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Dodging Antitrust Bullets in Patent Settlement Agreements: Lessons Learned from the “Reverse Payment” Dilemma

A. Paul Heeringa*

I. INTRODUCTION

Settlement agreements in patent dispute cases have recently come under intense antitrust fire.¹ These settlements commonly occur between business competitors, often include arguably anticompetitive terms, and, as such, raise significant antitrust issues.² Today’s patent lawyers face a challenge determining if their settlement agreements can withstand antitrust scrutiny. The Sixth Circuit is seemingly at odds with the Second and Eleventh Circuits as to whether such agreements constitute antitrust violations and what legal analysis should be employed during review.³ Moreover, there does not appear to be any relief in sight since the Supreme Court has declined three opportun-

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² See Herbert Hovenkamp, et al., Anticompetitive Settlement of Intellectual Property Disputes, 87 MINN. L. REV. 1719, 1720 (2003). See also Herbert Hovenkamp, Anticompetitive Settlement of Intellectual Property Disputes, IP & ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW §7, 7-3 (2007 Supplement) (hereinafter, “Hovenkamp Treatise”). Professor Hovenkamp also notes that settlement agreements in IP cases “often take the form of unrestricted or restricted licenses, which may or may not be exclusive...” and are often “horizontal” (i.e., between actual or at least potential competitors) — both of which serve to “raise significant antitrust issues.” Hovenkamp Treatise at 7-3.
³ Most commentators to address this problem to date have analyzed it as a two-circuit split, with the Sixth and Eleventh Circuits disagreeing as to whether the agreements at issue should be deemed “per se” illegal under the antitrust laws, and how such agreements should be analyzed.” Richard D. Chaves Mosier & Steven W. Ritcheson, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 497, 510–11 (2004). However, as discussed in Part III of this Comment, the landscape has changed considerably today, which makes this two-circuit view a bit myopic. See infra notes 213-238 and accompanying text. Nevertheless, this Comment operates under one basic assumption: there is legitimate discrepancy between the courts as to the extent to which patent settlement agreements warrant antitrust scrutiny.
ties to clarify any divergence. Consequently, this issue will affect intellectual property ("IP") practitioners for years to come because the lack of guidance in this area will continue to cause a variety of questionably-reasoned decisions and a marked lack of predictability/consistency when drafting patent settlement agreements.

Along these lines, the primary goals of this Comment are: (a) to outline and explain the conflict among the courts as it stands today; (b) to provide practical tips, in light of recent scholarship and case law, for avoiding antitrust pitfalls when drafting/defending patent dispute settlement agreements; and (c) to propose a position that the Supreme Court should adopt.

To meet these broad goals, Part II of this Comment discusses background concerns, including the turbulent interaction between the two applicable legal regimes — patent and antitrust law. This section also describes the typical antitrust analytical framework that courts employ when reviewing potentially anticompetitive activity. Part II further describes the environment in which patent dispute settlements have recently come before the courts — i.e., pharmaceutical "reverse payment" cases under the Hatch-Waxman Act — and how these cases implicate patent settlement agreements beyond the drug context. Part II concludes by discussing how recent courts have varied widely in their antitrust approaches to patent settlement agreements.

Then, based on examined cases and commentators, Part III begins by comparing and contrasting the various holdings to illustrate the depth of the problem, and then offers some practical tips on how to potentially draft/defend patent settlement agreements to survive antitrust review. Part III also offers a potential solution, discussing why the Supreme Court should adopt the Eleventh Circuit's analytical approach — comparing the "exclusionary potential" of the patent against the agreement — as its official test. Finally, Part IV discusses the impact that continued ambiguity will have on the ability of patent settlement agreements to weather antitrust challenges into the future, paying special attention to recent appeals to the Supreme Court and its thrice-denial of certiorari.

4. See infra note 383 and accompanying text.
5. See infra notes 15-31 and accompanying text.
6. See infra notes 32-44 and accompanying text.
7. See infra notes 45-70 and accompanying text.
8. See infra notes 71-209 and accompanying text. See also Hovenkamp Treatise, supra note 2, at 7-39.
9. See infra notes 213-355 and accompanying text.
10. See infra notes 356-400 and accompanying text.
11. See infra notes 383-400 and accompanying text.
II. BACKGROUND

This section will discuss the conflict between the two relevant legal regimes — patent and antitrust law — to give an overview of the turbulent environment in which IP practitioners must craft their settlement agreements.\(^{12}\) It will then discuss the typical antitrust analytical framework courts employ when reviewing questionably anticompetitive activity in general.\(^{13}\) It concludes by discussing the pharmaceutical "reverse payment" cases under the Hatch-Waxman Act, both generally and specifically, and how these cases have implications for all patent dispute settlement agreements.\(^{14}\)

A. Conflict Between Legal Regimes

Waters dividing legal regimes are not always calm. The Patent Act embodies a careful balance between encouraging new/useful discoveries and allowing inventors to reap the benefits of their labor through an exclusive right to use the invention for a limited time.\(^{15}\) Conversely, the Sherman Act seeks to thwart "unreasonable" restraints of trade (i.e., monopolies), both criminally and civilly.\(^{16}\) Thus, some authorities maintain that the Patent Act carves out an exception from the Sherman Act, with patent law giving the patent holder "a permissible monopoly over the patented work."\(^{17}\) Yet, a quick glance at the diminutive Sherman Act reveals no such exception, and neither Act

\(^{12}\) See infra notes 15-31 and accompanying text.

\(^{13}\) See infra notes 32-44 and accompanying text.

\(^{14}\) See infra notes 45-209 and accompanying text.


\(^{16}\) See generally The Sherman Act 15 U.S.C. §1, et seq. (2004). See also Michael A. Carrier, Resolving the Antitrust Paradox Through Tripartite Innovation, 56 VAND. L. REV. 1047, 1104 (2003) ("Section 1 of the Sherman Act targets agreements among competitors and prohibits 'unreasonable' restraints of trade"); David A. Balto & Andrew M. Wolman, Intellectual Property and Antitrust: General Principles, 43 IDEA 395, 398 (2003) ("Antitrust laws are intended to ensure that markets remain competitive."). This Comment applies and refers only to Section 1 of the Sherman Act since most of the recent controversy involving patent settlement agreements involves agreements between competitors (i.e., horizontal restraints), which fall under Section 1’s purview.

\(^{17}\) Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1067 (11th Cir. 2005) (emphasis added) (citation omitted). See also Valley Drug v. Geneva Pharm., Inc., 344 F.3d 1294, 1307 (11th Cir. 2003) ("The right of exclusion conferred by a patent has been characterized as a defense to an antitrust claim. . . or as a limited exception to the general rule that markets should be free from barriers to competition." (citations omitted)); Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 136 (1969) ("The heart of [the patent holder’s] legal monopoly is the right to invoke the State’s power to prevent others from utilizing his discovery without his consent." (emphasis added)).
provides guidance on how these two seemingly opposite legal regimes should properly co-exist when implicated in a single legal matter.\textsuperscript{18} Some commentators applaud the patent and antitrust regimes as complimentary.\textsuperscript{19} Both find their origins in the "fundamental notion of progress" in our free-market economy that promotes and rewards innovation, disclosure, and competition.\textsuperscript{20} Others see the two regimes as seeking "the same object: the welfare of the public," insofar as the "[antitrust law forbids certain agreements tending to restrict output and elevate prices. . . .]" and the patent law protects "invention against prompt imitation in order to encourage more innovation than would otherwise occur."\textsuperscript{21}

Other authorities note an inherent conflict.\textsuperscript{22} Generally speaking, "[a]lthough the patent and antitrust systems both attempt to increase total societal welfare, they pursue this goal through divergent paths."\textsuperscript{23} As the Eleventh Circuit recently noted, "[b]y their nature, patents create an environment of exclusion, and consequently, cripple competition."\textsuperscript{24} However, "[t]he very exclusion that forms the foundation of the patent system nevertheless may be punished under the antitrust laws."\textsuperscript{25} Patent licenses restrict competition by imposing quantity restrictions, royalty payments, territorial restrictions, and the like.\textsuperscript{26} Antitrust law, in contrast, favors agreements that result in lower prices, higher output, and increased innovation, and is thus disdainful of any agreements impeding such ideals.\textsuperscript{27} Since, as discussed below, patent settlements may contain provisions considered anticompetitive because they fix prices or restrict output, such settlements nat-

\textsuperscript{18} The Patent Act does mention antitrust law in 35 U.S.C. § 211, stating "[n]othing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law." 35 U.S.C. § 211(2004).

\textsuperscript{19} See Balto & Wolman, supra note 16, at 398.


\textsuperscript{21} Valley Drug, 344 F.3d at 1307-08 (quoting Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application, § 1780a (1999)).

\textsuperscript{22} See Mosier & Ritcheson, supra note 3, at 510 ("It has been said that the patent and antitrust regimes are in place to support competition and the consumer while fostering innovation, but they do so in ways that sometimes meet up like tectonic plates colliding."). See also In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187, 202 (2d Cir. 2006) (noting "the tension between restraints on anti-competitive behavior imposed by the Sherman Act and grants of patent monopolies under the patent laws. . . .") (emphasis added)). See also James C. Burling, Hatch-Waxman Patent Settlements: The Battle for a Benchmark, 20-SPG ANTITRUST 41, 42-43 (2006).

\textsuperscript{23} Carrier, supra note 16, at 1049.

\textsuperscript{24} Schering, 402 F.3d at 1065-66. But see Hovenkamp, et al., supra note 2, at 1761 ("a patent is not a right to exclude but rather a right to try to exclude." (emphasis added)).

\textsuperscript{25} Carrier, supra note 16, at 1050.

\textsuperscript{26} Id. at 1051.

\textsuperscript{27} See id. at 1050-51.
urally trigger antitrust concerns. Yet, as one commentator maintains, "IP law requires that we tolerate departures from a competitive marketplace, but only where legitimate IP rights in fact exist and are infringed."

So, despite arguments that the two regimes are complimentary at a very abstract level of analysis (i.e., they both protect the public), an inherent conflict between antitrust and patent law nevertheless remains. Even to the casual eye, this incongruence should be apparent — one regime prevents monopolies and the other grants them. Therefore, as "the exclusion that is the foundation of the patent system . . . appears suspicious when viewed through monopolization-tinted glasses" (i.e., viewing a patent settlement from the Sherman Act's perspective), it is not surprising that current authorities vary in their antitrust approaches to patent settlement agreements. However, before one can properly discuss these inconsistent analytical approaches, it is essential to understand the typical analytical framework that courts employ when reviewing potentially anticompetitive activity.

B. Typical Antitrust Analytical Framework For Reviewing Agreements

Courts have recognized that merely settling a patent dispute, by itself, does not violate antitrust laws. Yet, patent dispute settlement agreements, like all other potentially anticompetitive business arrangements, are not immune from antitrust review under the Sherman Act. As such, courts dealing with alleged Sherman Act violations

28. See infra notes 33, 42-44 and accompanying text.
30. See Leuenberger-Fisher, supra note 20, at 417. ("These areas of law [may be viewed as] at direct odds with one another in that antitrust law is aimed at preventing monopolies and allowing free competition wherever and whenever possible, whereas patent law provides monopolies of limited duration, in the form of patent protection in exchange for public disclosure.").
33. See Proctor & Gamble, 61 F. Supp. 2d at 107 (holding "...any agreement between competitors may be illegal if part of a larger plan to control interstate markets"). See also Department of Justice & Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property 1995, available at http://www.usdoj.gov/atr/public/guidelines/ipguide.pdf (last visited Nov. 1, 2005) ("As with other forms of private property, certain types of conduct with respect to intellectual property may have anticompetitive effects against which the antitrust laws can and do protect."); see also Mosier & Ritcheson, supra note 3, at 510 ("As a result of a patent grant, a patentee is entitled to engage in actions that, notwithstanding the patent grant, would be considered illegal under antitrust law. However, a patent does not absolve the owner
generally have two analytical paths to follow — a balancing test (the "rule of reason" test) or a strict liability test (the "per se" test).34

Unless a challenged activity is among a few categories of restraints deemed "per se" illegal, the courts usually employ the default test known as the "rule of reason" when examining allegedly anticompetitive agreements.35 This test requires courts to "weigh the anticompetitive consequences of a practice against its procompetitive benefits."36 One common formulation of this rule requires consideration of: (1) whether the challenged action has an actual adverse effect on competition; (2) whether the defendant established any pro-competitive redeeming virtues; and (3) whether the plaintiff can show the pro-competitive effects can be achieved through less-restrictive alternate means.37 Additionally, "[t]his analysis involves a number 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."38

of potential liability under the antitrust laws, and it is when the patentee 'overachieves' in a settlement that the legal analysis is most complicated.")

34. See Herbert Hovenkamp, Sensible Antitrust Rules For Pharmaceutical Competition, 39 U.S.F. L. Rev. 11, 21 (2004) ("It is commonly said that antitrust analysis proceeds under two different rules."). There is also a third analytical approach, commonly known as the "quick look" rule, which "falls somewhere between the per se rule and the rule of reason..." and is used in "...intermediate cases where the anticompetitive impact of a restraint is clear from a quick look, as in a per se case, but procompetitive justifications for it also exist." Leuenberger-Fisher, supra note 20, at 424 (citation omitted); accord In re Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1312 (S.D. Fla. 2005). However, the cases discussed in the Comment are generally torn between the two extremes of the per se rule or the rule of reason.

35. See Lektro-Vend Corp. v. Vendo Co., 660 F.2d 255, 265 (7th Cir. 1981). See also Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1064 n.11 (11th Cir. 2005) (holding “[t]he majority of antitrust claims are analyzed under the rule of reason” and citing State Oil Co. v. Khan, 522 U.S. 3, 20 (1997)).

36. Hovenkamp Treatise, supra note 2, at 7-11 n.6 .

37. See In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 520 (E.D.N.Y 2005). See also In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187, 202 n. 13 (2d Cir. 2006) ("The rule-of-reason analysis has been divided into three steps. First, a plaintiff must demonstrate that the challenged action has had an actual adverse effect on competition as a whole in the relevant market. If the plaintiff succeeds in doing so, the burden shifts to the defendant to establish the pro-competitive redeeming virtues of the action. If the defendant succeeds in meeting its burden, the plaintiff then has the burden of show[ing] that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition." (citations, emphasis, and internal quotations omitted)).

