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Solving the Procedural Quagmire for Testing Reverse Payment Settlements

Richard McMillan, Jr., Mary Bram & M. Brinkley Tappan*

I. INTRODUCTION

Patent disputes between branded and generic drug manufacturers governed by the Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Act")[1] are often settled under terms that contemplate some payment of money by the branded firm in exchange for the generic firm's agreement to withdraw wholly or partially from the market. For years, the Federal Trade Commission (FTC) has attempted to label these "reverse payment settlements" as anticompetitive under Section 5 of the Federal Trade Commission Act[2] and Sections 1 and 2 of the Sherman Act. [3] Such settlements have also been attacked in Congress; legislation has been introduced to prohibit reverse payment settlements on grounds that they retard the growth of less expensive generic drugs and increase health care costs for American consumers.[4] Most recently, the Department of

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1. Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. 355 and 35 U.S.C. 271(e) (2006)).

2. *See* 15 U.S.C. § 45 (2006).

3. *See* 15 U.S.C. §§ 1–2 (2006). According to FTC Commissioner Jon Leibowitz, "[e]liminating these pay-for-delay settlements is one of the most important objectives for antitrust enforcement in America today." Jacqueline Bell, *FTC, Calif. Launch Reverse Payment Challenge*, LAW360, Feb. 3, 2009.

4. Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (as introduced, February 3, 2009).

Justice (DOJ), in response to invitation by the Court of Appeals for the Second Circuit, has endorsed the proposition that reverse payment settlements should be deemed presumptively unlawful under a Section 1 rule of reason analysis, and permitted only in rare circumstances.[5]

Courts to date have largely rejected these criticisms. Practical-minded judges, even while expressing concerns regarding the risks posed by reverse payment settlements, have recoiled from the daunting prospect of probing the justifications for intricate settlements of complex patent disputes. Instead, courts have generally defaulted to the proposition that patent law, which contemplates legal monopolies by patent holders, should trump inconsistent antitrust concerns.[6] Government enforcement agencies, on the other hand, have continued to press their case that reverse payment settlements presumptively violate antitrust laws, but have yet to propose a meaningful set of procedures for how a rule of reason analysis should proceed in such circumstances or how any such presumption might be overcome.

The state of this debate is unsatisfactory because it has tended to be framed by two extremes—those proposing presumptive validity and those proposing presumptive invalidity, with neither side proposing attractive methods for assessing the presumption or appropriate standards for rebutting the presumption. More sensible treatment of reverse payment settlements might be possible if the courts were able to settle on a thoughtful and effective method for applying antitrust scrutiny to these types of settlements, but to date, a suitable formula has proven elusive.

As a matter of theory, there is credible cause for antitrust concern. Within the framework of Hatch-Waxman in which these settlements occur, there are substantial incentives that tend to encourage reverse payment settlements between

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5. Brief for the United States in Response to the Court's Invitation at 9–10, 19–32, Ark. Carpenters Health & Welfare Fund v. Bayer, AG, No. 05-2851-cv(L) (2d Cir. July 6, 2009) [hereinafter DOJ Brief].

6. *See, e.g.*, *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 202 (2d Cir. 2006). More recently, however, the Second Circuit has indicated a willingness to revisit the issue of how to balance antitrust and patent law in connection with reverse payment settlements. *See Ark. Carpenters Health & Welfare Fund v. Bayer,* AG, No. 05-2851-cv(L), 2010 WL 1710683, at *7 (2d Cir. Apr. 29, 2010).

branded and generic firms even when there will be negative impacts on competition and consumers. The branded company is defending "monopoly" profits, and thus has a huge incentive not to put that monopoly at risk by seeing the case through to a judgment that could potentially invalidate the patent. By comparison, the generic firm—whose entry into the market will predictably drive down prices—often anticipates lower profitability as a result and thus more limited upside opportunity. Accepting a slice of the branded company's monopoly profits in settlement entails less risk then a full-fledged market entry while still guaranteeing the generic some substantial return on investment. As courts and commentators have recognized, it is foreseeable that in some cases it would even be in the branded company's self-interest to offer the generic a reverse payment higher than the total economic benefit the generic might hope to achieve by successfully entering the market.[7]

The fact that a reverse payment settlement may be in the self-interest of the two participants does not, of course, automatically dispose of antitrust concerns. Indeed, any "contract, combination . . . or conspiracy"[8] that runs afoul of Section 1 of the Sherman Act will typically have been perceived by participants to be in furtherance of their mutual self-interest. That is usually the reason for the agreement in the first place. But while parties to a reverse payment agreement might be well satisfied, it is relatively easy to imagine circumstances in which consumers—the intended beneficiaries of antitrust law—would not be.

