶ 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.¹⁷⁷ 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.¹⁷⁸ Questions of jurisdiction may

174. *Cf. Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974) ("The patent law does not explicitly endorse or forbid the operation of trade secret law.").

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)).

176. *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1332 (Fed. Cir. 1998).

177. *See supra* text accompanying note 159.

178. *See* Amicus Curiae Petition for Review at 8, *In re Cipro Cases I & II*, 200 Cal. App. 4th 442 (2011), *rev. granted*, 269 P.3d 653 (Cal. 2012) (No. S198616). The California Court of Appeal used 28 U.S.C. § 1338(a), a jurisdictional rule requiring exclusive federal subject matter jurisdiction for cases where "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law," and cited *Hunter Douglas* as supporting this assertion. *In re Cipro Cases I & II*, 200 Cal. App. 4th 442, 473 (2011). However, the CAFC's determination of the jurisdiction issue was

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.¹⁷⁹ The preemption inquiry asks whether Congress has the constitutional power to occupy a particular field entirely, such that a state law cannot stand.¹⁸⁰ Proper jurisdiction is a threshold matter to adjudicating state law claims that relate to issues of patent law that are brought in state court,¹⁸¹ 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.¹⁸² 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.¹⁸³ 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.

180. *See Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

181. *See* 28 U.S.C. § 1338(a) (2006) ("No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents . . .").

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 prevailed¹⁸⁸—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

184. The Supreme Court has said that "state courts can and regularly do adjudicate state claims raising patent law questions." Reply Brief on the Merits at 46, *In re Cipro Cases I & II*, 200 Cal. App. 4th 442 (2011), *rev. granted*, 269 P.3d 653 (Cal. 2012) (No. S198616). But state courts do not have jurisdiction if there is "a substantial question of federal patent law." *Id.* at 51.

185. *Gunn v. Minton*, 133 S. Ct. 1059, 1068 (2013).

186. *Id.* at 1065.

187. *Id.* at 1068.

188. *See id.*

different fields.¹⁸⁹ 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.”¹⁹⁰ 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.¹⁹¹ 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.¹⁹² 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.¹⁹³ 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

189. See *Arizona v. United States*, 132 S. Ct. 2492, 2502 (2012).

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)).

193. See Reply to Answers to Petition for Review at 13, *In re Cipro Cases I & II*, 200 Cal. App. 4th 442 (2011), *rev. granted*, 269 P.3d 653 (Cal. 2012) (No. S198616).

more palpable conflict with federal patent law.¹⁹⁴ This consideration is applicable in determining the extent to which state antitrust laws *conflict* with federal patent law,¹⁹⁵ 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.¹⁹⁶ 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,¹⁹⁷ 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.

196. See *In re Cipro* Cases I & II, 200 Cal. App. 4th 442, 473 (2011), *rev. granted*, 269 P.3d 653 (Cal. 2012).

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.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.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.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.’”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

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).

199. See Petition for Review, *supra* note 148, at 22.

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).

201. *Altria Group Inc. v. Good*, 555 U.S. 70, 77 (2008) (alteration in original) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

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.

203. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

204. *Retail Clerks Int’l Ass’n. v. Schermerhorn*, 375 U.S. 96, 103 (1963).

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).

206. U.S. CONST. art. I, § 8, cl. 8.

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

(1989); *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 237–38 (1964); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 225 (1964).

209. *Kewanee Oil*, 416 U.S. at 491–92; *Goldstein v. California*, 412 U.S. 546, 571 (1973).

210. *See supra* Part I.A.3.

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”).

212. *Kewanee Oil*, 416 U.S. at 480 (quoting *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 231 (1964)).

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

215. *Hunter Douglas*, 153 F.3d at 1333.

216. *See supra* Part I.A.1.

217. *See* Liza Vertinsky, *An Organizational Approach to the Design of Patent Law*, 13 MINN. J. L. SCI. & TECH. 211, 224–25 (2012); Michele Boldrin & David K. Levine, *The Case Against Patents* 1 (Fed. Reserve Bank of St. Louis Research Div., Working Paper No. 2012-035A, 2012), available at <http://research.stlouisfed.org/wp/2012/2012-035.pdf>.

exceptional case.²¹⁸ Pharmaceutical research is hugely expensive and economically risky,²¹⁹ requiring immense investment, both public and private.²²⁰ Pharmaceutical innovation is largely dependent on expected revenue, but the extent to which the patent incentive causes innovation is uncertain.²²¹ 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.²²² 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.²²³ On the other hand, studies have shown that patents do, in fact, play an important role in pharmaceutical innovation.²²⁴ 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.²²⁵ 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

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.”).

219. See CONGRESSIONAL BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 2 (2006).

220. See *id.* at 27.

221. 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.

222. See generally Boldrin & Levine, *supra* note 217, at 4–5 (discussing the role of patent law in the pharmaceutical industry).

223. See *id.*

224. See Scherer, *supra* note 218, at 173–76. In several surveys, respondents from the pharmaceutical industry found patent protection to be more important in curbing competition than respondents in other R&D fields. See *id.*

225. See *supra* Part I.A.4.

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.”²²⁶ Commentators have also expressed concern that antitrust liability in the context of pay-for-delay may stifle innovation.²²⁷ 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.²²⁸

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.”²²⁹ In *Dow Chemical*, the CAFC, applied the *Kewanee Oil* analysis to a state unfair competition claim of contract interference by a patent holder.²³⁰ 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)).

228. *See generally* Christopher R. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34 J. CORP. L. 1259, 1269–85 (2009) (discussing conduct of patent-holders that stifles innovation, and arguing that antitrust law fills gaps where patent law fails to curtail innovation-stifling conduct of patentees).

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

230. *See* *Dow Chemical Co. v. Exxon Corp.*, 139 F.3d 1470, 1475 (Fed. Cir. 1998).

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

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.

233. *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1335 (Fed. Cir. 1998).

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.²³⁹ 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.²⁴⁰ 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.²⁴¹ State antitrust claims that approximate a given federal antitrust claim are brought in federal cases to provide an avenue for relief for indirect purchasers.²⁴² *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

apply to pay-for-delay settlements because “the anticompetitive consequences of the exclusion payment flow from the agreement between the private parties, not from the result of the petition to the court or from any action by that court.” 1 HOVENKAMP ET AL., *supra* note 6, at 15-31.

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.²⁴³ 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,²⁴⁴ and state antitrust laws may be given a more robust interpretation than a federal counterpart in state court.²⁴⁵ 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.²⁴⁶

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.²⁴⁷ 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

243. *California v. ARC Am. Corp.*, 490 U.S. 93, 100 (1989). The Court opined:

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.

245. See, e.g., *O'Brien v. Leegin Creative Leather Prods., Inc.*, 294 Kan. 318, 341, 349 (2012) (declining to follow the Supreme Court's application of rule of reason analysis to a Sherman Act section 1 challenge to vertical price-fixing based on a conflicting interpretation of applicable state antitrust law).

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.