A Return to Reason:
Antitrust Treatment of Pharmaceutical Settlements
Under the Hatch-Waxman Act

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I. INTRODUCTION

Intellectual property rights ("IP") confer upon the possessor the "right to exclude." Not surprisingly, interesting questions arise when intellectual property rights are subjected to the scrutiny of antitrust law analysis. Among these questions

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1. See DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 4 (Robert C. Clark et al. eds., 2d ed. 2001) (noting that "[t]he right to exclude, without the right to use, is somewhat peculiar to patent law (as well as the law of copyright and negative easements)").
are the issues raised during the settlement of intellectual property lawsuits between competitors.\textsuperscript{2} In the context of pharmaceutical patent settlements, a ripe conflict has arisen among academics and different courts as to the correct application of antitrust principles in light of various intellectual property concerns.\textsuperscript{3} A \textit{per se} antitrust rule should not apply, as such a standard does not adequately take into consideration the rights of the patent holder. A slightly less stringent rule of reason approach is recommended, which requires a large, yet not impossible, burden be met by the patentee in order to avoid condemnation under antitrust law.

Part II of this article provides the relevant statutory and common law framework affecting this particular problem. Part III delineates the varied and conflicting scholarly commentaries on this issue. Part IV details how this division in opinion is reflected in various court and FTC opinions, including an explicit split between decisions of the Sixth and Eleventh Circuits. Part V proposes a solution to the conflict.

\section*{II. STATUTORY AND LEGAL FRAMEWORK}

\subsection*{A. The Hatch-Waxman Act}

The most recent conflict in IP-antitrust jurisprudence concerns settlements between brand name and generic drug companies.\textsuperscript{4} In 1984, Congress passed the Hatch-Waxman Act to reform Food and Drug Administration ("FDA") procedures that were harming both brand name and generic drug manufacturers.\textsuperscript{5} A key provision of the act allowed a generic drug applicant to "piggyback on the safety and efficacy studies" of the brand name product by filing an abbreviated new drug application ("ANDA").\textsuperscript{6} The application must contain various declarations certifying that particulars such as labeling, ingredient composition, recommended dosage, and...

\textsuperscript{2} Herbert Hovenkamp et al., \textit{Anticompetitive Settlement of Intellectual Property Disputes}, 87 MINN. L. REV. 1719, 1720 (2003) ("Because these competitors may agree to stop competing, to regulate the price each charges, and to exchange information about products and prices, settlements of IP disputes naturally raise antitrust concerns.").

\textsuperscript{3} Some courts and academics apply a \textit{per se} rule, see, e.g., \textit{In re Cardizem CD Antitrust Litig.}, 332 F.3d 896 (6th Cir. 2003); Hovenkamp, supra note 2, while others apply a rule of reason, see, e.g., Valley Drug Co. v. Geneva Pharm., Inc. 344 F.3d 1294 (11th Cir. 2003); Thomas F. Cotter, Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis, and Lemly, 87 MINN. L. REV. 1789 (2003).

\textsuperscript{4} See Hovenkamp, supra note 2, at 1751-57.

\textsuperscript{5} The bill's senate sponsor, Orrin Hatch, remarked that "the FDA's regulatory system was discouraging brand or innovator companies from investing in new research and development. At the same time, it was blocking the introduction of low-cost generic products. No one was benefiting, not the brand companies, not the generic firms and not consumers." ORRIN HATCH, SQUARE PEG: CONFESSIONS OF A CITIZEN SENATOR 72 (2002).

\textsuperscript{6} Valley Drug Co., 344 F.3d at 1296.
biochemical composition are equivalent to those of the original FDA-approved drug.\textsuperscript{7} In addition, the applicant must certify that the new drug does not or will not infringe any of the patents listed with the FDA that relate to the original drug.\textsuperscript{8} One option for the generic drug applicant is to claim that "[each listed] patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."\textsuperscript{9}

If the patentee brings an infringement action against the applicant within forty-five days of the applicant filing this Paragraph IV certification, approval of the ANDA is automatically postponed for a period of thirty months.\textsuperscript{10} In addition, the first drug manufacturer to file and receive approval of an ANDA with a Paragraph IV certification is given 180 days to exclusively manufacturer and sell the generic product before any subsequent ANDA for the same drug will be granted FDA approval.\textsuperscript{11} This unique feature of the Hatch-Waxman Act gives rise to potential antitrust abuse, as Hovenkamp notes:

It is widely understood that the 180-day exclusivity period offers the potential for collusive settlement arrangements between pioneers and generics. A pioneer could initiate a patent infringement suit against a first generic ANDA filer and settle the litigation with a "non-entry" payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market indefinitely.\textsuperscript{12}

Such a feature demonstrates how "after twenty years, creative lawyers have been able to take advantage of a few portions of the legislation."\textsuperscript{13} The current crop of exclusionary pharmaceutical settlements can be traced directly to the passage of the Hatch-Waxman Act,\textsuperscript{14} primarily due to the fact that "a properly defined settlement-
plus-exit-payment keeps not only the immediate infringement defendant out of the market for a time, but also keeps other generic firms from entering as well.\textsuperscript{15}

While a variety of non-judicial remedies are currently being discussed,\textsuperscript{16} academics and even the courts are divided as to the correct treatment of such agreements under current antitrust law.\textsuperscript{17} In order to understand this division, a brief discussion of antitrust principles is in order.

\section{B. The Rule of Reason}

The Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade,"\textsuperscript{18} however, most agreements are evaluated under the rule of reason.\textsuperscript{19} Under this rule, "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."\textsuperscript{20} In any such analysis, the "focus should be on what conclusions regarding the competitive impact of a challenged restraint can confidently be drawn from the facts demonstrated by the parties."\textsuperscript{21}