Yet the perceived obstacles to addressing this dilemma remain unresolved. The bedeviling factors continue to be the myriad possible fact patterns in which the reverse payment concept might be used and the seeming unworkability of assessing the real thought processes that motivated the agreement in any particular instance. Faced with their own

7. If a reverse payment settlement exceeds the profit the generic hoped to realize, but is still substantially below the profit that the branded firm hopes to maintain, it could be in the branded firm's self-interest to offer such a settlement and in the generic's self-interest to accept it. *See* DOJ Brief, *supra* note 5, at 5 (quoting *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 209 (2d Cir. 2006)); *see also,* Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 503 (2007).

8. 15 U.S.C. § 1 (2006).

inability to define rules flexible enough to deal with the diverse fact patterns that are encountered, and their own reluctance to second-guess the motivations of parties who agree to settle complex litigation, courts to date have defaulted either to the position of essentially declaring a pox on all reverse payments (by labeling them per se illegal),[9] or throwing up their hands by declaring all disputes within the "exclusionary zone of the patent" off limits to antitrust scrutiny.[10] But while either the per se or "zone of exclusion" approaches may have the questionable benefit of allowing courts to avoid becoming mired in the hard work of careful antitrust analysis, neither does justice to the clear need for such analysis in appropriate cases.

This article proposes a middle ground between these two extremes. We believe the courts should look more seriously at the reverse payment scenario, but should do so with a set of existing and established tools that would allow effective scrutiny of reverse payment settlements without unduly chilling the desirability of such settlements in some circumstances. This would require recognition by litigants that their own litigation case assessments may be open to scrutiny, to the extent permitted under normal discovery procedures, if the parties choose the reverse payment method of settlement. At the core of this proposal is the need for courts to sanction these discovery tools to examine the actual settlement analyses and thought processes of the litigants in reaching their settlement. Such examination allows the most accurate assessment of the real motivations driving the settlement and is the only way to avoid the impossible task of undertaking a de novo study of a complex patent dispute and second-guessing the litigants' own assessments of that dispute through an independent jury trial.

While it may seem worrisome to some that a party's settlement communications may be discoverable in an antitrust challenge to a reverse payment settlement, current discovery and evidentiary principles, if properly applied, should already provide adequate protection to the settlement parties. Litigants can have no valid expectation that the communications

9. *See In re* Cardizem CD Antitrust Litigation, 332 F.3d 896, 908 (6th Cir. 2003).

10. *See*, *e.g.*, *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1333–36 (Fed. Cir. 2008).

between them are always privileged from antitrust analysis. While Federal Rule of Evidence 408 limits admissibility in some circumstances, this bar is not absolute.[11] Moreover, in some extreme cases, even internal communications within one party or the other may be subject to evaluation under exceptions to rules governing attorney-client privilege.

II. REVERSE PAYMENT SETTLEMENTS: A BY-PRODUCT OF THE HATCH-WAXMAN ACT

Reverse payment settlements occur in pharmaceutical patent infringement litigation when a patent owner of a pioneer drug and a generic drug manufacturer settle the suit by agreement that the generic company will cease or delay market entry of its generic in exchange for a settlement payment from the pioneer. Generally, the terms of the settlement also allow the patent owner to preserve the validity of the patents at issue in the infringement suit and both the patent owner and the generic drug manufacturer avoid further costly litigation. The Hatch-Waxman Act provides the regulatory context under which reverse payment settlements arise.