38. Balto & Wolman, supra note 16, at 400 (citation and internal quotations omitted). See also Tamoxifen, 466 F.3d at 202 n. 13 ("In most cases ... conduct will be evaluated under a 'rule of reason' analysis, 'according to which the finder of fact must decide 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.'" (citation omitted)).
Conversely, under the "per se rule," a court may declare a particular practice illegal without detailed inquiry into the merits of the case.\(^\text{39}\) A court will likely use this approach when "it has sufficient experience to conclude that a certain class of practices is so likely to be anti-competitive without offsetting social benefits" that the more-involved rule of reason analysis is unnecessary.\(^\text{40}\) Thus, the only issue that requires resolution is whether the defendant actually committed the alleged conduct.\(^\text{41}\) For example, most authorities agree that "[h]orizontal agreements among competing sellers to fix prices or restrict output are, absent more, per se violations of Section 1 of the Sherman Act."\(^\text{42}\) So, if General Electric agrees with Westinghouse (both competitors) that the latter will manufacture GE light bulbs, but stipulates the price at which Westinghouse can sell them, such an agreement will likely be considered a per se unlawful "price fixing" agreement.\(^\text{43}\) Therefore, patent settlement agreements "among competitors that set prices, limit output, or divide markets" also merit antitrust scrutiny.\(^\text{44}\)

**C. The General Environment: General Case and Regulatory Framework Overview**

There is no case directly on point that discusses what level of analytical treatment is appropriate for all patent settlement agreements. This should not be surprising given the almost infinite combination of patentable products and questionable settlement provisions. However, various courts and numerous commentators have recently dedicated much energy to the antitrust implications of pharmaceutical patent settlements, which is instructive for the purposes of this Comment and applicable to patent settlement agreements generally.\(^\text{45}\)

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39. See Hovenkamp Treatise, supra note 2, at 7-11 n.7.
40. Herbert Hovenkamp, Anticompetitive Settlement of Intellectual Property Disputes, IP & ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW §7, 7-11 (2007 Supplement). See also Valley Drug v. Geneva Pharm., Inc., 344 F.3d 1294, 1303 (11th Cir. 2003) ("Some types of agreements are so obviously anticompetitive . . . that such agreements can be deemed to violate the Sherman Act without much more than an examination of the agreement itself and the relationships of the parties to the agreement.").
41. See Balto & Wolman, supra note 16, at 399 (noting that "the defendant may not present evidence to show that, in fact, the conduct at issue had no anticompetitive effects or indeed had procompetitive benefits.").
42. Freedom Holdings, Inc. v. Spitzer, 357 F.3d 205, 225 (2d Cir. 2004) (citing Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of the Univ. of Okla, 468 U.S. 85, 100 (1984)). See also Balto & Wolman, supra note 16, at 399 ("Examples of conduct that is per se illegal under the antitrust laws are price fixing, bid rigging, and horizontal market allocations.").
43. See Hovenkamp Treatise, supra note 2, at 7-12.
44. See Hovenkamp, et al., supra note 2, at 1746.
One commentator has aptly and succinctly described the environment in which these cases operate:

While the facts of these cases differ considerably, many of them share a common kernel that exhibits the following pattern. The pioneer patentee of a drug files a patent infringement suit against a rival firm who has or is about to make a generic version of the drug. The rival may or may not have obtained requisite approval from the [Food and Drug Administration to market the generic]. The two parties then settle their patent dispute. Under the settlement the generic firm who is the infringement defendant agrees not to enter the market for the drug in question, or else agrees to exit from the market if it has already begun entry, and agrees not to challenge the pioneer's patent. In exchange, the patenantee/infringement plaintiff agrees to pay a significant sum of money to the infringement defendant. The result is that for a certain period of years this particular generic producer is disabled by the settlement agreement from entering the market. Under the Hatch-Waxman Act, which gives first comers to the generic market a temporary exclusive right, the effect of the agreement may also be to keep other generics from entering as well.46

Thus, the primary concern in these cases involves so-called "reverse payment settlements" (sometimes called "exit payments") where the patent holder "explicitly pays an alleged infringer to stay out of [i.e., exit] the market."47 Generally, "[w]hat makes these settlements unusual is that the settlement payment goes from plaintiff to defendant rather than, as one would assume is more common, from defendant to plaintiff."48 Moreover, when the parties settle, they essentially "be-

46. Hovenkamp, supra note 34, at 22–23.
48. Thomas F. Cotter, Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley, 87 MINN. L. REV. 1789, 1797 (2003). The Second Circuit also has provided an excellent example of how the typical infringement case works as opposed to the Hatch-Waxman context, which warrants repeating here. See In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187, 206–07 (2d Cir. 2006) ("In the typical patent infringement case, the alleged infringer enters the market with its drug after the investment of substantial sums of money for manufacturing, marketing, legal fees, and the like. The patent holder then brings suit against the alleged infringer seeking damages for, inter alia, its lost profits. If the patent holder wins, it receives protection for the patent and money damages for the infringement. And in that event, the infringer loses not only the
come collaborators rather than rivals in vindicating their patent rights,” which naturally looks suspicious to third parties and antitrust watchdogs. Accordingly, these agreements have been “criticized and sometimes invalidated on the theory that they prevent competition” because the reverse payment “is in effect a payment by the patent holder to the generic for a period of continued monopoly-like access to the market.”

Additionally, as noted above, these “reverse payment” cases occur within the Hatch-Waxman Act as well as the Food and Drug Administration (“FDA”) drug approval guidelines, both of which serve to heighten antitrust concerns. The Hatch-Waxman Act supplemented previous FDA guidelines, resulting in an abbreviated process through which potential generic drug manufacturers could bring their products to market. These generic drugs are usually not exact duplicates; instead, the generic maker must certify that the drug is a “bioequivalent” of an already-approved name-brand drug, meaning the generic “contains the same active ingredients, but not necessarily the same inactive ingredients, as the pioneer drug.” Thus, the approval process is quicker for a generic drug than for a name-brand drug because Hatch-Waxman allows the generic “to piggyback on the safety and efficacy studies” that the name-brand maker had already conducted and got approved. Yet, to get final FDA approval for a ge-

opportunity to continue in the business of making and selling the infringing product, but also the investment it made to enter the market for that product in the first place. And it must pay damages to boot. It makes sense in such a circumstance for the alleged infringer to enter into a settlement in which it pays a significant amount to the patent holder to rid itself of the risk of losing the litigation. By contrast, under the Hatch-Waxman Act, the patent holder ordinarily brings suit shortly after the [infringer's FDA filing] —before the filer has spent substantial sums on the manufacturing, marketing, or distribution of the potentially infringing generic drug. The prospective generic manufacturer therefore has relatively little to lose in litigation precipitated by [its filing] beyond litigation costs and the opportunity for future profits from selling the generic drug. Conversely, there are no infringement damages for the patent holder to recover, and there is therefore little reason for it to pursue the litigation beyond the point at which it can assure itself that no infringement will occur in the first place.”

53. Tamoxifen, 466 F.3d at 191 n.2 (citation omitted).
generic drug, the filer must also certify either: (a) the name-brand maker never filed a patent for its drug; (b) that the patent expired; (c) that the patent will expire on a certain date and that the generic maker will not market until that time; or (d) that the patent is invalid or the generic drug would not otherwise infringe on the name-brand. If the filer chooses the last option, the applicant must notify the patent holder, at which time the patent holder must file suit for infringement within a set period. However, if (1) another generic maker also tries to certify using this option, and (2) the first generic maker successfully challenges the patent scope or validity, the first generic maker gets a 180-day period where it is the only competitor to the name brand.

As the Eleventh Circuit fittingly noted, "[t]his exclusivity period is a significant incentive for generic manufacturers to challenge weak or narrow drug patents." However, this regulatory scheme has also been criticized as being "vulnerable to abuse" because the "exclusivity period offers the potential for collusive settlement arrangements between pioneers and generics." Once an infringement action is filed, an automatic thirty-month stay begins where "the FDA cannot approve any generic drugs related to the pioneer patent, regardless of the merits of the infringement claim." The court can extend this stay by granting the patent holder a preliminary injunction prior to the patent’s expiration, which extends the FDA approval process pretty much indefinitely until the court rules that the patent is either invalid or not infringed. However, rather than litigating the merits of the patent, the patentee can (and often will) settle with the alleged infringer and avoid costly litigation. The patent holder might, for example, convince the generic maker to forego litigating patent validity and chose the third FDA certification option — staying out of the

55. Tamoxifen, 466 F.3d at 191. The last option — that the patent is invalid or that the generic does not infringe — is a known as a "paragraph IV" certification. Id. This certification is prevalent throughout the cases analyzed in this Comment.

56. See Valley Drug, 344 F.3d at 1297. See also Larissa Burford, In re Cardizem and Valley Drug Co.: The Hatch-Waxman Act, Anticompetitive Actions, and Regulatory Reform, 19 BERKELEY TECH. L.J. 365, 368 (2004) (noting the patent holder has 45 days in which to file suit); accord Roger D. Blair & Thomas F. Cotter, Are Settlements of Patent Disputes Illegal Per Se?, 47 ANTITRUST BULL. 491 (2002).

57. See Valley Drug, 344 F.3d at 1297–98.

58. Id. at 1298.


60. Reed, supra note 45, at 459 (citing Hovenkamp, et al., supra note 2, at 1755).

61. Burford, supra note 56, at 368.

62. Id. at 368–69.

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market until the patent expires. The patent holder might also settle with the alleged infringer but require that it not relinquish its exclusivity period, thus keeping other potential competitors out of the market. Consequently, "unless and until the first . . . applicant actually enters the market, or the pioneer patent is judicially determined to be invalid or not infringed, other generic manufacturers will be precluded from entering and competing against the pioneer and the first generic entrant." So, in all, a pioneer drug maker can exclude would-be competitors for considerably extended periods under this regulatory scheme, and it is easy to see why these cases might raise antitrust red flags.

Yet, even though antitrust concerns in this environment are justifiably implicated, recent court decisions applying antitrust review principles when evaluating these settlements "have led to widely different outcomes. . . ." Generally, the courts disagree on whether the possibly offensive terms in these cases should be considered per se illegal or analyzed under the rule of reason. Moreover, at least two recent opinions from the Eleventh Circuit have questioned whether either of the two traditional analytical approaches are appropriate in the patent settlement context at all, and have crafted new review tests as such. Therefore, as the courts have grappled with this issue in the pharmaceutical context, they have unwittingly brought into question all forms of patent dispute settlements, not just those in the pharmaceutical world. The following section will analyze these cases in greater detail.

D. Current Authority Varies Its Antitrust Analytical Treatment of "Reverse Payment" Settlement Agreements

1. "Per Se" Illegality in the Sixth Circuit

The Sixth Circuit's Cardizem CD Antitrust Litigation decision was the first among the contemporary wave of cases dealing with the "re-

64. See, e.g., Valley Drug v. Geneva Pharm., Inc., 344 F.3d 1294, 1300 (11th Cir. 2003); Cipro, 363 F. Supp. 2d at 518–19.
65. See, e.g., In re Cardizem CD Antitrust Litig., 332 F.3d 896, 902 (6th Cir. 2003).
66. Cotter, supra note 48, at 1801.
67. Hovenkamp Treatise, supra note 2, at 7-41. Accord Carrier, supra note 16, at 1052 ("Courts have offered an array of [antitrust] analyses when confronted with patent-based activity.").
69. See supra notes 99-103, 142-143 and accompanying text.
70. See O'Rourke & Brodley, supra note 49, at 1773 (asserting the question of which analytical framework courts should employ when reviewing patent settlements is "one of the most vexing issues facing antitrust and intellectual property law today").
verse payment” problem, and it took the hard-line “per se” approach.\(^\text{71}\) In that case, the defendants were originally on opposite sides of a patent infringement case.\(^\text{72}\) In 1995, defendant Andrx sought FDA approval to sell a generic form of a name-brand drug, which defendant HMR manufactured.\(^\text{73}\) HMR held the patent for the active ingredient of the drug, but the patent expired in 1992.\(^\text{74}\) Under FDA guidelines, Andrx’s filing certified the generic drug did not infringe on any HMR patents.\(^\text{75}\) However, two months after the filing, a company called “Carderm Capital” received a patent for the “dissolution profile” of the drug, which it promptly licensed to HMR.\(^\text{76}\) In January 1996, HMR and Carderm filed an infringement suit alleging Andrx’s proposed generic drug would infringe on the new patent.\(^\text{77}\)

While this suit was pending, the FDA gave tentative approval to Andrx to market the generic drug.\(^\text{78}\) Shortly thereafter, HMR and Andrx signed an agreement where Andrx would not market its generic until either: (a) there was a final, unappealable resolution to the infringement case, or (b) the parties entered into a license agreement.\(^\text{79}\) In exchange, Andrx dismissed its counterclaims and was to receive $40 million per year for a period after final FDA approval.\(^\text{80}\) Andrx also agreed to diligently seek FDA approval and not to relinquish its 180-day exclusivity once it received it.\(^\text{81}\) The FDA gave final approval in June 1998, and the first outside challenger filed suit in August 1998 alleging the illegality of the settlement agreement under the Sherman Act.\(^\text{82}\) All the challenging suits were then consolidated in the Eastern District of Michigan, where the district court granted plaintiffs summary judgment and held the agreement was a per se illegal horizontal restraint of trade.\(^\text{83}\)

On appeal the Sixth Circuit initially acknowledged that the application of the per se rule might lead to the condemnation of agreements that the rule of reason might otherwise allow.\(^\text{84}\) However, the Court

\(^\text{71. See generally In re Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003).}\)
\(^\text{72. See id. at 902.}\)
\(^\text{73. Id. at 901–02.}\)
\(^\text{74. Id. at 901.}\)
\(^\text{75. Id. at 902.}\)
\(^\text{76. Cardizem, 332 F.3d 896 at 902.}\)
\(^\text{77. Id.}\)
\(^\text{78. Id.}\)
\(^\text{79. Id.}\)
\(^\text{80. Cardizem, 332 F.3d at 902.}\)
\(^\text{81. Id.}\)
\(^\text{82. Id. at 903.}\)
\(^\text{83. Id. at 903, 905.}\)
\(^\text{84. Id. at 907 n.11.}\)
found that, "[f]or the sake of business certainty and litigation efficiency, [the Supreme Court has] tolerated the invalidation of some agreements that a full blown inquiry might have proved to be reasonable." 85 The Court also found the agreement at issue had the effect of delaying other competitors into the market because Andrx had refused to relinquish its exclusivity. 86

Consequently, the Court could not escape the conclusion that the settlement agreement "was, at its core, a horizontal agreement to eliminate competition in the market . . . throughout the entire United States, a classic example of a per se illegal restraint of trade." 87 As such, the Court held that the agreement deserved per se illegality because the agreement was "presumed to have the effect of reducing competition for Cardizem CD and its generic equivalents to the detriment of consumers." 88 Moreover, the Court believed the agreement could not "be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation." 89 Rather, the Court said "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." 90

In short, the Sixth Circuit upheld the district court.

2. The Eleventh Circuit: Not "Per Se"

The Eleventh Circuit took a different approach than the Sixth Circuit in a case quite similar to Cardizem. The plaintiffs in the Valley Drug v. Geneva Pharmaceuticals case asserted that two agreements between the three parties to an earlier infringement case violated the Sherman Act. 91 Abbott made the name-brand drug and sued Geneva and Zenith for patent infringement when the pair sought FDA approval to market a generic version. 92 Abbott entered into a final settlement with Zenith wherein Zenith was paid not to market the generic until either: (1) someone else introduced a generic product first, or (2) until the patent for the name-brand expired. 93 Similarly,

86. 332 F.3d at 907.
87. Id. at 908.
88. Id. at 911.
89. Id. at 908.
90. Id.
92. Id. Both filed "paragraph IV" certifications. See id. at 1298-99.
93. Valley Drug, 344 F.3d at 1300.
Geneva agreed to the same terms with one additional caveat: Geneva could sell its generic if it obtained a court judgment that its product was non-infringing or that Abbott's patent was invalid. Subsequently, a Florida district court held both agreements were per se illegal.

On appeal the Eleventh Circuit refused to apply the per se label because the exclusionary effect of the agreements here were "at the heart of the patent right." Instead, the Court focused on the "potential exclusionary power of the patent," and held that "the exclusion of infringing competition is the essence of the patent grant." Consequently, the Court reversed the district court because that court failed to consider the patent's exclusionary power before applying per se scrutiny.