\section{C. Per Se Rules of Antitrust}

Although most alleged antitrust violations are evaluated under the rule of reason, some are considered to "have such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit, that they are deemed unlawful per se."\textsuperscript{22} Courts fashion per se rules "[o]nce experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it, [and] it has applied a conclusive presumption that the restraint is unreasonable."\textsuperscript{23} When a court applies a per se rule, "no consideration is given to the intent behind the restraint, to any claimed pro-competitive justifications, or to the restraint's actual effect on competition."\textsuperscript{24} Examples of such per se rules include

\begin{itemize}
  \item \textsuperscript{15} Id.
  \item \textsuperscript{16} Id.
  \item \textsuperscript{17} See supra note 3.
  \item \textsuperscript{18} 15 U.S.C. § 1 (2004).
  \item \textsuperscript{19} Arizona v. Maricopa County Med. Soc'y, 457 U.S. 332, 342-43 (1982).
  \item \textsuperscript{20} State Oil Co. v. Kahn, 522 U.S. 3, 10 (1997).
  \item \textsuperscript{21} Valley Drug Co., 344 F.3d at 1304.
  \item \textsuperscript{22} State Oil, 522 U.S. at 10.
  \item \textsuperscript{23} Maricopa County Med. Soc'y, 457 U.S. at 344.
  \item \textsuperscript{24} In re Cardizem CD Antitrust Litig., 332 F.3d 896, 906 (6th Cir. 2003).
\end{itemize}
price fixing or territorial divisions among horizontal competitors.\textsuperscript{25} Such extraordinary rules can be immensely efficient:

\[\textit{Per se} \text{ unreasonableness not only makes the type of restraints which are proscribed by the Sherman Act more certain to the benefit of everyone concerned, but it also avoids the necessity for an incredibly complicated and prolonged economic investigation into the entire history of the industry involved, as well as related industries, in an effort to determine at large whether a particular restraint has been unreasonable—an inquiry so often wholly fruitless when undertaken.}\textsuperscript{26}

\section*{III. ACADEMIC DISCORDANCE}

Although varying opinions exist throughout academia regarding this issue, most direct opinions can be sorted into two categories: (1) those in favor of a \textit{per se} rule for addressing exclusionary pharmaceutical agreements, and (2) those favoring a strong, yet less restrictive rule of reason type approach.\textsuperscript{27}

\textbf{A. A Case for a Per Se Treatment of Exclusionary Pharmaceutical Agreements}

There is little consensus among commentators as to the correct antitrust standard to be applied in the case of exclusionary pharmaceutical agreements.\textsuperscript{28} In support of a proposed \textit{per se} treatment, Hovenkamp argues:

In the typical Hatch-Waxman case involving a large exclusion payment, the rule of reason will not be a fruitful avenue of inquiry. The very fact that the pioneer finds it worthwhile to pay a large exclusion payment tends to establish market power. It also suggests some inherent uncertainty as to the validity or scope of the patent \ldots a patentee that is certain of winning will not pay anything more than its anticipated remaining legal fees in exchange for an agreement by a generic to exit the market. The very fact of that uncertainty suggests that exclusion payments are anticompetitive—that on average such agreements exclude at least some generics that in fact had a legal right to compete.\textsuperscript{29}

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\textsuperscript{25} N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958) ("Among the practices which the courts have heretofore deemed to be unlawful in and of themselves are price fixing, division of markets, group boycotts, and tying arrangements." (citations omitted)).
\textsuperscript{26} Id.
\textsuperscript{27} See Hovenkamp, supra note 2, at 1759-60 (\textit{per se} rule); Cotter, \textit{supra} note 3, at 1815-16 (rule of reason).
\textsuperscript{28} See, \textit{e.g.}, Hovenkamp, \textit{supra} note 2, at 1758-59.
\textsuperscript{29} Hovenkamp, \textit{supra} note 2, at 1757-58.
\end{flushleft}
Following this rationale, Hovenkamp proposes a *per se* rule "limiting exclusion payments to litigation costs." Any patentee, therefore, that enters into such an exclusionary agreement under the Hatch-Waxman Act, must demonstrate a significant likelihood of winning in the infringement lawsuit and that the payment itself does not exceed the anticipated attendant costs of litigating the infringement claim. Any amount exceeding the predicted litigation costs would be a *per se* violation of the Sherman Act, as "[o]n expectation, the patentee is paying for an advantage that it could not get if it went to trial." 

B. A Case for the Rule of Reason

In his response to the Hovenkamp article, Thomas Cotter agrees that courts "should remain moderately skeptical" of pharmaceutical settlements under the Hatch-Waxman Act that pay a generic manufacturer to delay or forego entry into an established drug market. Cotter does not agree, however, that this skepticism should rise to the level of a *per se* rule against such agreements when the payment amount, or "reverse payment" exceeds the potential litigation costs. Cotter believes that the application of such a *per se* rule as proposed by Hovenkamp unnecessarily requires the plaintiff to be "absolutely certain of prevailing at trial." Cotter believes further that such a rule ignores the legal reality that "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." Cotter recognizes that "[w]hen the amount of reverse payment is higher yet, the potential for anticompetitive harm is stronger." In spite of this fact, Cotter suggests a rule that is much friendlier to the patent holder than Hovenkamp's *per se* proposal. Specifically, he proposes:

In cases in which the amount of the payment substantially exceeds the parties' avoided litigation costs, the sensible solution may be to give them a choice of proving either that the payment is consistent with a high probability of success

30. *Id.* at 1759-60.
31. *Id.* at 1759.
32. *Id.*
34. *Id.* at 1816.
35. *Id.*
36. *Id.* at 1812.
37. *Id.*
39. *See id.* at 1815-16.
on the merits, in light of the parties’ expected gains and losses, or that the patent is valid and infringed.\textsuperscript{40} Such a rule accommodates the perspective that “[w]hen the amount of the reverse payment is higher than the saved litigation expenses but less than the defendant’s potential loss at trial, it is still likely that the patent was valid and infringed.”\textsuperscript{41} Cotter argues that the adoption of the \textit{per se} rule proposed by Hovenkamp would restrict “the parties from settling on terms that involve reverse payments” and consequently “decrease the value of at least some valid and infringed pharmaceutical patents.”\textsuperscript{42} Cotter rejects Hovenkamp’s consumer welfare justifications, noting that the Congressionally-granted rights of the patent holder should merit greater evaluation.\textsuperscript{43} Cotter feels that Hovenkamp’s rationale is too biased toward consumer surplus and does not sufficiently recognize that “[f]or better or worse, patents exist, and they reflect a legislative judgment that their benefits exceed their costs.”\textsuperscript{44} In Cotter’s view, “[f]or antitrust law to undermine the value of valid and infringed patents, which a rule discouraging reverse payments would in some instances do, is troubling.”\textsuperscript{45}

\textbf{IV. JUDICIAL DISCORDANCE}

This conflict regarding the correct treatment of pharmaceutical settlements extends beyond the ivory tower, with explicit division surfacing in remarkably similar disputes.