The Eleventh Circuit also explicitly took issue with the Sixth Circuit's Cardizem decision as such, holding: "[t]o the extent that the Sixth Circuit suggests that a settlement of patent litigation was a per se violation of the antitrust laws merely because it involves a generic's agreement to delay marketing until resolution of the patent infringement case in exchange for exit payments, we respectfully disagree." The Eleventh Circuit also noted that the "Sixth Circuit opinion did not purport to measure the several provisions [of the agreement at issue] against the exclusionary power of the patent, or differentiate between provisions that fell within the scope of the patent's protection and those which did not." Therefore, in contrast with the Sixth Circuit, the Eleventh Circuit held that, unless the exclusionary effects of an agreement exceeded the exclusionary scope of the patent, the agreements would "not [be] subject to per se antitrust condemnation." However, the Court also

94. Id.
95. Id. at 1301.
96. Id. at 1306.
97. Id. at 1306, 1311 n.26 (holding "the potential exclusionary power of the patent must first be considered").
98. Valley Drug, 344 F.3d at 1306.
99. Id. at 1311 n.26.
100. Id.  
101. Valley Drug, 344 F.3d at 1311. Here, the Court performs what may be classified as an "exclusionary potential" analysis: comparing the exclusionary potential of the settlement agreement with the exclusionary potential of the patent claims. For an in-depth discussion of the "exclusionary potential" analysis, see infra notes 265-355 and accompanying text. As discussed later in this Comment, other courts have utilized similar approaches to patent settlement agreements, but with varying terminology — not just within different decisions but also even within single decisions. Some courts prefer the phrase exclusionary "power" like the Eleventh Circuit did here. See supra note 97 and accompanying text. However, the Eleventh Circuit in Valley Drug later refers to the exclusionary "effect" of a patent. See infra notes 103-105 and accompa-
noted "rule of reason analysis [would be] similarly inappropriate, as the anticompetitive effects of exclusion cannot be seriously debated."\textsuperscript{102} Instead, "what is required . . . is an analysis of the extent to which antitrust liability might undermine [the patent laws'] encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability from such exclusionary effects."\textsuperscript{103}

Ultimately, the Court held that it could not "conclude that the exclusionary effects of the Agreements not to enter the market were necessarily greater than the exclusionary effects of the . . . patent merely because Abbott paid Geneva and Zenith in return for their respective agreements."\textsuperscript{104} However, the Court remanded the case and held, "[a]ny provisions of the Agreements found to have effects beyond the exclusionary effects of [the] patent may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects. . . ."\textsuperscript{105}

The Court did not say whether the \textit{per se} rule or "rule of reason" test would be the appropriate "traditional analysis" to employ on remand. Instead, the Court cautioned that one cannot not easily draw a categorical line "between restraints that give rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment."\textsuperscript{106} Rather, in making its analysis, any reviewing court must consider "the circumstances, details, and logic of a restraint."\textsuperscript{107}

3. The Eleventh Circuit on Remand: The Return of "Per Se"

Later, the Geneva agreement received further scrutiny when \textit{Valley Drug} was handled on remand in the \textit{Terazosin Hydrochloride Anti-
trust Litigation case. Since the Valley Drug decision did not provide an analytical framework for considering the "exclusionary scope" of the patent at issue, the Florida district court turned to Professor Herbert Hovenkamp, who the Court deemed knowledgeable on "the complex issues that arise when parties enter into a settlement agreement that would potentially constitute an antitrust violation in the absence of claimed IP rights." Accordingly, the Court adopted the following Hovenkamp-proffered test: "...once conduct is found that would likely be an antitrust violation in the absence of a settlement, some care must be taken to ensure (1) that the parties did have a bona fide dispute, (2) that the settlement is a reasonable accommodation, and (3) that the settlement is not more anticompetitive than a likely outcome of the litigation."

Along these lines, the Court also held that the "exclusionary value of [a] patent . . . cannot be defined by looking at the patent terms in a vacuum; instead, when litigation is pending as to the validity of the patent, the chances that the patent will be held valid must be considered as part of the analysis." Thus, after providing "a limited assessment of the underlying patent infringement case," the Court held that the likely outcome would be that the patent would have been declared invalid. As such, the Court deemed the Geneva agreement as being beyond the scope of the patent's protection.

After making this determination, the Court next considered the appropriate antitrust analysis to apply: either per se illegality or rule of reason. In other words, following the Valley Drug mandate, the district court still conducted a traditional antitrust analysis after it found the provision at issue "exceed[ed] the exclusionary scope of the patent." Accordingly, the district court recognized that "horizontal agreements between competitors are antitrust's most 'suspect' classification, which as a group provoke closer scrutiny than any other arrangement." The Court also ruled that "[i]f the Agreement is one that presents 'a naked restraint of trade with no purpose except sti-

109. Id. at 1295. Professor Hovenkamp, at the time of publication, teaches at the University of Iowa Law School, is an oft-cited authority on the antitrust implications of IP agreements, and is cited virtually in every case (in some form or another) analyzed in this Comment.
111. Id. at 1296–97.
112. See id. at 1299–1307.
113. See id. at 1307–10.
114. See id. at 1310–11.
115. Terazosin, 352 F. Supp. 2d at 1310.
116. Id. at 1313.
fling competition,' it qualifies for *per se* treatment."117 Moreover, "[a] particular horizontal agreement is defined as a naked restraint 'if it is formed with the objectively intended purpose or likely effect of increasing price or decreasing market wide output in the short run, measured by quantity or quality.' "118

Going further, the Court found that the Geneva agreement called for Geneva to refrain from marketing its generic product "even after an adverse district court ruling as to the validity of [the] patent."119 However, the Court also noted "Zenith settled this action and is no longer a party to this multi-district litigation."120 Thus, while it is not clear why from the opinion, the Zenith agreement was not subject to remand.121 Nevertheless, citing the *Cardizem* decision, the *Terazosin* court ultimately called the Geneva agreement "a ‘classic example’ of an output-reducing, naked restraint on trade that qualify[ed] for *per se* treatment" and stuck it down.122

4. The Eleventh Circuit Revisited: Not “Per Se” and Not Rule of Reason

The Eleventh Circuit upheld *Valley Drug* in the *Schering-Plough Corp. v. Federal Trade Commission* case.123 There, two generic manufacturers (Upsher and ESI) sought FDA approval to market a generic version of Schering’s name-brand drug.124 Both certified that neither infringed on Schering’s product.125 Schering then sued for patent infringement.126 Schering agreed to drop its patent claims against Upsher and paid Upsher approximately $60 million.127 Upsher then granted Schering the right to market a certain number of Upsher products (especially a product called “Niacon”) in various other fields.128 Upsher also agreed not to enter the market with its generic version of Schering’s product until about five years later but before

117. *Id.* at 1314.
119. *Id.* at 1314–15.
120. *Id.* at 1286 n.3.
121. *Id.*
122. *Id.* at 1315.
123. *See generally* Schering-Plough Corp. *v.* FTC, 402 F.3d 1056 (11th Cir. 2005).
125. *See id.* at 1059–60.
126. *Id.*
127. *Id.* at 1060.
128. *Schering*, 402 F.3d at 1060.
the patent expired. Schering and ESI also entered a similar settle-
ment agreement, although the sum paid was about half as much.130

The FTC filed an administrative complaint against Schering, Up-
sher, and ESI alleging the agreements were illegal restraints of trade
under the Sherman Act.131 An administrative law judge first tried
the case and held "both agreements were lawful settlements of legitimate
patent lawsuits, and dismissed the complaint."132 The judge further
found that the "presence of payments did not make the settlement
anticompetitive, per se" but instead assessed "the strength of the pat-
ent itself and its exclusionary power."133 Although the judge found no
monopoly, FTC counsel appealed the decision to the full Commis-
sion.134 The full Commission reversed but, while refraining from call-
ing the agreements per se illegal, it "concluded that the quid pro quo
for the payment was an agreement to defer the entry dates, and that
such a delay would injure competition and consumers."135 Therefore,
FTC issued an order barring the settlements.136

On appeal the Eleventh Circuit began by discussing the Valley Drug
case, which it had decided a mere two years earlier.137 The Court
noted that Valley Drug involved an "interim settlement agreement"
where the Court had "concluded that monetary payments made to an
alleged infringer as part of a patent litigation settlement did not con-
stitute a per se violation of antitrust law."138 The Court then stated
that, even though it had called the agreement at issue in Valley Drug
"clearly anticompetitive," it had "nonetheless reversed [in that case]
for a rather simple reason: one of the parties owned a patent."139

The Eleventh Circuit also took great care to mention that the Ter-
azosin decision (i.e., when the Geneva agreement was on remand in
Valley Drug) still applied a per se analysis anyway.140 However, the

129. Id.
130. See id. at 1060–61. Of the payments to ESI, $15 million was attributed to the licensing of
ESI products to Schering, but the remaining $15 million was for legal fees and a contingency
payment for ESI’s FDA approval. See id.
131. Schering, 402 F.3d at 1061.
132. Id.
133. Id.
134. Id. at 1061–62.
135. Id. at 1062. The FTC’s decision in this regard might strike some as particularly odd.
Not only does it ignore the administrative law judge who employed an “exclusionary power"
approach like the Schering court ultimately uses, but it also does not employ traditional antitrust
analysis language yet reaches an ultimate result arguably akin to a per se application.
136. Schering, 402 F.3d at 1062.
137. See id. at 1063.
138. Id. at 1063–64.
139. Id. at 1064.
140. Schering, 402 F.3d at 1066 n.14.
Schering court noted that its case was "wholly different than Valley Drug," insofar as Valley Drug partially involved an interim settlement of patent litigation that did not allow marketing of the product before patent expiration, whereas the case at bar involved a final settlement disposing of the case.141

Turning back to its case, the Schering court held "both approaches [either the "per se rule" or "rule of reason"] are ill-suited for an antitrust analysis of patent cases because they seek to determine whether the challenged conduct had an anticompetitive effect on the market," because patents "[b]y their nature... create an environment of exclusion" and thus "[t]he anticompetitive effect is already present."142 Therefore, in line with Valley Drug, [the Court held] the proper analysis of antitrust liability requires an examination of: (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."143 However, while its focus was on "the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection," the Eleventh Circuit did not discuss what, if any, antitrust analysis should be employed if the agreement is deemed in excess of the patent's protection as it had in Valley Drug.144 In the end, the Court granted the petition for review and set aside the FTC order.145

5. Judge Posner's Favorable Take on Patent Settlements

Even before Schering, Judge Richard Posner weighed in with his approval of patent litigation settlement agreements in the Asahi Glass v. Pentech Pharmaceuticals case.146 There, the plaintiff Asahi claimed a settlement agreement between defendants Glaxo and Pentech amounted to a market division in violation of the Sherman Act.147 In 2000, Glaxo sued Pentech, a generic manufacturer of Paxil-brand medication, for patent infringement.148 Pentech had begun to manu-

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141. Id.
142. Schering, 402 F.3d at 1065–66 (emphasis added).
143. Id. at 1066. See also Andrx Pharm. v. Elan Corp., 421 F.3d 1227 1235, (11th Cir. 2005) (recently upholding this test but not applying it).
144. Schering, 402 F.3d at 1076. See also supra note 105 and accompanying text.
145. Schering, 402 F.3d at 1076.
146. Asahi Glass was decided October 29, 2003, over a year before Schering. See generally Asahi Glass Co., Ltd. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003). However, Valley Drug, the Eleventh Circuit's precursor to Schering, had been decided a mere month before Asahi on September 15, 2003. See generally Valley Drug v. Geneva Pharm., Inc., 344 F.3d 1294, 1296, 1311 n.25 (11th Cir. 2003).
147. Asahi, 289 F. Supp. 2d at 990.
148. Id. at 988.
manufacturer, but not sell, a generic version of the drug.\textsuperscript{149} Under the settlement, Glaxo licensed Pentech to immediately sell its drug in Puerto Rico and throughout the rest of the United States only after another generic version came on the market.\textsuperscript{150} Pentech would also have to leave the U.S. market if the other generic maker left.\textsuperscript{151} While Glaxo did not charge Pentech for the drug that Pentech relabeled and resold, Glaxo did receive a "hefty royalty fee" for Pentech's sales.\textsuperscript{152} Pentech could buy from anyone else besides Glaxo including the plaintiffs, but would still have to pay the royalty.\textsuperscript{153}

After dismissing the plaintiff's patent invalidity claims for lack of federal subject matter jurisdiction, Judge Posner, sitting by designation as a district judge, turned to the antitrust claims.\textsuperscript{154} Since Asahi was merely a supplier of the active ingredient rather than a drug manufacturer, he quickly disposed of Asahi's antitrust claims due to lack of standing "to complain about a violation of the antitrust laws at the customer level."\textsuperscript{155}

Nevertheless, Posner held that, even if the plaintiff had standing, "its antitrust claim regarding the settlement and license must be dismissed."\textsuperscript{156} First, he noted that "[t]he general policy of the law is to favor settlement of litigation, and the policy extends to the settlement of patent infringement suits."\textsuperscript{157} Posner then held that "[o]nly if a patent settlement is a device for circumventing antitrust law is it vulnerable to an antitrust suit."\textsuperscript{158} Accordingly, he ruled that if "there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation."\textsuperscript{159} Since Glaxo and Pentech were not natural allies and that since he ruled the underlying patent was valid in another suit anyway, Posner found nothing suspicious or frivolous about the settlement agreement.\textsuperscript{160}

\textsuperscript{149} Id. at 988–89. It is not entirely clear from the opinion, but it appears as though Pentech never began the FDA approval process or made a paragraph IV certification. Id.
\textsuperscript{150} Asahi, 289 F. Supp. 2d at 989.
\textsuperscript{151} Id.
\textsuperscript{152} Asahi, 289 F. Supp. 2d at 989.
\textsuperscript{153} Id.
\textsuperscript{154} See id. at 990.
\textsuperscript{155} Id. at 990–1.
\textsuperscript{156} Id. at 991.
\textsuperscript{157} Asahi, 289 F. Supp. 2d at 991.
\textsuperscript{158} Id.
\textsuperscript{159} Id. at 991-2.
\textsuperscript{160} See id. at 993.
Even though the case ended on technical grounds, Posner did not stop there. In *dicta*, he turned to the “reverse payment” settlement issue, although he noted the issue did not arise between Glaxo and Pentech. He explicitly questioned authorities asserting that such payments prevent competition, including Professor Hovenkamp. Instead, Posner noted, “if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent.” He also found “[a] ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger’s settlement options should he be sued for infringement . . .” Moreover, Posner opined, “*any* settlement agreement can be characterized as involving ‘compensation’ to the defendant, who would not settle unless he had something to show for the settlement.” Thus, he found that “[i]f any settlement agreement is thus to be classified as involving a forbidden ‘reverse payment,’ we shall have no more patent settlements.”

6. The Eastern District of New York: Rule of Reason

Just a few weeks after *Schering*, the Eastern District of New York chimed in to further muddy the “reverse payment” waters in the *Ciprofloxacin Hydrochloride Antitrust Litigation* (“*Cipro*”) case. Bayer owned the patent on the active ingredient in a drug. From 1987 until 2004, Bayer was the only producer of the drug in this country. However, in 1991, Barr sought FDA approval to market its generic version before the patent’s expiration. Consequently, Bayer sued Barr for patent infringement, and the parties entered into a settlement agreement wherein Bayer paid Barr $49 million in exchange for agreeing not to market the generic until the patent’s expiration. The parties also entered into a “consent judgment” which: (a)

161. See id. at 994.
163. *Id.*
164. *Id.*
165. *Id.* (emphasis in original).
166. *Id.* See also *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074–75 (11th Cir. 2005) (citing *Asahi* with approval).
169. *Id.*
170. *Id.*
171. *Id.* at 518–19.
terminated the litigation; (b) admitted patent validity; and (c) admitted Barr’s infringement. Then, of course, the agreement was subsequently challenged as an antitrust violation.

In 2003, the Court heard the case for the first time held that, since the “[t]he policies behind the patent laws and the Sherman Act are to some extent in conflict,” the rule of reason “should be employed” because of “[t]he flexibility necessary to balance these competing policies.” The Court also held that, while the law’s general policy of favoring settlement agreements cannot save per se violations of the Sherman Act, “a rule that too quickly condemns actions as per se illegal... does competition — and thus, the Sherman Act — a disservice.” As such, the plaintiffs moved for summary judgment alleging the reverse payment scheme met the “anticompetitive conduct” requirement under the rule of reason analysis.

Considering the same case in 2005, the Court discussed the Schering case, which the Eleventh Circuit decided a mere three weeks earlier. The Cipro court noted the Eleventh Circuit had questioned “the appropriateness of the per se versus rule of reason approach for claims of antitrust violations involving patents.” Yet, the Cipro court interpreted the Schering decision “as breaking the first step of [the] rule of reason analysis — assessing the actual adverse effects on competition — into three steps to determine whether there are any anti-competitive effects that exceed the scope of the patent.”

This distinction notwithstanding, the Cipro court held that, “[r]egardless of whether the Eleventh Circuit intended to jettison the rule of reason analysis in the patent context or simply refine the analysis,” it was going to use the rule of reason analysis in the 2005 case as it had dictated in 2003. Ultimately, the plaintiffs failed to show the anticompetitive effect of the agreement since it did not go beyond the

172. Id. at 518–19. The Court also implied that Barr filed a paragraph IV certification even though “there [was] no dispute that Barr’s product would have infringed Bayer’s patent.” Id. at 518. This certainly looks suspicious.


175. Id. at 256.

176. Cipro, 363 F. Supp. 2d at 520.

177. See generally 363 F. Supp. 2d 514.

178. See id. at 520, n.48.

179. Id.

180. Id.
scope of the patent claims. Consequently, the Court did not go further into the rule of reason analysis and held for the defendants.

7. Recent Ruling in the Second Circuit Apparently Follows the Eleventh Circuit

Most recently, the Second Circuit decided the Tamoxifen Citrate Antitrust Litigation case, in which it arguably followed the Eleventh Circuit’s Schering opinion. Yet, the Tamoxifen case is unique from the others discussed above because it includes a published dissenting opinion.

The facts of Tamoxifen are similar to the preceding cases, although they are perhaps more complex. Imperial Chemical Industries (“ICI”) held the patent for the drug “tamoxifen” which today is (according to the Court) the most prescribed breast cancer treatment drug in the world. In 1985, a competitor, Barr, sought FDA approval to market a generic version of the drug four months after ICI was awarded the patent. Barr filed its FDA form saying it was not infringing (or alternatively that the patent was invalid) and was then promptly sued for patent infringement. In 1992, a New York district court judge declared the patent invalid because ICI had withheld some side effect information from the Patent Office. ICI quickly appealed the invalidity decision to the Federal Circuit, but while the Federal Circuit mulled it over, ICI’s successor (“Zeneca”) entered into a settlement agreement with Barr.

Under the agreement, Barr agreed not to market its generic drug until Zeneca’s patent expired in exchange for $21 million and a non-exclusive license to sell Zeneca-made tamoxifen under Barr’s brand name. Zeneca also had to pay Barr’s raw materials supplier Heumann (who Zeneca had also sued for infringement) $9.5 million up front and $35 million over the next ten years. The parties further agreed that if: (1) another lawsuit was brought; (2) another generic manufacturer prevailed like Barr had; and (3) said judgment was

182. Id.
183. In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 passim (2d Cir. 2006).
184. See id. at 221–233 (Pooler, C.J., dissenting).
185. Id. at 193.
186. Id.
187. Id. Barr began the FDA approval process in 1985, but did not file its form until 1987. Id.
188. Tamoxifen, 466 F.3d at 193.
189. Id.
190. Id. at 193-94.
191. Id. at 194.
not appealed or affirmed on appeal, Barr would revert to the same position as if the Federal Circuit had ruled in its favor.\textsuperscript{192} The parties subsequently filed a joint motion to dismiss/vacate the district court’s decision holding the patent invalid, which the Federal Circuit later granted thus restoring the patent.\textsuperscript{193} Third party suits challenging the settlement agreement under antitrust law came next, which were consolidated into a multi-district litigation before the Eastern District of New York.\textsuperscript{194}

The district court upheld the settlement agreement distinguishing it from the Geneva agreement in \textit{Valley Drug} and the agreement in \textit{Cardizem}, both of which “did not conclude the underlying litigation and instead prolonged the period during which other generic manufacturers could not enter the market.”\textsuperscript{195} Additionally, although it is not clear from the Second Circuit’s opinion, the district court below may have used some form of a rule of reason approach, insofar as the district court “concluded that even if the plaintiffs had stated an antitrust violation, they did not suffer antitrust injury . . . .”\textsuperscript{196} In other words, the district court looked at what adverse impact the agreement had on competition, which is the first step in the rule of reason analysis\textsuperscript{197} but is not allowed under the \textit{per se} rule.\textsuperscript{198} Consequently, the district court found that any injury the plaintiffs had suffered was not an antitrust injury, “but rather the result of the legal monopoly that a patent holder possesses.”\textsuperscript{199}

On appeal the Second Circuit began its analysis by first noting “the tension between restraints on anti-competitive behavior imposed by the Sherman Act and grants of patent monopolies under the patent

\begin{itemize}
\item 192. \textit{Id.}
\item 193. \textit{Tamoxifen}, 466 F.3d at 194. The Second Circuit also noted that “[s]uch a \textit{vacatur}, while generally considered valid as a matter of appellate procedure by courts at the time of the Settlement Agreement, was shortly thereafter held to be invalid in nearly all circumstances by the Supreme Court.” \textit{Id.} (citing U.S. Bancorp Mortgage Co. v. Bonner Mall P’ship, 513 U.S. 18, 27–29 (1994)). However, fortunately for the parties involved in \textit{Tamoxifen}, the Supreme Court’s new rule did not apply retroactively. \textit{Id.} at 194 n.8 (citing U.S. Philips Corp. v. Sears Roebuck & Co., 55 F.3d 592, 598 (Fed. Cir. 1995), \textit{cert. denied}, 516 U.S. 1010 (1995)). Therefore, the tamoxifen patent was suddenly valid once more. Later, when other generic manufacturers tried to challenge patent validity, said plaintiffs were rebuffed and the patent’s validity was upheld in its own right. \textit{See id.} at 195 (“In each case, the court rejected the generic manufacturer’s attempt to rely on the vacated \textit{Tamoxifen I} decision, and—contrary to the \textit{Tamoxifen I} judgment—upheld the validity of Zeneca’s tamoxifen patent.”).
\item 194. \textit{Id.} at 196.
\item 195. \textit{Id.} at 197.
\item 196. \textit{Id.} at 198.
\item 197. \textit{See supra} note 37 and accompanying text.
\item 198. \textit{See supra} notes 40-41 and accompanying text.
\item 199. \textit{Tamoxifen}, 466 F.3d at 198 (quoting the district court).
\end{itemize}
laws, as complicated by the Hatch-Waxman Act . . . .” 200 The Court also noted “[r]ules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation.” 201 Accordingly, the Court, citing Valley Drug and Asahi with approval and distinguishing Cardizem, “decline[d] to conclude . . . that reverse payments are per se violations of the Sherman Act such that an allegation of an agreement to make reverse payments suffices to assert an antitrust violation.” 202

Instead, the Second Circuit specifically agreed with the Eleventh Circuit’s Schering holding that a patent holder paying a generic competitor money cannot be the only basis of a Sherman Act violation unless the “exclusionary effects of the agreement exceed the scope of the patent’s protection.” 203 Ultimately, the Court held the settlement agreement being reviewed did “nothing that would place it beyond the legitimate exclusionary scope of Zeneca’s patent,” and therefore the Court affirmed the district court. 204 However, although the Tamoxifen opinion frequently cited the lower Cipro decisions with seeming approval, 205 it did not explicitly adopt the rule of reason as the appropriate test like the Cipro court, assuming the patent scope had been exceeded. 206

The Tamoxifen dissent would have taken an entirely different approach. 207 The dissent somewhat agreed with the majority, insofar as

200. Id. at 202. For a brief discussion on the interaction and conflict between the two regimes, see supra notes 15-31 and accompanying text.

201. Id. at 203.

202. Id. at 206. Along these lines and in distinguishing Cardizem, the Court also said: “[w]e do not think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation.” Id. (emphasis added).

203. Id. at 212 (citing In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 528 (E.D.N.Y 2005). and Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005) (internal quotations omitted)). See also id. at 213 n.27 (“The central criterion as to the legality of a patent settlement agreement is whether it exceeds the scope of the patent’s protection.” (internal quotations omitted)).

204. Tamoxifen, 466 F.3d at 215, 221. Moreover, the Court also assessed the potential anticompetitive effects (even though this was probably unnecessary given the settlement did not exceed the patent scope) and concluded that the agreement “did not entirely foreclose competition in the market for tamoxifen.” Id. at 215.

205. See, e.g., id. at 212-215 (citing both the 2003 and 2005 Cipro cases).

206. See supra notes 177-182 and accompanying text. This is particularly relevant as both Cipro and Tamoxifen originated from the Eastern District of New York, but Cipro to date has not been appealed to the Second Circuit. Consequently, whether the Second Circuit will adopt the rule of reason test to review patent settlement agreements that exceed the exclusionary potential of the patent at issue remains to be seen.

207. See generally Tamoxifen, 466 F.3d at 221-232. (Pooler, C.J., dissenting).
"the strength of the patent must be central to any antitrust analysis involving a patent." However, the dissent proposed that a reviewing court must also look at: "(a) the amount the patent holder paid to keep the generic manufacturer from marketing its product, (b) the amount the generic manufacturer stood to earn during its period of exclusivity, and (c) any ancillary anti-competitive effects of the agreement including the presence or absence of a provision allowing the parties to manipulate the generic's exclusivity period."

III. Analysis

This section will briefly compare the holdings of the reverse payment cases so that one can fully understand the extent of the varying opinions between the courts. It continues by offering some practical tips for drafting/defending patent dispute settlement agreements based on patterns derived from these cases and various commentators. It concludes by offering a proposed position for the Supreme Court to adopt — namely, comparing the "exclusionary potential" of the agreement versus the patent before condemning the agreement as a Sherman Act violation.

A. Tying Everything Together: A Holding Comparison

Before Cipro and Tamoxifen, one could fairly say that the key points of disagreement between the courts were whether the agreements being reviewed "[were] per se illegal under the antitrust laws, and how such agreements should be analyzed." The courts appeared to be at opposite ends of a spectrum, with "[t]he Sixth Circuit believ[ing] that such agreements are per se illegal, while the Eleventh Circuit [maintaining] that the extent of the patent grant must be analyzed before any decision on the antitrust claim can be made." However, this oversimplifies the disagreement between the courts as it stands today.

At a rudimentary level, it looks like the Sixth and Eleventh Circuit decisions are at odds, but upon deeper reflection the positions might

208. Id. at 228.
209. Id. Accord Hovenkamp, et al., supra note 2, at 1759 (proposing that reverse payments be "presumptively unlawful" (i.e., per se unlawful), to only be rebutted by the "infringement plaintiff" showing, inter alia, "the size of the payment is no more than the expected value of litigation").
210. See infra notes 213-238 and accompanying text.
211. See infra notes 240-356 and accompanying text.
212. See infra notes 357-383 and accompanying text.
213. Mosier & Ritcheson, supra note 3, at 510.
214. Id.
not be that far apart. The Sixth Circuit in Cardizem was quick to apply the *per se* rule when it determined the settlement agreement would have reduced the market for the name-brand drug and generic equivalents.\(^{215}\) In contrast, the Eleventh Circuit in Valley Drug took issue with the Sixth Circuit because the Sixth Circuit failed to compare the settlement agreement with the "exclusionary power" of the patent or differentiate between agreement provisions that had exceeded the patent scope.\(^{216}\)

Are the two holdings in Cardizem and Valley Drug really as incongruent as they may seem on the surface? As discussed, the Sixth Circuit also explicitly condemned the settlement agreement being reviewed because it had gone beyond "merely an attempt to enforce patent rights . . . ."\(^{217}\) Moreover, the Sixth Circuit referenced the court below, which had determined that the "agreement's restrictions extended to noninfringing and/or potentially noninfringing versions" of the generic drug at issue.\(^{218}\) A fair reading of this language suggests the Sixth Circuit *might* be inclined to accept a settlement agreement so long as it did not go beyond an attempt to enforce patent rights or cover noninfringing products. In other words, perhaps the Sixth Circuit gave at least some credence to whether the agreement exceeded the patent's "scope" and, finding that it had indeed exceeded the patent's protections, the Court applied the *per se* rule. The Eleventh Circuit in Valley Drug is then arguably analogous to Cardizem, insofar as the Eleventh Circuit held that, once an agreement has exceeded the patent scope, a court could then apply "traditional" antitrust analysis (i.e., either *per se* or rule of reason).\(^{219}\)

Any similarity notwithstanding, one cannot be sure if the Sixth Circuit would adopt the Eleventh Circuit's position, especially since Cardizem is the only Sixth Circuit opinion available discussing this issue. Moreover, the Valley Drug opinion operates under the assumption that the two courts are indeed at odds, apparently believing that the Sixth Circuit applied *per se* scrutiny "merely" because the parties had delayed the generic's entry with the reverse payment.\(^{220}\) Never-

\(^{215}\) In re Cardizem CD Antitrust Litigation, 332 F.3d 896, 911 (6th Cir. 2003).


\(^{217}\) Cardizem, 332 F.3d at 908.

\(^{218}\) Id. at 908 n.13. See also M. Elaine Johnston & Matthew Galvin, Antitrust Aspects of Settling Intellectual Property Litigation, 867 PLI/PAT 159, 182 (2006).

\(^{219}\) See Valley Drug, 344 F.3d at 1312.

\(^{220}\) See id. at 1312 n.26 (holding that "[t]o the extent that the Sixth Circuit suggests that a settlement of patent litigation was a *per se* violation . . . merely because it involves a generic's agreement to delay marketing until resolution of the patent infringement case in exchange for [reverse] payments, we respectfully disagree.").
theless, there is no need to reconcile the holdings here. The Eleventh Circuit in *Valley Drug* is correct — the Sixth Circuit did not compare the settlement with the "exclusionary power" of the patent or determine if any provisions did not exceed this power. Also, most commentators analyzing the reverse payment problem seem to believe these two opinions are fundamentally incongruous.\(^2\) Thus, unless the Sixth Circuit decides to clarify, one can safely operate under the same assumption of incongruity.

Comparing the remaining cases, the divergence does not necessarily get any easier to swallow. On remand from *Valley Drug*, the *Terazosin* court applied the *per se* rule to the agreement at issue (like the Sixth Circuit),\(^2\) but only after it considered the "exclusionary scope" of the patent (unlike the Sixth Circuit).\(^2\) However, the *Schering* court later declared that both of the traditional analytical approaches are "ill suited for an antitrust analysis of patent cases", and crafted its own test.\(^2\) Moreover, although the Eleventh Circuit did so in *Valley Drug*,\(^2\) the same court in *Schering* did not say whether traditional antitrust analysis could then be applied if the agreement exceeded the patent's exclusionary scope.\(^2\) This distinction could be extremely

\(^{221}\) See, e.g., Burford, supra note 56, at 371 (comparing *Valley Drug* to *Cardizem* and asserting "[i]n cases with similar facts, the Sixth Circuit and Eleventh Circuit have ruled differently on issues of alleged pharmaceutical antitrust violations."); Deborah A. Coleman, Antitrust Issues in the Litigation and Settlement of Infringement Claims, 37 Akron L. Rev. 263, 276–77 (2004) (noting that the Sixth Circuit applied the *per se* standard in *Cardizem*, whereas "most tribunals have considered the purpose and actual effect of an infringement settlement agreement . . ."); Mosier & Ritcheson, supra note 3, at 497 (referring to *Cardizem and Valley Drug* as "seemingly contradictory"); Hovenkamp, supra note 34, at 26 (asserting that *Valley Drug* "required a full rule of reason analysis," which was "in contrast" to the Sixth Circuit's *per se* approach in *Cardizem*); Reed, supra note 45, at 468 (asserting that "[a] mere three months after the Sixth Circuit decided *In re Cardizem*, the Eleventh Circuit reintroduced ambiguity at the circuit level with its decision in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*").