\textbf{A. In re Cardizem}

In \textit{In re Cardizem}, decided in June of 2003, the Sixth Circuit adopted a \textit{per se} rule for intellectual property settlements.\textsuperscript{46} Hoescht Marion Roussel, Inc. (“HMR”) held a patent on diltiazem hydrochloride.\textsuperscript{47} Diltiazem hydrochloride is the active ingredient in HMR’s Cardizem CD medication, used in the treatment and prevention of such maladies as angina, heart attack, hypertension, and stroke.\textsuperscript{48} HMR also held a

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\textsuperscript{40.} \textit{Id.} at 1815. \\
\textsuperscript{41.} \textit{Id.} at 1814. \\
\textsuperscript{42.} \textit{Id.} at 1809. \\
\textsuperscript{43.} Cotter, \textit{supra} note 3, at 1809-11 (opining that Hovenkamp’s \textit{per se} approach fails to adequately consider the implied societal benefits of the patent grant). \\
\textsuperscript{44.} \textit{Id.} at 1810. \\
\textsuperscript{45.} \textit{Id.} \\
\textsuperscript{46.} \textit{In re Cardizem CD Antitrust Litig.}, 332 F.3d 896, 906-08 (6th Cir. 2003). \\
\textsuperscript{47.} \textit{Id.} at 901. \\
\textsuperscript{48.} \textit{Id.}
\end{flushright}
license from Carderm Capital, L.P. ("Carderm") for U.S. Patent No. 5,470,584 ("the '584 patent") covering a particular dissolution profile of Cardizem CD.49

Andrx Pharmaceuticals, Inc. ("Andrx") was the first generic drug manufacturer to file an ANDA with a Paragraph IV certification seeking to manufacture and sell a generic form of Cardizem CD.50 Prior to Andrx receiving FDA approval for its ANDA, HMR and Carderm sued Andrx for infringement of the '584 patent.51 The filing of this suit invoked the automatic thirty-month waiting period before FDA approval could be granted for Andrx's generic version of Cardizem CD.52

Approximately twenty months later, the FDA tentatively approved Andrx's generic product, contingent upon a showing of noninfringement of the '584 patent, or, alternatively, upon expiration of the thirty-month waiting period.53

Shortly after the FDA's tentative approval of Andrx's ANDA, HMR entered into an agreement with Andrx wherein Andrx agreed to not bring its generic product to market upon final FDA approval nor to transfer its 180-day exclusivity to any other drug company.54 In exchange, HMR agreed to make payments to Andrx of $40 million.55 Upon expiration of the thirty-month waiting period, Andrx received final FDA approval for its generic Cardizem CD, and HMR began making payments to Andrx in order to keep the generic off the market.56

The court found that the agreement not only delayed Andrx from introducing its product, but "also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx's 180-day period of marketing exclusivity, which Andrx had agreed not to relinquish or transfer."57 The court held this agreement to be "a naked, horizontal restraint of trade that is per se illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers."58 Although the validity of the HMR's intellectual property claims were not determined, the court noted its suspicion that "had HMR been confident of the independent durability of its patent and the validity of its infringement claim, it would not have paid $89 million to effect what the patent and infringement suit had already accomplished."59

This decision comports with the rationale advanced by Hovenkamp. The court clearly felt that the $89 million payment was not characteristic of a patentee that is

49. Id. at 902.
50. Id.
51. Id.
52. Cardizem, 332 F.3d at 902.
53. Id.
54. Id.
55. Id.
56. Cardizem, 332 F.3d at 903.
57. Id. at 907.
58. Id. at 911.
59. Id. at 915.
certain of winning. Even if HMR could have shown a strong “ex ante likelihood of prevailing” in its suit against Andrx, the court suggested that “had HMR been confident of the independent durability of its patent and the validity of its infringement claim, it would not have paid $89 million to effect what the patent and infringement suit had already accomplished.” Such a payment, therefore, exceeded any anticipated litigation costs, and the court was justified under Hovenkamp’s reasoning in applying per se treatment and finding the agreement to be an “illegal horizontal market restraint.”

B. In re Ciprofloxacin Hydrochloride Antitrust Litigation

Shortly before the In re Cardizem decision, the Eastern District of New York handed down a key pharmaceutical settlement decision that served to be reasonably predictive of the circuit split which would follow later that same year. Bayer AG and its domestic subsidiaries (“Bayer”) are the makers of the antibiotic Cipro. Bayer holds a patent on ciprofloxacin hydrochloride, the key ingredient in Cipro. Bayer entered into a number of agreements with various generic drug companies—paying substantial sums of money to the companies for their declarations that the Cipro patent is valid, and agreeing not to manufacture generic forms of Cipro for different lengths of time.

60. Hovenkamp, supra note 2, at 1759.
61. Thus satisfying the first prong of the proposed Hovenkamp rule, requiring “that the ex ante likelihood of prevailing in its infringement lawsuit is significant.” Id.
62. Cardizem, 332 F.3d at 915.
63. The second prong in the proposed Hovenkamp rule, requires “that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit.” Hovenkamp, supra note 2, at 1759.
64. Compare Cardizem, 332 F.3d at 911 (finding that “HMR’s agreement to pay Andrx $40 million per year not to bring its generic product to market and compete with Cardizem CD, is a naked, horizontal restraint of trade that is per se illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and it generic equivalents to the detriment of consumers” with Hovenkamp, supra note 2, at 1759 (demonstrating that payments exceeding the costs of litigation are “inherently anticompetitive” as they remove any “chance that the patent would be held invalid or not infringed and the market would become competitive”)).
65. Cardizem, 332 F.3d at 910.
67. Id. The Eastern District of New York decided In re Ciprofloxacin on May 20, 2003, just weeks before the Sixth Circuit’s decision in In re Cardizem on June 13, 2003, and a few short months between the conflicting decision in Valley Drug Co. v. Geneva Pharm., Inc., which was decided on September 15, 2003. Ciprofloxacin, 261 F. Supp. 2d at 188; Cardizem, 332 F.3d at 896; Valley Drug Co., 334 F.3d at 1294.
68. Ciprofloxacin, 261 F. Supp. 2d at 194.
69. Id.
70. Id. at 195-96.
The consumer plaintiffs challenged the validity of these agreements under Section 1 of the Sherman Act, alleging that the agreements resulted in Bayer paying "hundreds of millions of dollars to suppress generic competition in the domestic market for Cipro."\(^{71}\) The plaintiffs alleged that the agreements harmed consumers as they eliminated any uncertainty regarding the patent, specifically the risk of a court finding Bayer's patent invalid.\(^{72}\) As such, plaintiffs asserted that Bayer's behavior constituted "a per se illegal market allocation agreement that violates Section 1 of the Sherman Act."\(^{73}\)