\(^{223}\) See id. at 1310–11.

\(^{224}\) Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1065–66 (11th Cir. 2005) (holding "the proper analysis of antitrust liability [of a patent settlement] requires an examination of: (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"). Yet, recall that *Schering* did not overrule *Terazosin* because the district court was considering an interim settlement as opposed to a final settlement. *Id.* at 1066 n.14. Consequently, the *Schering* court held that "[g]iven these material distinctions, the same analysis cannot apply." *Id.*

\(^{225}\) See *Valley Drug v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003).

\(^{226}\) See *Schering*, 402 F.3d at 1076. To be fair, the *Schering* court never got a chance because it apparently found that the settlement agreement did not exceed the patent. See infra notes 293–299 and accompanying text. Yet, while the Eleventh Circuit recently upheld the *Schering* analytical approach in *Andrx Pharmaceuticals v. Elan Corp.*, the Court never made an antitrust analysis, as the *Andrx* decision is a pleading sufficiency matter under Federal Rule of Civil Procedure 12(c). See *Andrx Pharm. v. Elan Corp.*, 421 F.3d 1227, 1235 (11th Cir. 2005).
important for settling parties because Valley Drug leaves the door open for both traditional antitrust approaches even after an exclusionary scope analysis.227 In other words, broadly read, an agreement under Valley Drug could fail an exclusionary analysis and might still garner either the more flexible rule of reason analysis or the ominous "per se" rule, and this approach would effectively give settling parties a second chance at salvation. Conversely, Schering can be read as a mandate to stop any antitrust consideration of a patent settlement at the exclusionary scope doorstep, as the Court said "both approaches" are inappropriate for patent cases.228 This would be a one-shot deal. In short, even within the Eleventh Circuit alone, there is some perplexing ambiguity that warrants clarification.

To make matters worse, remember the Terazosin court, following Valley Drug but before Schering, considered exclusionary scope but then went into a traditional antitrust analysis and chose per se illegality.229 However, recall that Schering differentiated itself from Terazosin because the agreement the lower court reviewed was not "final."230 One could fairly interpret this as the Eleventh Circuit believing that further "traditional" antitrust analysis (per se analysis at that) is appropriate in the "interim" agreement context, but otherwise a reviewer should only make an "exclusionary potential" analysis and stop there. One cannot be sure, but again this distinction could be important to settling parties facing later antitrust challenges.

Furthermore, shortly after Schering, the Eastern District of New York, in Cipro, held that it was unable to determine "whether the Eleventh Circuit intended to jettison the rule of reason analysis in the patent context or simply refine the analysis . . . ."231 Certainly, Schering does not make this clear. Yet, the Cipro court ultimately held it was going to use the rule of reason anyway in order to properly balance the "competing policies" between patent and antitrust law.232 In other words, like Terazosin, the Cipro court did not merely stop at the "exclusionary scope" analysis. Finally, while the Second Circuit in Tamoxifen frequently cited the lower Cipro decision with approval,233

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227. See supra note 219 and accompanying text.
228. See Schering, 402 F.3d at 1065–66.
229. See supra notes 222–223 and accompanying text.
230. See supra notes 140-141 and accompanying text.
it did not purport to adopt the rule of reason as the appropriate analytical test — even though the Tamoxifen opinion formally disapproves of the per se approach and purports to adopt the Schering court's exclusionary effect of the patent approach. In other words, like Schering, it is not clear if Tamoxifen dictates stopping at the "exclusionary" analysis or if there is still a place for the rule of reason.

Thus, all told, the divergence between approaches goes beyond merely the Sixth and Eleventh Circuits today, but nevertheless remains just as muddled. Except for the Sixth Circuit, the balance of the cases discussed above support some form of comparison between exclusionary potential of a settlement agreement versus the exclusionary potential of the patent before condemning the agreement as an antitrust violation. However, those opinions seem to disagree markedly as to whether, and to what extent, the traditional antitrust analytical schemes can or should come into play after such comparison. Also, one cannot minimize Posner's holding in Asahi, because "[f]or decades Judge Posner's jurisprudence has had a substantial impact on the development of antitrust law." As David Balto, former policy director for the Federal Trade Commission stated: "[w]hile many of the elements of [the] decision were only decided in dicta, the reasoning [in Asahi] will probably be looked to by the courts as welcome guidance in this contentious area." In short, the antitrust implications of patent settlement agreements remains very much in flux between jurisdictional lines.

B. Lessons Learned: How to Potentially Avoid an Antitrust Roadblock

At first blush, one might be inclined, especially after reading the foregoing summary of the case law, to avoid patent settlement agreements that might fall under the per se flag. Indeed, it can be a scary proposition for any practitioner to craft a settlement agreement designed to protect the client's interests and yet be uncertain of its severance. Moreover, with the changing face of the Supreme Court in the Chief Justice Roberts era, one cannot be sure whether the Su-

234. Id. at 206.
235. Id. at 212. Hovenkamp suggests that the Second Circuit found exclusion payments "per se legal" unless the underlying lawsuit is a "sham," but this may be a far reach. Hovenkamp Treatise, supra note 2, at 7-49.
236. See also Coleman, supra note 221, at 276-77 (finding that, unlike the Sixth Circuit, "most tribunals have considered the purpose and actual effect of an infringement settlement agreement." (emphasis added)).
238. Id.
preme Court will follow the Second/Eleventh Circuit's "exclusion-
ary"-oriented approach or the Sixth Circuit's strict antitrust
approach.\textsuperscript{239}

Nonetheless, these cases, along with recent commentators, provide
some guidance as to viable approaches for drafting and/or defending
patent settlement agreements that might otherwise offend antitrust
sensibilities. Although there is no "right" answer until the Supreme
Court weighs in, the following represents a few of the techniques one
might explore:

1. Use "Noerr-Pennington" Immunity to Avoid Antitrust Liability

Using a clearly defined antitrust immunity doctrine could be the
fastest and most efficient way to avoid the application of antitrust law
altogether. Accordingly, some commentators have noted, "parties
have attempted to use the Noerr doctrine to immunize patent litiga-
tion settlements from antitrust attack."\textsuperscript{240} Generally, "[t]he Noerr-
Pennington immunity is a First Amendment-based doctrine that pro-
tects private parties from liability under the Sherman Act in connec-
tion with efforts to petition for anticompetitive legislation."\textsuperscript{241} To put
it another way, under this doctrine, "a defendant is immune from
Sherman Act liability for concerted efforts to petition government to
pass legislation which has the effect of restraining or monopolizing
trade in favor of the defendant."\textsuperscript{242} Here, a defendant could argue
that, since a settlement arises from a judicial proceeding, the agree-
ment reached should be immune under Noerr (i.e., they are "petition-
ing").\textsuperscript{243} However, while such an argument may be potentially
availing, at least one recent commentator has found that "such argu-
ments have not yet been accepted by the courts."\textsuperscript{244} Thus, a Noerr

\textsuperscript{239} The Supreme Court denied certiorari to Valley Drug, Cardizem, and Schering). See dis-
cussion infra Part IV and text accompanying notes.

\textsuperscript{240} Mark L. Kovner, et al., Applying the Noerr Doctrine to Pharmaceutical Patent Settlements,

\textsuperscript{241} Freedom Holdings, Inc. v. Spitzer, 357 F.3d 205, 233 (2d Cir. 2004).

\textsuperscript{242} Andrx Pharm. v. Elan Corp., 421 F.3d 1227, 1233 (11th Cir. 2005).

\textsuperscript{243} Kovner, et al., supra note 241, at 623.

\textsuperscript{244} Id. See also Balto & Wolman, supra note 68, at 74–5 (noting that, while some courts have
accepted Noerr arguments, others have found that settlements between private parties may be
subject to antitrust challenges). See also Columbia Pictures Indus., Inc. v. Prof. Real Est. Inves-
tors, Inc., 944 F.2d 1525, 1528 (9th Cir. 1991), aff'd, 508 U.S. 49 (1993) (holding that "(a) decision
to accept or reject an offer of settlement is conduct incidental to the prosecution of the suit" and
therefore immune under Noerr); accord Balto & Wolman, supra note 16, at 468 n.486. Additionally,
in one recent case from the Eleventh Circuit, a Noerr argument was indeed successful, but
did not immunize the settlement agreement at issue. See Andrx Pharm., 421 F.3d at 1234 (hold-
ing defendant immune under Noerr for infringement suit against alleged infringer when the pat-
approach could be a practicable first line of defense, but should be used with caution.

2. **Focus on The Nature of the Agreement: Interim Versus Final**

The extent to which a client’s settlement did not completely settle the patent dispute may also play an important role in a future antitrust case. The Eleventh Circuit’s *Schering* decision was quick to differentiate itself from *Terazosin*, noting that the district court in *Terazosin* had applied the *per se* rule because the settlement agreement being reviewed did not finally resolve the dispute (i.e., it was an “interim” settlement).245 However, in *Schering*, the parties fully resolved the dispute with the agreement (i.e., it was a final settlement that disposed of the litigation).246 The Eleventh Circuit called this distinction both “material” and “critical” to the approach it adopted, under which it upheld the settlement agreement being reviewed.247 Other “final” agreements discussed include the Zenith agreement in *Valley Drug*,248 the Bayer/Barr agreement in *Cipro*,249 and the Zeneca/Barr agreement in *Tamoxifen*250 — all of which did not garner *per se* scrutiny and were upheld by their respective courts. Also, although one cannot be sure of the Supreme Court’s reason for denying *certiorari* to *Cardizem*, the Solicitor General argued against reviewing that case because the Sixth Circuit’s opinion could fairly be read as applying the *per se* rule only to “interim” settlement agreements.251 Thus, it is apparent that drafters of patent settlement agreements should at a minimum craft these agreements as fully resolving the dispute rather than as an interim agreement that only temporarily settles the case.

3. **Spotlight Public Policy Considerations**

Another useful argument in an antitrust suit involving a patent settlement agreement requires the proponent to focus on public policy. Dispute settlement agreements are encouraged in our legal system.252

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245. *See Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1064–65 (11th Cir. 2005). *See also supra* notes 140-142 and accompanying text.  
246. *See Schering*, 402 F.3d at 1064–65. *See also supra* notes 140-142 and accompanying text.  
248. *See supra* notes 93-94 and accompanying text.  
249. *See supra* notes 171-172 and accompanying text.  
250. *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 214 (2d Cir. 2006) (noting that the agreement at issue “ended all litigation between Zeneca and Barr.”).  
251. *See infra* notes 393–395 and accompanying text.  
Scholars and courts alike agree that judges should favor settlements as a matter of sound public policy because settlements conserve time and limit expensive litigation.253 Along these lines, one recent commentator asserted that the rule of reason test better balances three different public policy interests — "fostering innovation, competition, and the consensual resolution of disputes."254 This argument mirrors the 2003 reasoning in Cipro, where the Eastern District of New York found the rule of reason best provided the flexibility needed to compare the competing policies behind patent and antitrust law.255 Similarly, another observer has said that public policy must "take into account and balance all three relevant social policies — pro-competition, pro-patent, and pro-settlement — and formulate rules leading to the lowest net social cost when all relevant costs are factored."256 Since the per se approach is not a balancing test and does not take into account these policies, adopting the per se rule "would be overinclusive, proscribing far more actions than required by the principles of antitrust."257

Furthermore, Judge Posner in Asahi noted that “[t]he general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.”258 The Eleventh Circuit in Schering held that “[t]here is no question that settlements provide a number of private and social benefits as opposed to the in-veterate and costly effects of litigation.”259 In the 2005 Cipro case, the Eastern District of New York found that “[r]equirign parties to a lawsuit to either litigate or negotiate a settlement in the public interest . . . is, as a practical matter, tantamount to establishing a rule requiring litigants to continue to litigate when they would prefer to settle and to act as unwilling private attorneys general and to bear the various costs and risks of litigation.”260 Finally, in Tamoxifen, the Second Circuit said that, “[w]here a case is complex and expensive, and resolution of

253. Speed Shore Corp. v. Woudenberg Enter., 605 F.2d 469, 473 (9th Cir. 1979). Accord O’Rourke & Brodley, supra note 49, at 1773 (“The law generally favors settlements because they conserve public administrative and judicial resources. . . .”). See also Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976) (“[settlement agreements should . . . be upheld whenever equitable and policy considerations permit”).
254. See Coleman, supra note 221, at 277.
257. Reed, supra note 45, at 479–80.
259. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1075 (11th Cir. 2005).
the case will benefit the public, the public has a strong interest in set-
ttlement. The trial court must protect the public interest, as well as the
interests of the parties, by encouraging the most fair and efficient
resolution.”261

However, public policy may only get a questionable patent settle-
ment agreement so far. According to the Supreme Court, only settle-
ments of infringement proceedings involving legitimately conflicting
patent claims are favored.262 Where the purpose of a settlement is not
to resolve a bona fide patent dispute but to exclude a mutual competi-
tor of the settling parties, the settlement may be subject to antitrust
scrutiny.263 Thus, while a settlement’s favored status might be given
some credence in later antitrust review, a patent settlement with ex-
tensive antitrust baggage may not necessarily escape unscathed.264

4. Focus on the Patent’s “Exclusionary Potential”

Finally, the most viable argument attorneys have in defending pat-
ent settlement agreements is focusing the court’s attention on the “ex-
clusionary potential” of the patent as compared to the settlement
agreement. As Professor Hovenkamp asserted, “most licenses that
limit output or divide markets are lawful if the underlying IP rights
are valid and infringed, since the owner of a valid IP right would have
the right to prevent the licensee from selling into the market at all.”265
Moreover, while some agreements may “create clear competitive
harm. . . .” Hovenkamp believes “[t]hose competitive harms are toler-
able if — but only if — they are part of the supracompetitive return
the government has granted to an IP owner under a social policy de-
dsigned to encourage innovation.”266

261. In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187, 202 (2d Cir. 2006) (quoting
United States v. Glen Falls Newspapers, Inc., 160 F.3d 853, 856-57 (2d Cir. 1998)).
264. See Coleman, supra note 221, at 264.
265. Hovenkamp Treatise, supra note 2, at 7-27. However, Hovenkamp also cautions that “if
a licensee could have produced a noninfringing substitute, but chose to enter into an arrange-
ment with the patentee to divide markets, cartel concerns are heightened.” Id. at 7-27 n.34.
266. Hovenkamp Treatise, supra note 2, at 7-27 (emphasis added). Hovenkamp does not to
define the term “supracompetitive.” The Cipro court also uses the term, opining that “charging
supracompetitive prices [is] at the core of the patentee’s rights.” In re Ciprofloxacin Hydrochlo-
ride Antitrust Litig., 363 F. Supp. 2d 514, 540 (E.D.N.Y 2005) (citation omitted). Unfortunately,
Black’s Law Dictionary does not contain the term either, at least as the Cipro court or
Hovenkamp are using it. However, the phrase “supra” is Latin for “above,” see BLACK’S LAW
DICTIONARY, 8th ed. (2004), so a fair reading of the phrase “supracompetitive” would be activi-
ties that appear as not competitive (e.g., charging prices above what one would consider competi-
tive). In other words, since the government grants the patentee under the Patent Act to what
amounts to a legal (i.e., permissible or tolerable) monopoly, the patentee can charge whatever
Accordingly, a court following the Second and Eleventh Circuits might be inclined to compare the exclusionary potential of the patent against the settlement agreement before turning to the typical antitrust analysis methods. The same court might also focus on the exclusionary potential comparison alone without ever getting into traditional antitrust law. Either way, as long as the exclusionary potential of a client’s settlement is not broader than the patent’s exclusionary potential, the agreement might survive — at least in the Eleventh (and now Second) Circuit anyway. Assuming a court is willing to entertain such an argument, what does “exclusionary potential” mean exactly? The “reverse payment” cases and commentators have shown three paths to explore.

a. Patent Validity

The extent to which a patent may be found invalid might be determinative of its “exclusionary potential,” but a court may decide not to separately assess patent validity in an antitrust case. For example, the Eastern District of New York in Cipro extensively reviewed Valley Drug, Cardizem, Asahi, and Schering to determine whether “the exclusionary power of the patent for the purposes of the anti-competitive effects analysis should be tempered by its potential invalidity.” From a practical standpoint, this would seem logical — a patent can only exclude others if it is a valid patent. If it is found invalid, the patent is then, at an abstract level, no longer a patent and thus loses its power to legally exclude under the Patent Act. However, the Cipro court found that, “[a]lthough those courts have come to different conclusions regarding the legality of [reverse] payments at issue in those cases, they have generally agreed that an antitrust court need not make an independent assessment of the underlying patent’s validity.” Similarly, the Court also held it would be inappropriate “to discount the exclusionary power of the patent by any probability that the [patent might later be] found invalid.” Instead, “[s]uch an in-
quiry would undermine any certainty for patent litigants seeking to settle their disputes." This reasoning is also persuasive — there might be no advantage to settlement if resolving a potential antitrust challenge would require diving headlong into the patent litigation that the parties sought to avoid in the first place. Thus, the Court held that it would not conduct an "after-the-fact" validity inquiry in a settled case, and instead the only inquiry would be "whether the Agreements constrained competition beyond the scope of the patent claims." The Second Circuit essentially approved this approach in Tamoxifen, holding that it would not judge a "post-trial, pre-appeal settlement on the basis of the likelihood vel non of [the patent holder’s] success had it not settled but rather pursued its appeal." Instead, the Second Circuit opted to "embrace the general rule that [courts should] ordinarily refrain from guessing what a [different] court will hold or would have held."

Along these lines, some pundits maintain that "[d]etermining patent validity in an antitrust proceeding would greatly complicate antitrust litigation" because, inter alia: (1) "[t]he enforcement agencies [i.e., the Department of Justice and the Federal Trade Commission] lack expertise in patents," and (2) "antitrust judges may be reluctant to second-guess how a patent court might rule in a pending infringement case." While this may be true for the agencies, both the Patent Act and the Sherman Act are federal causes of action, so there is no such thing as an "antitrust judge" or a "patent court" — at least not at the federal district level. But, there still could be reluctance at the appellate level, as only the Federal Circuit hears patent infringement cases on appeal. Even still, other scholars assert that "[p]roving that the pioneer would prevail in an infringement action neither comports with a patent’s statutory presumption of validity, nor with the judicial clear and convincing evidence standard required to invalidate an issued patent."

Yet, recall that the Terazosin court held that, because the patent was likely to be held invalid, the settlement agreement exceeded the
Several commentators have also endorsed this approach, arguing that assessing the exclusionary value of a patent should involve at least some form of validity inquiry. In short, the extent to which a patent may be found invalid may be determinative of its exclusionary potential, if validity is considered at all.

b. Patent Terms

If the court decides not to separately assess a patent’s validity, where does that decision leave our definition of “exclusionary potential”? Generally speaking, the right of a patent holder to exclude others from using his or her invention is also found within the patent’s “claims,” which are “determined in large part through a patentee’s written description, as limited by existing prior art, novelty, and obviousness limitations.” In other words, the “exclusionary potential” of a patent — the patent’s innate ability to exclude others except for the patent holder — is found within the terms of the patent itself. As such, if the patent terms would have allowed the patent holder to


282. See Crane, supra note 45, at 698-99 (asserting IP settlement agreements, at least in the reverse payment context, “should not be accorded per se treatment under the antitrust laws and should be approved so long as the patentee has a strong ex ante likelihood of succeeding on the merits of its infringement claim and thereby excluding the infringing use from the market.”); Hovenkamp, et al., supra note 2, at 1759 (proposing that reverse payments be “presumptively unlawful,” to only be rebutted by the “infringement plaintiff” showing, inter alia, “the ex ante likelihood of prevailing in its infringement lawsuit”). Accord Remarks of R. Hewitt Pate, Acting Assistant Attorney General, Antitrust Division, U.S. Justice Department, Address at the American Intellectual Property Law Association: Antitrust & Intellectual Property (Jan. 24, 2003), available at http://www.usdoj.gov/atr/public/speeches/200701.htm (last visited Dec. 1, 2006) (noting Justice Department policy as of 2003 that “[i]f a patent is valid and infringed, then any competitive entry allowed by a settlement is up to the patent holder.”). Cf. O’Rourke & Brodley, supra note 49, at 1781-1787 (agreeing that what makes reverse payments suspicious is their potential for invalidity, but asserting that a rule of presumptive illegality will provide an incentive for parties to enter into more procompetitive settlements and that a direct determination of validity would consequently not be needed).

283. The Cipro court acknowledges Terazosin as the one “possible exception” to the general rule that patent a patent validity analysis is inappropriate. See In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 529 (E.D.N.Y 2005). For an in-depth article on the tension between patent validity and antitrust law, see generally Christopher R. Leslie, The Anticompetitive Effects of Unenforced Invalid Patents, 91 M I N N . L. REV. 101 (2006). Leslie concludes that “neither patent law or antitrust law is up to the task of deterring and punishing monopolists who maintain market power through the possession of invalid patents.” Id. at 183.


285. See Terazosin, 352 F. Supp. 2d at 1297 (“The legal scope of [a patent] is measured by its numbered claims.”). See also Valley Drug v. Geneva Pharm., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003) (holding that the “precise terms of the [patent] grant define the limits of a patentee’s monopoly and the area in which the patentee is freed from competition of price, service, quality, or otherwise” and quoting United States v. Line Material, 300 U.S. 287, 300 (1948)).
exclude the alleged infringer even without settlement agreement, the agreement ought to withstand an "exclusionary potential" analysis.

_Schering_ is an excellent example of such a case. There, the Eleventh Circuit noted that, "[e]ngrafted into the patent law is the notion that a patent grant 'bestows the right to exclude others from profiting by the patented invention.' "286 The Court also noted some important policy arguments regarding the "delicate balance" between the antitrust and patent regulatory schemes, saying the "application of antitrust law to markets affected by the exclusionary statutes set forth in the patent law cannot discount the rights of the patent holder."287 From this, the Court concluded "a patent holder does not incur antitrust liability when it chooses to exclude others from producing its patented work."288

Turning once again to the facts of the case, the Court noted that, by virtue of its patent right, Schering had obtained the legal right to exclude Upsher and ESI from the market until either proved the patent's invalidity or that their respective products were not infringing.289 In short, the Court determined that the patent's description was broad enough to exclude the competitors because the patent's scope "gave Schering the lawful right to exclude infringing products from the market" until the patent's expiration.290 Additionally, the evidence showed that Upsher and ESI could not have entered into the market before the patent's expiration without infringing, which "reinforce[d] the validity and strength of the patent."291

However, since patent law does not allow the patent holder to extend his or her "monopoly beyond the statutory right to exclude," the _Schering_ court turned its attention to the scope of the settlement agreements.292 The Court looked at whether a $60 million payment to Upsher was not a bona fide royalty payment under the licenses Schering had obtained for Upsher's product, and held Schering "had a long-documented and ongoing interest in licensing" a product similar to Upsher's "Niacor" product.293 Thus, the Court held the payment was a fair price for the Upsher products rather than an attempt to extend

287. _Schering_, 402 F.3d at 1067 (emphasis added) (citing Simpson v. Union Oil Co., 377 U.S. 13, 14 (1964)).
288. _Id._
289. _Id._ at 1066.
290. _Id._ at 1067.
291. _Id._ at 1068.
292. _Schering_, 402 F.3d at 1067.
293. _Id._ at 1069.
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Schering's patent monopoly, and just because the agreement also included Upsher's entry date into the relevant market, "one cannot infer that the payments were solely for the delay rather than the licenses."\(^{294}\)

As to ESI, the Federal Trade Commission complained that portion of the $30 million payment to ESI contained provisions for legal fees and a payment contingent of FDA approval, unlike the Upsher agreement where the entire payment was supposedly for licensing of Upsher's products.\(^{295}\) In response, the Court noted "[t]hat parties to a patent dispute may exchange consideration to settle their litigation has been endorsed by the Supreme Court."\(^{296}\) The Court also held that "[p]atent owners should not be in a worse position, by virtue of the patent right, to negotiate and settle surrounding lawsuits."\(^{297}\) Accordingly, the Court found that, since ESI could not have entered into the market before the expiration of Schering's patent, "this [was] not the case of a 'naked payment' aimed to delay the entry of a product that [was] 'legally ready and able to compete with Schering.'"\(^{298}\)

The recent Tamoxifen decision is further applicable to an "exclusionary potential" argument. There, the Second Circuit held the settlement agreement at issue "did not extend the patent monopoly by restraining the introduction or marketing of unrelated or non-infringing products."\(^{299}\) Instead, "Zeneca's tamoxifen patent [was] not a formulation patent, which covers only specific formulations or delivery methods of compounds; rather, it [was] a patent on a compound that, by its nature, excludes all generic versions of the drug."\(^{300}\) Thus, since all generic versions of the drug would infringe on Zeneca's patent, the settlement agreement, by merely excluding the manufacture of one generic version, did not violate the Sherman Act and was within the patent's exclusionary potential.\(^{301}\)

What can reasonably be taken from Schering and Tamoxifen is as follows: courts that decide to look beyond a patent's potential invalidity may look to the scope of the patent claims. If, under the patent

\(^{294}\) Id. at 1071.

\(^{295}\) Id. at 1071-72.

\(^{296}\) Id. at 1072 (citing Standard Oil, 283 U.S. 163 (1931)).

\(^{297}\) Schering, 402 F.3d at 1072.

\(^{298}\) Id. at 1072 (quoting from FTC's arguments).

\(^{299}\) In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187, 213 (2d Cir. 2006). Recall that the Second Circuit also purposefully distinguished itself from the Sixth Circuit's Cardizem decision, insofar as the problematic agreement in that case "included not only a substantial reverse payment but also an agreement that the generic manufacturer would not market non-infringing products." Id. at 213-14.

\(^{300}\) Id. at 214 (emphasis added).

\(^{301}\) Id.
claims alone, the patent holder could have legally excluded the competitor from the market, then any settlement agreement, no matter what the payment structure is, ought to be upheld. If the settlement agreement goes beyond that patent’s scope — i.e., the agreement allows the patent holder to exclude a competitor when the holder could not have done so under the patent terms or the agreement extends the patent monopoly period — then that settlement agreement has gone beyond the “exclusionary potential” of the patent and is in jeopardy.

c. Analysis of Professor Hovenkamp’s Take on “Exclusionary Potential”

Professor Hovenkamp seems to implicitly endorse the “exclusionary potential” approach. He believes that “the traditional ‘rule of reason’ analysis is not a good fit for settlement agreements that would be unlawful per se but for the presence of an IP claim.” To explain why, he reminds us that the rule of reason is a balancing test that considers whether an agreement is more anticompetitive than any offsetting pro-competitive benefits — i.e., “whether the agreement yields lower or higher marketwide output.” In simpler terms, “[t]he rule of reason is designed to assess whether a practice tends to diminish marketwide output.” In contrast, Hovenkamp believes the problem of an agreement that would be unlawful per se but for the presence of an IP claim involves, inter alia, “the likely validity and scope of the claimed IP rights.” Consequently, he asserts such cases should be disposed of “on IP grounds” alone since the agreements would be procompetitive if the patent were valid and infringed. Using his example:

[S]uppose that two competitors in a patent dispute reach a [settlement] agreement. Under the settlement agreement the infringement plaintiff gives the infringement defendant a license to practice the disputed technology east of the Mississippi, while reserving to itself the right to practice the technology west of the Mississippi. [Without] integration of operations [between] the firms, . . . this agreement would be a per se unlawful naked territorial division in the absence of an IP dispute. At the same time, however, it would

302. Hovenkamp Treatise, supra note 2, at 7-10. Conversely, Professor Hovenkamp believes patent settlement agreements should qualify for rule of reason treatment generally “when they involve competitors but create only non-exclusive rights” because nonexclusive rights allow for production outside the settlement agreement and therefore do not cause output below competitive levels, especially if the agreement allows for sublicensing. Id. at 7-14 and 7-14 n.21.
303. See Hovenkamp Treatise, supra note 2, at 7-11.
304. Id. at 7-10.
305. Id. at 7-10.
306. Id.
be a completely legal license of a patent, because the Patent Act expressly provides that a patentee may make territorially restricted licenses.\textsuperscript{307}

In such a case, Hovenkamp instructs there would be no point to a rule of reason analysis since that test looks for output reducing agreements, whereas such an agreement is presumptively output increasing since the patent holder could have rightfully excluded the other party within its IP rights.\textsuperscript{308} As such, Hovenkamp asserts “[a]ntitrust’s rule of reason cannot help with that IP inquiry.”\textsuperscript{309} This would hold true not just for agreements that restrict territory but also price restricted licenses\textsuperscript{310} or production (i.e., output) limits,\textsuperscript{311} both of which are part of a patent holder’s rights under the Patent Act.\textsuperscript{312} Therefore, Hovenkamp’s approach here could be seen as in line with the Eleventh Circuit’s opinion in Schering, which says both the \textit{per se} rule and the rule of reason are “ill-suited for an antitrust analysis of patent cases because they seek to determine whether the challenged conduct had an anticompetitive effect on the market” and “[t]he anticompetitive effect is already present” for patents.\textsuperscript{313}

On the other hand, Hovenkamp would probably only agree to the applicability of the \textit{Schering} approach to patent settlement agree-

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\textsuperscript{307} Id. at 7-12, 7-13. \textit{But see} Balto & Wolman, supra note 16, at 438 (“On occasion, territorial restrictions in licenses have been struck down where the licensing agreements itself was seen by the courts as a sham or pretext for implementing a market division scheme between competitors.”).

\textsuperscript{308} Hovenkamp Treatise, supra note 2, at 7-13.

\textsuperscript{309} Id. at 7-10.

\textsuperscript{310} See Hovenkamp Treatise, supra note 2, at 7-12 n.11 (noting that the Supreme Court has “held that a patentee could license a competitor subject to a restriction on the price the competitor would charge for goods embodying the patent.”). \textit{But see} Balto & Wolman, supra note 16, at 439 (“There is considerable uncertainty regarding the circumstances when price restrictions will be considered antitrust violations.”).

\textsuperscript{311} See Hovenkamp Treatise, supra note 2, at 7-28 (“Production limits should generally be treated in the same way [as territory restricted licenses], because inherent in the concept of a license is the right to license a specific amount.”). \textit{See also} Balto & Wolman, supra note 16, at 440-41 (asserting that “…the courts have generally held that provisions in patent licenses that restrict the quantity of patented articles produced by the licensor are lawful. There is a split of authority, however, as to whether the patent grant protects a patentee who includes a provision in a patent license that limits the quantity of unpatented products produced by the patented apparatus.”).

\textsuperscript{312} \textit{See also} Hovenkamp, et al., supra note 2, at 1749 (asserting that “price- and output restricted licenses are generally illegal in the absence of a valid IP right, but generally legal where such a right exists.”).

\textsuperscript{313} Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1065-66 (11th Cir. 2005). This is not to suggest that Hovenkamp actually agrees with the Eleventh Circuit. He feels the \textit{Schering} decision gives too much deference to the Patent & Trademark office (“PTO”), as the validity of patents should always be an issue and not left to presumptive validity. \textit{See} Hovenkamp Treatise, supra note 2, at 7-46. He also notes that, while the decision serves the interests of judicial economy, it ignores “the competitive realities” of the case. Id. at 7-47.
ments beyond the "reverse payment" context. He maintains that reverse payment agreements are, "[i]nsofar as antitrust is concerned, among the most problematic settlement agreements. . ." because "there is no plausible procompetitive reason to enter into such an agreement." Instead, these types of agreements are particularly irksome for Hovenkamp, because "[o]ne can easily give reasons why exclusion payments are anticompetitive: they invoke a government regulation to exclude all competitors from a market, even in circumstances where entry would be likely absent the payments." As such, he supports the Sixth Circuit's position of "presumptive illegality" for such payments. However, Hovenkamp would make any payment from a patentee to an infringement defendant "presumptively unlawful" unless the patentee shows both: "(1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit." Fortunately, this is a rebuttable presumption but it still puts the patentee under the gun.