In deciding the case, the court recognized that "[t]he Supreme Court has long recognized that a limited class of restraints are so manifestly anticompetitive that they are per se violations of the antitrust laws."\(^{74}\) The court felt, however, that there were three key obstacles to the application of a per se rule in this case: (1) that the defendant is a patent holder, with a valid patent previously challenged in various court proceedings and through a reexamination proceeding with the United States Patent and Trademark Office ("PTO"); (2) that this case arises under the Hatch-Waxman Act, under which generic drug manufacturers can quickly and cheaply challenge the validity of a patent; and (3) that settlement agreements are, "generally speaking, encouraged by the legal system and entered into with great frequency."\(^{75}\)

Plaintiffs asserted that, despite the existence of Bayer's patent rights, the agreements "should nonetheless be held per se unlawful because they illegally allocate the domestic market for Cipro."\(^{76}\) The court disagreed, stating that antitrust decisions must account for intellectual property rights, namely:

> [w]hen patents are involved, case law directs that the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is per se illegal. Therefore, the proper analysis in this case is whether the plaintiffs have proven as a matter of law that the challenged agreements restrict competition beyond the exclusionary effects of the [Bayer] patent.\(^{77}\)

Under this rubric, the court found that the agreements "do not restrict competition in areas other than those protected by Bayer's 444 Patent and, thus, are not per se illegal under the Sherman Act."\(^{78}\)

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71. *Id.* at 199.
72. *Id.* at 212.
74. *Id.* at 232.
75. *Id.* at 233.
76. *Id.*
77. *Id.* at 249.
The court cited the Hatch-Waxman Act as an additional justification for not applying per se treatment in this case.\textsuperscript{79} The Act, although rational, creates an "artificial" imbalance between patent holder and potential infringers.\textsuperscript{80} Accordingly, "because of the generic manufacturer's entitlement under the Hatch-Waxman Amendments to institute patent litigation merely by filing an ANDA IV, the statutory scheme has the unintended consequence of altering the litigation risks of patent lawsuits."\textsuperscript{81} Therefore, "so-called reverse payments are a natural by-product of the Hatch-Waxman Act\textsuperscript{82} and absent a showing of "nefarious" action, such payments should not be subjected to a per se analysis.

Finally, the court was hesitant to proscribe the inherent efficiencies of settlements through the application of a per se rule.\textsuperscript{83} In addressing the policy behind the Hatch-Waxman Act and IP settlements, the court stated:

Nothing in the legislative history supports a conclusion that Hatch-Waxman lawsuits cannot be settled. Moreover, a rule that makes it per se illegal to settle a Hatch-Waxman lawsuit . . . limits the options available to both generic and brand-name manufacturers. If brand-name manufacturers are unable to control or limit their risk by settling Hatch-Waxman litigation, they, like the generic manufacturers, may be less inclined to invest the research and development ("R&D") costs associated with bringing new drugs to the market. The pharmaceutical industry depends greatly on R&D and the economic returns to intellectual property created when a successful new drug is brought to market.\textsuperscript{84}

As a result, the court concluded that per se treatment was inappropriate for pharmaceutical settlements under the Hatch-Waxman Act.\textsuperscript{85}

\textsuperscript{79} Id. at 256.
\textsuperscript{80} Id. at 251.
\textsuperscript{81} Id.
\textsuperscript{82} Id. at 257-58.
\textsuperscript{83} Id. at 252.
\textsuperscript{84} Ciprofloxacin, 261 F. Supp. 2d at 256.
\textsuperscript{85} Id. at 257.
Unfortunately, the court did not indicate the relative weight given to each of three rationales used to reject the application of a per se rule. If the fact that the patent had previously been found valid by the courts and the PTO through reexamination was the most relevant or dispositive factor in the court’s decision, then this holding has little applicability outside the unique circumstances of this particular case. If, on the other hand, the second and third factors—the ease of challenging invalidity under Hatch-Waxman and the efficiencies of settlement in general—were of greatest importance, then the implications of this case in future proceedings are far greater.

C. Valley Drug Co. v. Geneva Pharmaceuticals

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. Abbott Laboratories holds several patents related to the compound terazosin hydrochloride, the principle ingredient in its brand-name drug Hytrin. Two generic drug companies, Geneva Pharmaceuticals (“Geneva”) and Zenith Goldline Pharmaceuticals (“Zenith”), filed a number of ANDAs for various generic variations of terazosin hydrochloride drugs, with the requisite paragraph IV certifications addressing Abbott’s patents.

In response to Geneva and Zenith’s efforts, Abbott filed a number of claims alleging infringement of its terazosin hydrochloride patents. In a manner reminiscent of HMR in In re Cardizem, Abbott eventually settled these cases with Geneva and Zenith, with each generic company agreeing to forego introduction of competing generic products for a period of time, in exchange for significant monetary compensation. The district court held that the “exclusionary effect of the Agreements constituted an allocation of the market between horizontal competitors and that the Agreements were therefore per se illegal.

The Eleventh Circuit disagreed. In overturning the lower court’s grant of summary judgment, the Eleventh Circuit rejected the idea that this is a typical per se exclusionary antitrust case, finding this case different because “one of the parties

86. See generally id.
87. 344 F.3d 1294 (2003).
88. Valley Drug Co., 344 F.3d at 1298.
89. Id. at 1298-99.
90. Id. at 1299-1300.
91. Id. at 1300-01.
92. Id. at 1304. See In re Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340, 1349 (S.D. Fla. 2000) (holding that the agreements between the companies “to forestall competition in the United States for sales of terazosin hydrochloride drugs confront the Court with ‘one of the classic examples of a per se violation’—‘an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition.’” (quoting United States v. Topco Assoc., Inc., 405 U.S. 596, 608 (1972)).
93. Valley Drug Co., 344 F.3d at 1304.
owned a patent." The Eleventh Circuit argued that the district court had improperly ignored the principle that exclusionary conduct is "at the heart of the patent right and cannot trigger the per se label." In making this determination, the Eleventh Circuit Court was undoubtedly aware of its conflict with the Sixth Circuit's case in In re Cardizem. Nevertheless, the Eleventh Circuit held that "[w]hen the exclusionary power of a patent is implicated... the antitrust analysis cannot ignore the scope of the patent exclusion." As such, the court "[d]id not think that a payment from the patentee to the alleged infringer should be automatically condemned under the antitrust laws." The court even went so far as to criticize the Sixth Circuit for not adequately considering the implication of intellectual property rights in such exclusionary settlement agreements. Specifically the court held that:

To 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. We believe that the potential exclusionary power of the patent must first be considered.

The Eleventh Circuit, therefore, suggested that "[t]he appropriate analysis... will likely require an identification of the protection afforded by the patents and the relevant law and consideration of the extent to which the Agreements reflect a reasonable implementation of these." If payments grant rights that exceed the traditional "exclusionary effects" of the patent rights in question, then it is appropriate to subject the agreement to "traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether those provisions violate... the Sherman Act." The efficiency concerns raised by rejecting the per se approach are not addressed by this decision. Hovenkamp correctly noted that "[f]or courts to evaluate the

94. Id.
95. Id. at 1306.
96. Id. at 1310 ("We recognize that the Sixth Circuit appeared to take the opposite view in In re Cardizem CD Antitrust Litig.").
97. Id.
98. Valley Drug Co., 344 F.3d at 1310-11.
99. Id. at 1311, n.26 ("[T]he Sixth Circuit opinion did not purport to measure the several provisions [of the settlement agreement] 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.").
100. Id.
101. Id. at 1312.
102. Id.
103. See Valley Drug Co., 344 F.3d at 1294.
competitive consequences of settlements of IP disputes, they must sometimes inquire into the merits of those IP disputes. Because this inquiry is time-consuming and difficult, it threatens to undo many of the benefits of settling the dispute in the first place. Thus, the rejection of a per se rule can result in a sub-trial to determine the strength of a potential patent claim in these cases—a proceeding similar to the one the settlement was intended to prevent.

The Valley Drug decision better reflects the Cotter approach to the per se rule of reason debate, as it lends greater consideration to preserving the value of the intellectual property rights in question than the per se rule proposed by Hovenkamp. Specifically, Cotter would most likely agree with the Eleventh Circuit's criticism of the Sixth Circuit's failure to consider the salient patent rights in In re Cardizem. Although Cotter does not completely reject the rationale behind Hovenkamp's proffered rule, he would certainly prefer a less restrictive approach—such as the one suggested by the Eleventh Circuit in Valley Drug.

D. In re Schering-Plough Corporation

In April of 2004, the FTC added a new voice to the debate in its In re Schering-Plough Corp. decision. The initial FTC complaint was filed in March of 2001, alleging that Schering-Plough had entered into an anticompetitive agreement with Upsher-Smith that effectively delayed entry of generic versions of Schering drug K-Dur 20.

Schering holds a formulation patent on K-Dur 20 that is set to expire on September 5, 2006. Upsher-Smith had filed the first ANDA on K-Dur 20 in August 1995 with an accompanying Paragraph IV certification. As is customary,
Schering countered with a patent-infringement suit against Upsher-Smith, automatically beginning the thirty-month stay before FDA approval could be obtained. In June 1997, shortly before trial, Schering and Upsher-Smith settled the patent-infringement suit, agreeing that Schering would pay Upsher-Smith $60 million not to bring a generic version of K-Dur 20 to the market until September 2001.

A two-month trial was conducted on the FTC complaint on June 26, 2002, resulting in the Administrative Law Judge (“ALJ”) dismissing all charges. The ALJ concluded, among other things, that because Complaint Counsel had not shown “either invalidity or non-infringement” of Schering’s patent on K-Dur 20, “it was not possible to conclude that the settlement agreements in issue delayed generic entry that would otherwise have occurred.” The ALJ also rejected Complaint Counsel’s argument that the traditional exercise of “market definition is not necessary when direct evidence of anticompetitive effects can be shown.”

In an order dated December 8, 2003, the FTC on appeal reversed and vacated the ALJ decision. The Commission held that a rule of reason standard should apply in this particular matter, but that it did not require “a traditional full-blown rule-of-reason analysis.” In choosing this standard, the Commission indicated that “it is necessary to recognize that patent issues exist .... and the issues cannot be resolved in a summary way.”

The Commission disagreed with the Ciprofloxacin court, asserting that any alteration of the traditional risks of patent litigation due to Hatch-Waxman was intended by Congress. Therefore, the commission rejected the idea suggested in Ciprofloxacin that this new allocation of risk is an “unintended consequence” that requires compensation under an antitrust analysis.

In the end, the Commission declined to take a firm stance on the correct standard to be applied in all cases of reverse payments made during pharmaceutical settlements under Hatch-Waxman. Specifically, the Commission concluded:

113. Id.
115. Id. at *21.
116. Id.
117. Id. at *22.
118. Id. at *1.
120. Id. at *37.
121. Id. at *64-65. (“We agree with the court that Hatch-Waxman may have altered the litigation incentives of pioneer and generic manufacturers. The statute was intended to do just that.”).
122. Id. at *65. (“[A]ntitrust analysis must accept statutes and regulations as they are, and evaluate restraints in the context of the existing legal framework.”); see also Ciprofloxacin, 261 F. Supp. 2d at 252 (“[T]he statutory scheme has the unintended consequence of altering the litigation risks of patent lawsuits.”).
123. See generally Schering-Plough, 2003 FTC LEXIS, at *66.
We therefore believe that the possible existence of a so-called "reverse payment" raises a red flag that distinguishes this particular litigation settlement from most other patent settlements, and mandates a further inquiry. All of the pioneer/generic patent settlements that we have thus far challenged included a payment of this kind. . . . However, for the reasons discussed . . . , we are not now prepared to say that all such payments should be viewed as per se illegal or "inherently suspect." We believe that this particular case warrants a more extensive analysis of competitive effects, without foreclosing the possibility that a more truncated process would be appropriate in some future case.124

The Commission felt that it was not necessary to address the merits of the underlying patent dispute in making the decision.125 The Commission defended this approach on four grounds:

First, Schering's presumptively valid patent did not necessarily confer a right to exclude generic entry in the circumstances of this case. Second, there is a recognized distinction between the standard for proving that an agreement is likely to cause competitive harm and the standard for proving damages after the fact. Third, we believe that an inquiry into the merits of the patent case would not be conclusive in most of our antitrust cases anyway. Fourth, we are also concerned that a mandated inquiry into these issues, as part of the antitrust review, would ultimately have a chilling effect on the efficient settlement of patent litigation.126

The Commission concedes that there are situations in which a settlement under Hatch-Waxman that includes a reverse payment may in fact be competitive.127 Specifically, "[a] settlement can save public and private resources that would otherwise be consumed by litigation, and it can provide certainty that will encourage business investment."128 The respective risk exposure of the different parties in such an agreement might also affect the competitiveness of the settlement.129 The Commission concluded that this type of evaluation is highly dependent on the facts of the individual case, and thus "another reason why we do not apply a truncated analysis in this particular case."130

Although the Commission generally supports a non-per-se treatment of these settlements, the most interesting contribution to the discussion made by In re Schering-Plough is the Commission's claim that a sub-trial into patent validity would

124. Id. at *66-67.
125. Id. at *68-70.
126. Id. at *69.
127. See id. at *82.
129. Id. at *84 ("It is also possible that there are wildly differing risk preferences.").
130. Id. at *85.
never "be necessary, practical, or particularly useful." If this claim is accurate, then this strikes a blow to the per se argument, as it diminishes the anticipated efficiency gain of a per se rule. Unfortunately, none of the four reasons advanced by the Commission for such a proposition is persuasive.