But, Hovenkamp is not without his critics in this regard, chief among them being Judge Posner in Asahi. As Posner notes, a "payment" does not have to involve money. Virtually any settlement agreement with consideration going from holder to infringer may be viewed as a "reverse payment" to the defendant "who would not settle unless he had something to show for the settlement. . ." Thus, to call such settlements presumptively illegal would mean certain death for patent settlements all together. However, fairly read with his other conclusions in this area, it appears that Hovenkamp prefers presumptive illegality only in the "novel" area of pharmaceutical industry reverse payments, but would accept an "exclusionary potential" approach for other types of patent settlement agreements.

315. Hovenkamp Treatise, supra note 2, at 7-43.
317. Id. at 712. Hovenkamp also approves of the dissents' arguments in Tamoxifen. See Hovenkamp Treatise, supra note 2, at 7-50.
318. Hovenkamp, et al., supra note 2, at 1759.
319. See Asahi Glass Co., Ltd. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003). See also supra notes 161-166 and accompanying text. For further criticism on Hovenkamp's approach to reverse payments, see generally Crane, supra note 45.
321. Id.
322. Id.
323. See Hovenkamp, supra note 34, at 24.
Yet, even if the case did not involve reverse payments, Hovenkamp would not let a patent dispute settlement go without at least some examination of its potential anticompetitive effects; just not as extensively as the rule of reason mandates. Rather, he proposes the following test: "once conduct is found that would likely be an antitrust violation in the absence of a settlement, some care must be taken to ensure (1) that the parties did have a bona fide dispute, (2) the settlement is a reasonable accommodation, and (3) that the settlement is not more anticompetitive than the likely outcome of the litigation."324 This test might be viewed favorably in future antitrust cases, as the district court on remand from Valley Drug used this test when it lacked guidance from the appellate court.325

Both the Supreme Court and Judge Posner support the first part of Hovenkamp's test. In Asahi, Posner held that "[o]nly if a patent settlement is a device from circumventing antitrust law is it vulnerable to an antitrust suit."326 Similarly, the Supreme Court has said that where a settlement's purpose is not to resolve a bona fide patent dispute but to exclude a mutual competitor of the parties to the agreement, the settlement should be subjected to antitrust scrutiny.327 However, Posner also instructed that, under Supreme Court precedent, "a suit charging sham litigation as a method of monopolization must fail unless the litigation is objectively baseless," which means that subjective intent to harm or even hostility towards competitors is immaterial.328 Posner also held that "[i]t is not 'bad faith'... to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights."9329 Even if the patent holder is not confident in the validity of his patent, the Patent Act gives all patents a presumption of validity and entitles the patent holder to defend that validity in court.330 Thus, a settlement along these lines should be upheld "unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment."331 So,

324. Hovenkamp, et al., supra note 2, at 1727; accord Hovenkamp Treatise, supra note 2, at 7-10.
328. Asahi, 289 F. Supp. 2d at 993 (emphasis supplied and citing Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., 508 U.S. 49, 60-61 (1993)).
330. Id. at 992-93 (citing 35 U.S.C. § 282 (2007)).
331. Id. at 993 (emphasis added).
according to Posner, as long as there is a "colorable infringement claim," the infringement suit should not be viewed as an "anticompetitive measure."\textsuperscript{332} The Second Circuit has essentially sided with Posner, holding ". . . so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."\textsuperscript{333} This standard gives settling parties considerable wiggle room.

The second and third parts of Professor Hovenkamp's test are problematic however. Restating these elements somewhat differently in the same article, Hovenkamp stated that ". . . the settlement agreement must be within the range of likely outcomes of litigation, or no more anticompetitive than such an outcome would have been."\textsuperscript{334} The "likely" outcome of a trial is hard to predict and is thus a vague review standard. Generally speaking, a "likely" outcome of any patent infringement litigation is one that does not exceed the remedies allowable under the Patent Act, which include continued exclusion of competitors for the remaining patent term as well as further injunctive and monetary relief if the patent holder prevails.\textsuperscript{335} Thus, it naturally follows that a patent dispute settlement agreement should not exceed these remedies without running afoul of the Sherman Act. This is just another way of saying that the agreement should not exceed the power that the patent gives that patentee, and is not inapposite to an "exclusionary potential" analysis.

Beyond this however, it is difficult to conceive of an agreement that is not within the "likely" range of outcomes of the litigation but still within the bounds of the Patent Act. One form of agreement that comes to mind is a reverse payment. A reverse payment agreement is not what one would expect as the "likely" outcome of litigation, but such agreements are not prohibited anywhere in the Patent Act. If the patentee prevailed and the patent was deemed valid and infringed,

\textsuperscript{332} Id. at 995.

\textsuperscript{333} In re Tamoxifen Citrate Antitrust Litigation., 466 F.3d 187, 208-09 (2d Cir. 2006).

\textsuperscript{334} Hovenkamp, et al., supra note 2, at 1734 (emphasis added).

\textsuperscript{335} See generally 35 U.S.C. § 154 (2007) (outlining the general rights of a patent holder, including "the right to exclude others from making, using, offering for sale, or selling" the patented product for a term of 20 years); 35 U.S.C. §283 (2007) (providing for further injunctive relief that the court deems "reasonable"); 35 U.S.C. §284 (2007) (providing for damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court); 35 U.S.C. § 285 (2007) (providing that, in an exceptional case, the court may award attorney fees to the prevailing party).
he would get damages and other relief.\textsuperscript{336} The middle ground result would be settlement where, in Hovenkamp's words, "probably the most common outcome . . . is some type of agreement in which the infringement defendant pays a fee to the infringement plaintiff for a license coupled with some restrictions on the production or sale of the patented article."\textsuperscript{337} Conversely, if the patent holder lost and the patent was deemed invalid/not infringed, the patentee would be out court fees and the other attendant costs of litigation. Thus, if the patentee settles with the defendant for anything beyond these costs, this agreement would have gone beyond the "likely" outcome of the litigation in Hovenkamp's test. Indeed, as discussed above, Hovenkamp has said that, if litigation costs exceed a reverse payment, the reverse payment settlement should be prohibited.\textsuperscript{338} Hovenkamp also maintains that, "even a patentee who is one hundred percent certain that its patent will be declared valid and infringed would be willing [only] to make a payment that is lower than anticipated litigation costs."\textsuperscript{339} But, even conceding that reverse payments are not the usual outcome of a trial and that a likely victor would not normally settle beyond litigation costs, neither of these notions is universally true. As another commentator recently noted, economically rational companies will pay more than the costs of the litigation to settle a patent dispute, even if they would have prevailed at trial, due to the uncertainties of the litigation process.\textsuperscript{340} A variety of intangible factors go into settlement agreements and the amounts parties are willing to pay to dispose of a sticky litigation, and even a slam-dunk infringement case could still end badly for the patentee.\textsuperscript{341} Thus, considering any value exchanged between the parties compared to litigation costs is troubling.

Moreover, the anticompetitive effects of any settlement agreement are less relevant, perhaps merely red herrings, if the settlement agreement does not exceed the exclusionary potential of the patent. To put it another way, recall that Schering dictates "the proper analysis of antitrust liability [in a patent dispute settlement] requires an examination of: (1) the scope of the exclusionary potential of the patent; (2)

\textsuperscript{336} See supra note 335 and accompanying text.
\textsuperscript{337} Hovenkamp, supra note 34, at 23.
\textsuperscript{338} See also Hovenkamp, et al., supra note 2, at 1760.
\textsuperscript{339} Hovenkamp, supra note 34, at 25; accord Hovenkamp Treatise, supra note 2, at 7-39 n.98 ("[I]f the patentee was 100 percent sure of victory in the patent infringement suit, a settlement payment would not exceed the expected litigation costs.").
\textsuperscript{340} See Reed, supra note 45, at 476.
\textsuperscript{341} See Cotter, supra note 48, at 1813 (asserting "absolute certainty is probably rare and reverse payments are to be expected even when the plaintiff's probability of success is high but not certain.").
the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.” 342 (Step three is similar to the last part of Hovenkamp’s test, which states the settlement should not be “more anticompetitive than the likely outcome of the litigation.” 343) Once a defendant survives elements one and two of the Schering test, element three is arguably moot.

Take for example a basic patent for any conceivable invention, no matter how simple. As the Cipro court aptly noted, “an exclusion of competitors and charging of supracompetitive prices are at the core of the patentee’s rights, and are legitimate rewards of the patent monopoly.” 344 As part of these rights, the patentee may assign/license “to the whole or any specified part of the United States.” 345 Thus, outside of the dispute context, the patentee is allowed, under the Patent Act, to assign some or all of his/her patent rights, including the right to manufacture the claimed invention, or any aspect thereof, covered under the patent claims. 346 The holder could therefore license to another person the limited right to manufacture a certain number of items under the patent, which certainly would raise antitrust red flags as a classic “output” restriction outside of the IP context. 347 However, granting such a license would mean more competition than not, because the patent holder could simply choose not to grant the license at all, which is also his or her right under the Patent Act. 348

This also holds true within the litigation context, because “[i]f settlement negotiations fail[ed] and the patentee prevail[ed] in its suit, competition would be prevented to the same or an even greater extent because the [competitor] could not enter the market prior to the expiration of the patent.” 349 In other words, a patent, by virtue of being a

342. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005). See also supra notes 140-145 and accompanying text.
343. Hovenkamp, et al., supra note 2, at 1727.
346. See Schering, 402 F.3d at 1067 (“A patent grant gives its owner the right to grant licenses if it so chooses, or it may ride its wave alone until the patent expires.”).
347. Of course, if you are limiting the number of items a competitor can manufacture, you are restricting output. As discussed above, output restrictions are usually viewed as per se Sherman Act violations, at least outside of the patent context. See supra notes 33, 44 and accompanying text.
348. See Schering, 402 F.2d at 1056 (“Engrafted into the patent law is the notion that a patent grant bestows ‘the right to exclude others from profiting by the patented invention.’” (citation omitted)).
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patent, has some anticompetitive effects on the market (i.e., allowing the patent holder the choice of whom to license or defining how much of a patented invention may be produced); but, a settlement agreement within the scope of a patent that allows at least some production of the patented invention as opposed to none at all is more pro-competitive than anticompetitive. Indeed, even Professor Hovenkamp has said a settlement agreement is "competitively preferable to an outcome under which the patent is declared valid and the infringement defendant is excluded from the market altogether." And, even if the parties could have reached a more pro-competitive result than the licensing scheme/settlement agreement employed, the Supreme Court has essentially held that would-be challengers "have no right to second-guess whether some different agreement would have been more palatable." In short, as long a competition is prevented within the scope of the patent claims, a patent settlement agreement ought to withstand antitrust scrutiny under the "exclusionary potential" analysis, and reviewing any resulting anticompetitive effects would be a needless exercise.

In sum, settlement agreement drafters and defenders should be wary of any rights in the agreement beyond what the patent right gives — i.e., agreements that also extend to products not covered by the patent or agreements that delay entry into the relevant market beyond patent expiration. If this line is crossed, the exclusionary

350. See Hovenkamp Treatise, supra note 2, at 7-4 ("In an IP case, assuming a genuine dispute, the outcome of a settlement agreement that would otherwise produce an antitrust violation might be no more anticompetitive than the outcome of the underlying litigation. A judgment establishing the validity of a rival's claim might prevent a competitor from entering the market altogether, leaving the other with a monopoly. In such a case, a settlement that excludes the competitor from the market would not reduce competition that would otherwise legally exist, and a settlement involving a license even on restrictive terms would create more competition than if the IP owner had merely enforced its rights to the fullest extent.") (emphasis added).

351. Hovenkamp, supra note 34, at 23 (emphasis added).

352. In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 536 (E.D.N.Y 2005) (citing Verizon Comm'n, Inc. v. Law Offices of Curtis V. Trinko, 540 U.S. 398, 415-16 (2004)). But see Hovenkamp, et al, supra note 2, at 1727-28. ("In the face of uncertainty, the antitrust tribunal must also consider whether the parties might have settled on alternative, less restrictive terms."). Hovenkamp recently discussed the Trinko decision in a separate article, but does not seem to discuss this aspect of the case and how this would affect his analytical approach. See generally Hovenkamp, supra note 34.

353. However, the Tamoxifen court still looked at the resulting anti-competitive effects anyway. See In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187, 216 (2d Cir. 2006).

354. Hovenkamp provides a useful example of when patent scope has been exceeded. To paraphrase: suppose Ford claims that Chevrolet has infringed on its windshield wiper blade patent. The parties settle the dispute with an agreement that licenses use of design to Chevy but also restricts Ford from selling cars west of the Mississippi River and Chevy from selling to the east for some reason. Such a market division would be unlawful even if the patent right was valid and infringed because enforcing the patent for the blades has nothing to do with Chevy
effect of the settlement agreement extends beyond the exclusionary potential of the patent claims, and thus the settlement agreement is more than likely in antitrust jeopardy.\textsuperscript{355}

C. Proposed Solution: Adopt the "Exclusionary Potential" Approach

To resolve this issue, the Supreme Court should adopt a clear test to eliminate any further confusion — unless the Sixth Circuit clarifies its position in \textit{Cardizem}, putting it more in line with the Eleventh Circuit in \textit{Schering} in the meantime. Nevertheless, selecting an official test need not be an arduous task for the Supreme Court. As discussed below, the Court could justifiably adopt the "exclusionary potential" approach for a variety of reasons.\textsuperscript{356}

First, the Court is dealing with a systemic conflict — patent law and antitrust law simultaneously allowing and preventing monopolies — and it must carefully balance between competing objectives. Both regimes are equally important and, barring some future legislation creating an explicit antitrust exemption in the Patent or Sherman Acts covering patent dispute settlements, the Court must do nothing to tip the scales. With this broad goal guiding its hand, the Court should thus steer away from the harsh application of the \textit{per se} rule because "such a standard does not adequately take into consideration the rights of the patent holder."\textsuperscript{357} Indeed, the very language Patent Act gives the patentee "the right to exclude others from making, using, offering for sale, or selling the invention. . .."\textsuperscript{358} The patent right to exclude (or for that matter \textit{any} right to exclude) is inherently anticompetitive.\textsuperscript{359} So, applying a rigid test that does not consider any pro-competitive effects in spite of exclusion fails to give deference to the essential nature of the patent right and instead seemingly favors anti-

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\textsuperscript{355} See \textit{Tamoxifen}, 466 F.3d at 212-13 ("Whatever damage is done to competition by settlement is done pursuant to the monopoly extended to the patent holder by patent law unless the terms of the settlement enlarge the scope of that monopoly.").

\textsuperscript{356} In an article published contemporaneously with drafting of this Comment, Kristopher Reed proposed adopting a form of this approach as well. See Reed, \textit{supra} note 45, at 478. Reed does not however take into account the test as articulated in \textit{Schering} (at least not the 2005 version), nor does he consider any court decision after \textit{Valley Drug} as part of his proposal. Nevertheless, Reed's analysis appears well reasoned, and some of it has been incorporated in this sub-section.

\textsuperscript{357} Reed, \textit{supra} note 45, at 458.