First, the claim that the presumption of validity does not extend to the question of infringement, while correct in most instances, has far less applicability in the Hatch-Waxman context where the generic manufacturer must attest that its drug is effectively identical to the original FDA-approved drug.

Second, the Commission states that the reasonableness of a settlement must be evaluated "at the time they entered into the settlement agreement, when they could not be sure how the litigation would turn out." However, whether an agreement is "likely to cause competitive harm" is as equally premised on the validity of the patent as the infringement action that would go forward absent a settlement. This is especially true where the agreement, as in Schering-Plough, increases competition if the patent is valid by allowing generic entry prior to the expiration of the patent exclusivity period.

Third, the Commission asserts:

An after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be particularly helpful, but also likely to be unreliable. As a general matter, tribunals decide patent issues in the context of a true adversary proceeding, and their opinions are informed by the arguments of opposing counsel. Once a case settles, however, the interests of the formerly contending parties are aligned. A generic competitor that has agreed to delay its

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131. Id. at *79.
132. See generally Cotter, supra note 3, at 1802 (stating that "the per se treatment of reverse payment settlements is inappropriate, because these agreements also have some potential to enhance rather than impede efficiency.").
134. Schering-Plough, 2003 FTC LEXIS, at *73.
135. Id. at *69.
136. The Commission oversimplifies the issue with the comment "[t]he uncertainty posed by patent litigation is, of course, only one of many types of uncertainty that affect whether a new product can be successfully introduced into a market. But the existence of such uncertainties cannot justify an agreement whose very purpose is to ensure against an increase in competition, by guaranteeing that the new product will not be introduced." Id. at *73, n.62. Few uncertainties of market entry carry a disfavorable governmentally-imposed legal presumption and raise such a specter of complete market exclusion as does a patent on a particular drug.
137. Schering's patent is due to expire on September 5, 2006, but the agreement postponed entry by Upsher-Smith only until September 2001. See id. at *15-16.
entry no longer has an incentive to attack vigorously the validity of the patent in issue or a claim of infringement.\textsuperscript{138}

However, the Commission itself recognizes the key flaw in this argument, namely, "[t]he fact that the generic’s counsel has switched sides does not destroy all potential for an adversary proceeding" as it is possible for the Commission "to step in for the generic’s newly complaisant counsel and champion the generic’s abandoned claims."\textsuperscript{139} If the absence of an adversarial process between non-FTC parties were truly a dispositive obstacle, then no complaints of unlawful collusion could ever be successfully prosecuted by the FTC.

Lastly, the Commission concludes that "a mandated inquiry into [patent validity] issues, as part of an antitrust review, would ultimately have a chilling effect on the efficient settlement of patent litigation."\textsuperscript{140} In light of this legitimate concern, the Commission adopts a new "standard" that "if the parties simply compromise on the entry date, standing alone, they do not need to worry about a later antitrust attack."\textsuperscript{141}

This new "standard" is somewhat more permissive than a \textit{per se} rule against these pharmaceutical settlements.\textsuperscript{142} However, given the varying risk tolerances of the parties involved in such settlements, it is not clear that this narrow range of settlement terms would not have a greater chilling effect on such settlements than the prospect of a patent-validity evaluation by the FTC.\textsuperscript{143}

V. BRIDGING THE DIVIDE

A. The IP / Antitrust Intersection

In order to determine the best treatment of the agreements, an examination of the historical role of patents in antitrust is instructive.\textsuperscript{144} Behavior that would normally be condemned under traditional antitrust principles is often tolerated when intellectual property rights are implicated.\textsuperscript{145} For instance, market allocation between horizontal competitors is \textit{per se} illegal under the \textit{Sherman Act}.\textsuperscript{146} In contrast, when someone

\begin{itemize}
  \item \textsuperscript{138} Id. at *76-77.
  \item \textsuperscript{139} \textit{Schering-Plough}, 2003 FTC LEXIS 187, at *77-78.
  \item \textsuperscript{140} Id. at *69.
  \item \textsuperscript{141} Id. at *78.
  \item \textsuperscript{142} See id. (stating that "[t]his test may not be perfect, but at least it is easy to apply at the time of settlement, when the outcome of the patent case is uncertain").
  \item \textsuperscript{143} Id. at *84-85.
  \item \textsuperscript{144} The logic followed by the court in \textit{Valley Drug} is persuasive here. See \textit{Valley Drug Co.}, 344 F.3d at 1304-05 (providing an overview of instances where patent rights justify what would normally be anticompetitive behavior).
  \item \textsuperscript{145} See \textit{Valley Drug Co.}, 344 F.3d at 1305.
  \item \textsuperscript{146} Id. at 1304.
\end{itemize}
holds a patent, they can exclude as many people as they want from the market, divide territories among licensees, and even partition markets in other ways, "such as by customer class." Although courts recognize that "[s]uch arrangements undoubtedly tend to result in lower production and higher prices of the patented article than if competition were unrestrained, ... these anticompetitive tendencies do not render them in violation of the Sherman Act." Such a discrepancy can be reconciled by looking to the Congressionally-granted rights inherent in the patent grant.

B. The Reasonable Rule

The ability of patent rights to alter the application of antitrust rules is what makes a per se rule inappropriate for pharmaceutical settlements under the Hatch-Waxman Act. While Hovenkamp and the Sixth Circuit have taken formidable stabs at defining a clear standard in an uncertain area of law, their arguments are flawed because they omit or misinterpret the role of patent rights in evaluating drug settlements. Specifically, the court held the agreement between HMR and Andrx to be "a naked, horizontal restraint of trade that is per se illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers." The Eleventh Circuit is correct in its criticism of the Sixth Circuit's decision. The 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. Such exclusion, however, was anticipated and even intended by Congress. As Cotter aptly notes, "[f]or better or worse, patents exist, and they reflect a legislative judgment that their benefits exceed their costs." The Sixth Circuit's failure to consider this fundamental principle of patent protection undermines the credibility of the proposed per se rule determination.

Hovenkamp takes a more reasoned approach in his advocacy of a per se rule, making illegal any settlement that exceeds the expected costs of litigation for the

147. See id. at 1304-05.
148. Id. at 1305.
149. Ciprofloxacin, 261 F. Supp. 2d at 248 ("The patent laws, authorized by the Constitution, were enacted by Congress to stimulate invention and reward innovation by granting a patent holder a limited monopoly on the manufacture, use and sale of the patented invention.").
150. See Valley Drug Co., 344 F.3d at 1304-05.
151. See id. at 1311, n.2.
152. Cardizem, 332 F.3d at 911.
153. Ciprofloxacin, 261 F. Supp. 2d at 248 ("It is well established that the exclusion of infringing rivals is at the 'heart' of the patent right." (citations omitted)).
154. Cotter, supra note 3, at 1810.
patent holder.\footnote{155} Hovenkamp takes an antitrust-first approach when evaluating settlements, contending that "[t]he very fact that the pioneer finds it worthwhile to pay a large exclusion payment tends to establish market power[,]" and "[i]t also suggests some inherent uncertainty as to the validity or scope of the patent."\footnote{156}

Hovenkamp's approach disregards two important points: first, absolute certainty of intellectual property rights is a myth, as imperfections within the PTO, juries, courts, etc. make such certainty unattainable; and second, given this uncertainty, economically rational companies will be willing to pay more than is possibly necessary to compensate for this systemic risk. In other words, a company may pay more than the costs of litigation to settle a patent case, even when trial would find the patent both valid and infringed.\footnote{157}

Patents involved in litigation are given a mere presumption of validity.\footnote{158} In spite of this fact, Hovenkamp's proposed rule requires a patentee to proceed as if the patent was valid to a legal certainty.\footnote{159} The EDNY's argument is also persuasive on this point, as the Hatch-Waxman Act has changed the typical balance between the patent holder and the alleged infringer, transferring the majority of the traditional risk to the patentee.\footnote{160} Although the FTC suggests this balance shifting was intended by Congress,\footnote{161} to require the patent holder to act as if that risk is non-existent is still irrational at best.

Hovenkamp's reliance on consumer welfare as the keystone of the per se argument is also unpersuasive. Hovenkamp justifies his per se proposal saying that, "[t]he very fact of that uncertainty suggests that exclusion payments are anticompetitive—that on average such agreements exclude at least some generics that in fact had a legal right to compete."\footnote{162} By appealing to the settlements in the aggregate, Hovenkamp glosses over a key problem in his per se rationale. A fundamental of per se rules is:

\begin{enumerate}
\item Hovenkamp, supra note 2, at 1759.
\item Id. at 1757-58.
\item Cotter, supra note 3, at 1812 (noting that a per se "would rule out the availability of reverse payments except in cases in which the patent plaintiff was absolutely certain of prevailing at trial, but 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").
\item \textit{See} Med. Instr. & Diagnostic Corp. v. Elekta AB, 344 F.3d 1205, 1220 (Fed. Cir. 2003) (noting that "[w]hen looking at this prefered evidence of invalidity, it must be kept in mind that issued patents enjoy a presumption of validity").
\item \textit{See} Hovenkamp, supra note 2, at 1758 ("The very fact of that uncertainty suggests that exclusion payments are anticompetitive. . .").
\item \textit{Ciprofloxacin}, 261 F. Supp. 2d at 251 (finding that Paragraph IV certification infringement actions shift the vast majority of the risk in the suit to the patent holder).
\item \textit{Schering-Plough}, 2003 FTC LEXIS, at *65 ("We agree with the court that Hatch-Waxman may have altered the litigation incentives of pioneer and generic manufacturers. The statute was intended to do just that.").
\item Id
\end{enumerate}
[I]t also avoids the necessity for an incredibly complicated and prolonged economic investigation into the entire history of the industry involved, as well as related industries, in an effort to determine at large whether a particular restraint has been unreasonable—an inquiry so often wholly fruitless when undertaken.\textsuperscript{163}

Unlike the situations where an inquiry is so often fruitless, in a great number of pharmaceutical settlement cases, the patent is likely valid and infringed, and consequently the consumer is not harmed.\textsuperscript{164} Thus, a per se rule would both undermine the actions of economically rational companies and be overinclusive, proscribing actions that in the great number of cases are in no way anticompetitive or injurious to consumer welfare.\textsuperscript{165} Furthermore, in cases such as \textit{Schering-Plough} where the settlement allowed for generic entry prior to the expiration of the patent, a per se rule may actually hurt consumers, as the generic entry would actually be \textit{delayed} by a finding of patent validity.\textsuperscript{166}

Hovenkamp's reliance on consumer welfare also falters when analogized to patent settlements outside of the pharmaceutical context.\textsuperscript{167} In the conventional case, a patent holder detects potential infringement by a company or individual and files a lawsuit for infringement.\textsuperscript{168} Often the case will settle with some amount of money being paid by the alleged infringer to the patentee.\textsuperscript{169} In addition, the alleged infringer may end up licensing the patented technology in order to continue production of the allegedly infringing product.\textsuperscript{170} Such agreements seldom set off antitrust alarms, yet under Hovenkamp this should not be the case.\textsuperscript{171} Applying the rationale in Hovenkamp's proposed rule,\textsuperscript{172} if the amount of the settlement is less than the lost monopoly profits minus anticipated litigation costs, then this traditional

\begin{itemize}
  \item \textsuperscript{163} \textit{Ciprofloxacin}, 261 F. Supp. 2d at 232 (quoting North Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958)).
  \item \textsuperscript{165} \textit{Id.} at 748-49.
  \item \textsuperscript{166} \textit{See Schering-Plough}, 2003 FTC LEXIS 187 at *69.
  \item \textsuperscript{167} \textit{See Cotter, supra} note 3, at 1790. Even Hovenkamp et al. admit that exclusionary payments are a problem particularly in the pharmaceutical industry because of "its unique patent rules." Hovenkamp, \textit{supra} note 2, at 1751.
  \item \textsuperscript{169} \textit{Id.}
  \item \textsuperscript{170} Hovenkamp, \textit{supra} note 2, at 1721.
  \item \textsuperscript{171} \textit{See id.} at 1722.
  \item \textsuperscript{172} \textit{See Hovenkamp, supra} note 2, at 1759 (suggesting "a payment from a patentee to an infringement defendant for the latter's exit from the market is presumptively unlawful" unless the plaintiff can demonstrate "that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit").
\end{itemize}
patent settlement should also be per se unlawful. Although the direction of the pecuniary flow is reversed, this is still analogous to the pharmaceutical cases under Hatch-Waxman, as you have a patentee settling for less than could be gained in court under his patent grant, with an accompanying decrease in consumer welfare through eliminating the risk of a finding of invalidity. Such an extension of Hovenkamp's proposed rule would likely prove a fatal blow to the efficient resolution of patent cases. Yet to permit such agreements in one context and outlaw them per se in another would be highly disingenuous.