\textsuperscript{359} See \textit{Schering-Plough Corp. v. FTC}, 402 F.3d 1056, 1066 (11th Cir. 2005).
trust over patent law. In other words, "[t]he problem with the Sixth Circuit's reasoning is that the patent itself could have the same detrimental effect on competition and consumer, irrespective of the settlement." Thus, the Cardizem approach should not be followed, especially since the Eleventh Circuit's approach in Schering best provides balance to the two competing regimes as it would condemn only those agreements that exceed the patentee's IP rights.

Furthermore, adopting the "exclusionary potential" approach would not offend the lower courts' present understanding of the proper balance between antitrust and patent law, and instead would comport with a discernible trend. As discussed, many of the lower courts have recently used some form of an exclusionary potential analysis when considering the antitrust implications of patent litigation settlements. Even Professor Hovenkamp, who thinks the Cardizem decision got it right, would likely accept an official adoption of an "exclusionary potential" analysis, at least outside of the "reverse payment" context. This trend among courts and scholars endorsing this approach, or at least some variance of it, ought to be followed to its logical conclusion and solidified as the proper analytical scheme.

Embracing the "exclusionary potential" approach also accords with much older patent settlement/antitrust jurisprudence. As far back as the early 1980's, the D.C. Circuit apparently employed an analogous approach in the U.S. v. Studiengesellschaft Kohle case. There, the Court overruled the district court who had applied the per se rule without considering the patent scope because "the very object of [the patent law] is monopoly . . . . The fact that the conditions in the contract keep up the monopoly does not render them illegal." Accordingly, the Court ruled that "a rule of reason rather than a per se rule" should apply because "the protection of the patent laws and the coverage of the antitrust laws are not separate issues." As such, "the conduct at issue [would only be deemed] illegal if it threaten[ed] competition in areas other than those protected by the patent . . . ." Ultimately, the Court held the lower court in error for "consider[ing] the scope of the patent protection irrespective of any competitive effects . . . , and then rul[ing] separately on the anticompetitive effects of

360. Reed, supra note 45, at 475.
361. See Schering, 402 F.3d at 1066.
362. See supra note 236 and accompanying text.
363. See supra notes 316–324 and accompanying text.
365. Id.
366. Id.
367. Id. (emphasis added).
the arrangement without consideration of the protection of the patent."368 While this holding is not precisely in line with Schering since the Eleventh Circuit explicitly said the rule of reason was inappropriate in patent cases,369 the D.C. Circuit nevertheless advocated looking at the scope of the patent’s protection before deeming the agreement illegal under the antitrust laws — definitely an “exclusionary potential” approach.

However, many aspects of this approach require further clarification before its official adoption. The Eleventh Circuit in Schering was unclear whether traditional antitrust analysis can be used if a court determines the exclusionary potential of the agreement exceeds the exclusionary potential of the patent, as the Valley Drug decision had.370 Can an agreement still receive rule of reason scrutiny even if it fails an “exclusionary potential” analysis? Both Professor Hovenkamp and the Schering decision seem to agree that further review would not be needed,371 but even the Cipro court was not sure if the rule of reason was being abandoned or merely refined in Schering.372 Additionally, although it is arguably implicit, some care should be taken to ensure that the litigation is not a sham, which follows Posner’s reasoning in Asahi as well as prior Supreme Court precedent.373 This should not be hard to accept — to have an exercisable IP exclusion right, there at least should be some colorable right to start with as opposed to a completely illusory one. Moreover, as one commentator noted, “a provision of an agreement which may be per se unlawful in isolation may not be enough, when part of a larger agreement, to make the whole agreement unlawful.”374 It may be that only a portion of an offensive agreement has exceeded the exclusionary scope of the patent, and a court could merely sever the cancerous provisions from the agreement without wholly condemning it. Finally, although it may be a useless exercise since patents are inherently exclusionary and anticompetitive, an examination of “the resulting anticompetitive effects” pays proper homage to the objectives of the Sherman Act while still considering the rights of the patent holder.375 But, the

368. Id. (emphasis added).
369. See Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1065 (11th Cir. 2005).
370. See supra notes 225–235 and accompanying text.
371. See supra notes 309–314 and accompanying text.
372. See supra notes 177–280 and accompanying text.
373. See supra notes 327–333 and accompanying text.
374. Burford, supra note 56, at 379.
375. Considering “resulting anticompetitive effects” was the third part of court’s analytical approach. See Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005). As discussed above, this approach may not be needed, see supra notes 342-353 and accompanying text, but it is certainly not harmful.
Schering opinion is not clear enough: exactly what "anticompetitive effects" is the court concerned about (i.e., harming consumers, other competitors, or both)? Some further guidance could clarify this issue, but with this and the foregoing caveats, the Court should adopt the "exclusionary potential" approach fundamentally as it appears in Schering.

Sadly, the "exclusionary potential" approach will not be without critics despite its seemingly abundant support. Some may argue that "a per se approach provides attractive efficiency, avoiding a 'time-consuming and difficult' inquiry into the merits of any underlying intellectual property rights or claims."376 In contrast, the "exclusionary potential" approach would enquire into the merits of a patent (perhaps into validity but certainly into the patent terms), which antitrust agencies and judges may be ill equipped or hesitant to handle.377 Future tribunals would have to "determine the scope of the right to exclude, presumably through extensive discovery, expert analysis, and claim construction."378 This problem would be difficult to counteract systemically, but special masters well versed in patent law would be useful to pick up any slack. Moreover, the exclusionary potential approach could be seen as "inefficient and unnecessarily punishing to valid antitrust plaintiffs."379 Adoption of this rule might "push[] every agreement into a complex, time-consuming, and extremely costly analysis of the patent grant; essentially a district court would have to conduct an entire patent infringement and invalidity trial before even reaching the substantive antitrust issues."380 However, such a rule is necessary to promote fair treatment of patent holders in antitrust cases,381 and it might not be any more time-consuming than a full-blown rule of reason analysis.382

IV. IMPACT

Unfortunately, the Supreme Court denied certiorari to Cardizem and Valley Drug, which could have clarified the divergence among the

376. Reed, supra note 45, at 479.
377. See supra note 277-279 and accompanying text. See also Reed, supra note 45, at 478 (noting that the antitrust trial ironically becomes a patent litigation, which is what the parties wanted to avoid with the settlement agreement in the first place, under the "exclusionary potential" approach).
378. Mosier & Ritcheson, supra note 3, at 511.
379. Id. at 511.
380. Id. at 511.
381. See Reed, supra note 45, at 478.
382. See Hovenkamp Treatise, supra note 2, at 7-14 ("Courts should have considerable discretion on summary judgment to dispose of a weak case on the antitrust merits without getting into the underlying IP issues.").
circuits. The Court did not explain why it declined review (it never does). However, the Court's lack of guidance in this area will continue to have a disparate impact on patent settlement agreements as the lower courts decide which analytical approach to follow.

Remember, a court will apply the per se rule when it has enough "experience to conclude that a certain class of practices is so likely to be anticompetitive" that the more detailed rule of reason test is thought unnecessary. Without clear guidance from the high court, lower courts dealing with the antitrust implications of patent settlement agreements remain free to choose when either test is appropriate in a given case. The Sixth Circuit felt that, based on its "experience," the settlement agreement in Cardizem warranted the strict per se approach. However, the Second and Eleventh Circuits felt otherwise and focused first on the patent itself and the attendant IP rights rather than on traditional antitrust principles. For whatever reason, the Supreme Court did not pick up on this and denied certiorari to what most pundits, including the venerable Professor Hovenkamp, have considered a clear circuit split in need of clarity. Therefore, whether a patent settlement agreement will survive antitrust bombardment remains jurisdiction dependent, and it would be hard to imagine any parties — especially if their settlement involved a dreaded "reverse payment" — preferring the Sixth Circuit over the Eleventh or Second Circuits at this juncture.

Some of the briefs to the Supreme Court further illustrate the gravity of this situation. Back in 2003, the petitioner in Cardizem correctly foresaw that "parties to intellectual property disputes need immediate guidance regarding whether antitrust liability may attach to their settlements because it is common for intellectual property disputes to be settled by agreements in which the infringer receives consideration in exchange for a promise to withhold its product from the market." Indeed, from Valley Drug to the recent Tamoxifen case, the controversy surrounding the antitrust implications of patent settlement agreements in the reverse payment context has continued to swell. Three separate circuits have chimed in all with comparable but ultimately contrasting approaches, and there is no clear mandate as to which is the "correct" approach. Commentary from outside observers

384. Hovenkamp Treatise, supra note 2, at 7-11.
385. See supra note 221 and accompanying text.
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has also grown exponentially, each advocating a new approach for the Supreme Court to adopt. All told, this flood of information from the various viewpoints makes drafting a patent dispute settlement agreement extremely difficult, as the law in this area remains blurred and uncertain. One cannot now, in good confidence, draft a settlement agreement for a patent dispute and then tell the client with a straight face that the patent dispute is definitely over.

Additionally, the petitioner in Cardizem fittingly pointed to the multidistrict nature of these cases and how this situation could be a long-term nightmare because of a circuit split. Under the Federal Rules of Civil Procedure, cases with common questions of fact can be consolidated for pre-trial proceedings, otherwise known as a “multidistrict litigation” (more commonly known as an “MDL”). Once the pre-trial phase is over, each individual case that comprised the consolidated MDL returns back to the district from which it originated for further proceedings, assuming that case was not completely disposed of at the pre-trial phase. So, take for example an antitrust/patent settlement MDL where the cases involved consist of one case originating from Florida, another from New York, and another from Michigan. A federal district court in one of these states will conduct the MDL, and your client and the MDL court are in different jurisdictions. Now assume that the case goes up on interlocutory appeal, for which the district court submits certified questions to the federal circuit court of appeals above it. Which antitrust approach to patent settlements — the Second, Sixth, or Eleventh — will ultimately apply in this scenario?

Such was the environment in Cardizem, but at the time of the petition, there was only a two-circuit split. Thus, the petitioner feared a two front choice-of-law problem because its case had originated in Florida (in the Eleventh Circuit bound by Valley Drug) but the Sixth Circuit was answering certified questions from a Michigan district court (the MDL court) on interlocutory appeal. Does the origin court, after the MDL has concluded, apply the law of its jurisdiction or the law that applied for the MDL? The petitioner in Cardizem, of course, argued Valley Drug would have to apply or the Florida district court would face certain reversal for not following the Eleventh Cir-

387. See id. at *14
389. See id.
If petitioner's assertions in this regard were correct, the problem would today be exacerbated. If the MDL was in Michigan, the Florida and New York defendants could be governed by the Sixth Circuit's *per se* approach even though the law in their own jurisdiction takes a different path. Alternatively, even if the Florida or New York defendants garnered an approach more akin to their home jurisdiction (i.e., an “exclusionary potential” approach), the Michigan defendant who might have received a favorable result in New York MDL could return home to find that result changed. The Florida defendant could also return home to subtle differences within its own jurisdiction. In short, this is certainly a sticky problem that only creates further turmoil for settling parties.

Going further, the Solicitor General and the Federal Trade Commission filed an *amicus* brief in *Cardizem* essentially agreeing with the petitioner that it would be wrong to treat every such agreement as *per se* illegal. This brief proffers that “[r]everse payments may have the salutary effect of facilitating efficient settlements that advance consumer welfare” and thus should not be condemned to *per se* illegality. However, the brief also recommends against granting *certiorari*, primarily because *Cardizem* could be read as applying the *per se* rule only to “interim” agreements (i.e., not finally settling the litigation) covering even non-infringing products. As discussed, this may not be an entirely inaccurate reading of *Cardizem*, but most commentators agree there is a circuit split that needs addressing.

Recently, the Court had another chance to speak up, but it came from a seemingly unlikely source — the Federal Trade Commission. In its appeal of *Schering*, the FTC argued against the “exclusionary potential” approach, asserting that “review of the . . . issue is needed not only because of disarray among the lower courts on this issue, but because of the dramatic impact the present ruling could have on U.S. consumers.” In other words, even though the FTC argued against review in 2004, they changed their tune and just appealed *Schering* to the Supreme Court. Naturally, the opposing brief picks up on this,

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391. *Cardizem*, at 900.
393. *Id.*
394. *Id.* at *12.
395. *See* supra notes 217-219 and accompanying text.
396. *See* supra note 221 and accompanying text.
398. *Id.*
and rightly so — it is a little hard to argue there is no controversy and turn around a year later and claim that there is.\[399\] This change of heart notwithstanding, the FTC's brief further reveals the impact this circuit split is having on the law. Even the chief antitrust regulatory agency recognized the problem and argues it is time to be addressed. However, the Supreme Court, for whatever reason, did not grant certiorari in Schering.\[400\] Thus, in sum, this area of law remains very much unsettled.

V. Conclusion

Until the Supreme Court settles this controversy, the amount of antitrust scrutiny that may apply to patent settlement agreements remains up to the individual courts which, thus far, have been fairly inconsistent. The Sixth Circuit seems to favor the traditional antitrust approach of per se illegality, whereas several other jurisdictions (most notably the Second and Eleventh Circuits) have analyzed agreements from an IP rights perspective but with varying methodology. The Supreme Court has had three chances to clarify, but for whatever reason declined to do so. Yet this area of law is clearly under development and in much need of guidance.

In the meantime, lawyers facing an antitrust challenge should entertain several lines of defense when arguing to uphold a patent settlement agreement, including: (1) that the agreement is immune from antitrust scrutiny under the Noerr-Pennington doctrine; (2) that public policy concerns outweigh antitrust concerns as well as favor a balancing approach; (3) that the agreement is a "final" resolution to the dispute rather than an "interim" agreement; and/or (4) that the

\[399\] See Brief in Opposition, FTC v. Schering-Plough Corp., 2005 WL 2428345 at *3 (Sept. 30, 2005).

\[400\] See F.T.C. v. Schering-Plough Corp., 126 S.Ct. 2929 (2006). The Supreme Court recently granted certiorari to a non-reverse payment, patent settlement case from the federal circuit. Medimmune, Inc. v. Genentech, 427 F.3d 958 (Fed. Cir. 2005), cert. granted 126 S.Ct. 1329 (2006). At the appellate level, the Federal Circuit held that "[t]he settlement of disputes such as priority in patent interferences is not a presumptive violation of antitrust law; such a violation requires a showing of market power and other antitrust predicates. A patent does not of itself confer market power or a presumption thereof for the purposes of the antitrust laws." 427 F.3d at 965-66. However, while it seems that the Federal Circuit implicitly rejects the application of the per se rule, the Court does not discuss Cardizem, Valley Drug, or their progeny. However, as seen in the Petition for Certiorari (2005 WL 3067195) and the oral argument transcript (2006 WL 3069259, Oct. 4, 2006), the appeal is based on a limited jurisdictional issue regarding the Declaratory Judgment Act, 28 U.S.C. § 2201(a), and not patent settlement agreements. The Supreme Court finally decided Medimmune in early 2007, but did not take up Cardizem, et al., which leaves the antitrust / patent settlement agreement very much unanswered for the time being. See 127 S. Ct. 764 (2007). For Hovenkamp’s take on the Medimmune case, see Hovenkamp Treatise, supra note 2, at 7-8.1 – 8.3 and 7-55.
agreement is within the scope or "exclusionary potential" of the patent. The third option could be a preemptive measure, whereas the last option is of particular importance as it represents the direction the circuit courts seem to be heading and would not be problematic for the Supreme Court to adopt officially. Until that day, IP practitioners must remain particularly vigilant of future antitrust complications when resolving patent disputes through settlement agreements and advise their clients accordingly.401

401. See Coleman, supra note 221, at 286. ("Neither the pursuit nor the settlement of patent infringement litigation is an unfettered right. Both the litigation and infringement cases should be undertaken with sensitivity toward antitrust risks."). For more practical tips, see William H. Rooney, New Developments in the Application of Antitrust to Patent-Holder Conduct, 858 PLI/PAT 913, 929-30 (2006).