I propose the adoption of a new rule akin to the policy rationales discussed in Valley Drug and In re Ciprofloxacin—a rule instructing "that the potential exclusionary power of the patent must first be considered." Thus, a party challenging a pharmaceutical settlement must meet the burden of showing that the agreement rewards the patentee with protection that exceeds this "potential exclusionary power" for the patent in question. Under such a rule of reason, evidence of payments exceeding the expected costs of litigation would still be persuasive, but not dispositive. The more such payments exceed the expected litigation costs, the more relevant the argument that the underlying intellectual property right is not as strong and the agreement is more anticompetitive.

Such a rule may be less efficient than Hovenkamp's proposed per se treatment and may require greater investigation into the merits of the intellectual property issue in dispute. Ironically, such an inquiry could result in a sub-trial highly similar to the patent trial the parties had hoped to avoid through settlement. Yet the increase in fairness to the patent holders and realism of expectations should more than compensate for any such decrease in judicial efficiency. In addition, once such a rule of reason has been established, the expectation of this additional litigation work

173. See id.
174. This reversal in payment is perhaps most accurately attributable to the ease with which generic drug manufacturers can challenge patent validity under the Hatch-Waxman Act. See Ciprofloxacin, 261 F. Supp. 2d at 251 (finding that Paragraph IV certification infringement actions shift the vast majority of the risk in the suit to the patent holder).
175. See Cotter, supra note 168, at 1071-76 (discussing several settlement situations giving rise to reverse settlement payments).
177. See, e.g., Crane, supra note 164, at 748-49 (discussing advantages and disadvantages of a per se rule).
179. See id.; Ciprofloxacin, 261 F. Supp. 2d at 257.
180. Valley Drug Co., 344 F.3d at 1310-11.
181. See Cardizem, 332 F.3d at 908.
183. See North Pac. Ry., 356 U.S. at 5.
184. See Crane, supra note 164, at 748-49.
will inevitably factor into the patent holder's decision to settle in the first place in a pharmaceutical case.  

VI. CONCLUSION

Although the Hatch-Waxman Act is heralded for its benefits to original drug manufacturers, generic drug manufacturers, and consumers alike, intellectual property settlements, under the Hatch-Waxman Act's auspices, have given rise to considerable conflict both in and out of the federal court system. The question of which antitrust analysis to apply to pharmaceutical settlements under the Hatch-Waxman Act is not easily answered, as efficiency and fairness are placed in direct conflict by supporters and retracted of a per se treatment of such settlements.

Recent academic articles and circuit court cases on both sides of the argument have clouded the picture as to the correct antitrust treatment of these exclusionary agreements. 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. Despite such appeal, the prerequisite justifications for adopting a per se rule are simply not met in these distinct cases. Such a rule does not sufficiently take into account the relevance of the brand name drug manufacturer's patent rights in its evaluation. Also, there must be more allowance for the actions of economically rational companies than a per se rule can provide. Although a per se rule would certainly conserve judicial resources, such a rule would

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185. The FTC goes so far as to predict a "chilling effect" on settlements. Schering-Plough, 2003 FTC LEXIS at *69. The Commission does not, however, suggest any less-prescriptive alternatives. See, supra, Part IV-D.

186. Despite the initial concerns, the Drug Price Competition and Patent Term Restoration Act of 1984 [Hatch-Waxman] is now considered to be one of the greatest pro-consumer bills of all time. It has been credited with revitalizing research and innovation in the pharmaceutical industry, enabling these businesses to become one of the most successful sectors in our economy. Generics benefited as well. Hatch, supra note 5, at 80.

187. See, e.g., Cardizem, 332 F.3d 896; Valley Drug Co., 344 F.3d 1294; Hovenkamp, supra note 2, at 1720-21.

188. See, e.g., Cotter, supra note 168, at 1081 (discussing the conflicting literature concerning exclusionary payments).

189. See, e.g., Hovenkamp, supra note 2, at 1765 (per se); Cotter, supra note 3, at 1816 (rule of reason).

190. Hovenkamp, supra note 2, at 1765.

191. See Ciprofloxacin, 261 F. Supp. 2d at 232 (noting that per se treatment is appropriate when the antitrust question is "an inquiry so often wholly fruitless when undertaken" (quoting North Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958)).


be overinclusive, proscribing far more actions than required by the principles of antitrust.\textsuperscript{194}

Once the \textit{per se} rule structure has been set aside, a difficult problem remains as the court must draw a fine distinction between the acceptable exercise of the exclusionary power inherent in the patent grant and unacceptable collusion and exclusion in violation of the Sherman Act.\textsuperscript{195} Such an inquiry may require investigation into the merits of the underlying intellectual property dispute, in effect vitiating much of the efficiency and certainty sought by the parties when entering into the settlement agreement.\textsuperscript{196} Yet, “a deep investigation of the merits of the case will sometimes be the cost of accuracy.”\textsuperscript{197}

A \textit{per se} rule is a simple and clean method for evaluating the antitrust implications of pharmaceutical settlements under the Hatch-Waxman Act.\textsuperscript{198} Unfortunately, the potential inaccuracies and inequities of a \textit{per se} rule outweigh any potential efficiency gains. Although courts, like the Sixth Circuit, might be tempted to follow Hovenkamp’s suggestion and “avoid this inquiry whenever possible”\textsuperscript{199} through the institution of a \textit{per se} rule, the demands of equity should dissuade the courts from taking such an extreme stance.

\begin{enumerate}
\item \textsuperscript{194} See id.
\item \textsuperscript{195} See, e.g., Cotter, \textit{supra} note 168, at 1074-75 (engaging in a complex analysis of a potential reverse payment scenario).
\item \textsuperscript{196} See \textit{Ciprofloxacin}, 261 F. Supp. 2d at 232.
\item \textsuperscript{197} Hovenkamp, \textit{supra} note 2, at 1766.
\item \textsuperscript{198} See \textit{id.} at 1757-58.
\item \textsuperscript{199} \textit{id.} at 1765.
\end{enumerate}