Under the Hatch-Waxman Act, a generic drug manufacturer seeking approval of its generic drug by the Food and Drug Administration (FDA) can file an Abbreviated New Drug Application (ANDA).[12] The ANDA requires that the generic manufacturer demonstrate bioequivalence between its generic drug and an FDA-approved pioneer drug.[13] Additionally, the ANDA requires that if there are potentially relevant patents that will not have expired as of the anticipated market entry date, the generic manufacturer must certify to its belief that such patents are "invalid or not infringed by the manufacture, use, or sale of the generic drug."[14] This certification is called a "Paragraph IV Certification," and is deemed an act of infringement that can be challenged by the pioneer in court.[15]

The generic manufacturer must notify the patent owner of

11. FED. R. EVID. 408.

12. 21 U.S.C.A. § 355(j) (West 1999 & Supp. 2009).

13. § 355(j)(2)(A).

14. § 355(j)(2)(A)(vii).

15. Mona Gupta & William C. Youngblood, *High-Stakes ANDA Pharmaceutical Litigation and Paragraph IV Challenges*, INTELLECTUAL PROPERTY SUPPLEMENT TO THE LEGAL INTELLIGENCER, April 21, 2008.

its Paragraph IV Certification. The patent owner then has forty-five days to bring a patent infringement suit against the generic manufacturer.[16] If suit is filed, FDA approval of the ANDA is postponed for either thirty months from the notification date or until, within the thirty- month period, a court issues a decision regarding validity or infringement of the patent.[17]

Paragraph IV Certification is attractive to generic manufacturers because the first ANDA filer receives a 180 day exclusivity period within which it is the only company allowed to market the generic drug.[18] Notified patent owners usually bring suit, however, and most often settle with the first ANDA filer. Those settlements typically take one of two forms: (1) the generic pays some amount to the patent owner, albeit perhaps less than the patent owner originally demanded, and proceeds to enter the market; or (2) the patent owner pays some amount to the generic, in exchange for the generic's agreement to delay market entry (the so-called "reverse payment" scenario). In the former case, the settlement is justified on normal grounds, namely, it resolves uncertainty regarding the patent rights and avoids the potentially enormous cost and time associated with litigation. In the latter case, however, the assertion of patent rights by the branded firm was not sufficient to prevent market entry by the generic. Rather, it took the assertion of patent rights plus some payment of money to secure that result. The issue is whether that payment, together with the remaining terms of settlement, fairly addresses not only the private interests of the litigants but also the public interests and requirements of both patent and antitrust law.

III. ANTITRUST SCRUTINY OF REVERSE PAYMENT SETTLEMENTS

Reverse payment settlement agreements commonly attract antitrust scrutiny from private plaintiffs or government regulators, and sometimes both. Given that a generic drug is, by definition, comparable to the pioneer drug with regard to "dosage form, strength, route of administration, quality,

16. § 355(j)(5)(B)(iii).
17. *Id.*
18. Gupta & Youngblood, *supra* note 15.

performance characteristics and intended use,"[19] there is no question that a generic drug competes with a name-brand drug when introduced to the market. Such competition has the potential to reduce prices and benefit consumers. When the possible introduction of a generic drug is forestalled by a confidential settlement between two competing drug companies, consumers may become naturally suspicious, if the pioneer remains the only seller in the market and/or prices remain higher than they would have had the two companies been forced to compete for sales. Although these settlements have been attracting antitrust scrutiny for years, the courts have not developed a common analytical approach.

On one side of the current debate regarding the appropriate form of analysis is the Sixth Circuit's seminal opinion in *In re Cardizem CD Antitrust Litigation*.[20] In that case, the Court found the reverse payment settlement at issue to be per se unlawful.[21] The court found the agreement "a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade."[22]

One distinguishing feature of *Cardizem*, however, was that the generic agreed not to introduce products that fell outside the scope of the patent, and the case has been distinguished on that basis.[23] No other appellate court to date has followed the Sixth Circuit. Rather, a new trend has developed in favor of an analysis of the "exclusionary zone" of the patent. In *Valley Drug Co. v. Geneva Pharmaceuticals*, the Eleventh Circuit refused to uphold the district court's characterization of the settlement agreement as per se illegal because a patent was involved.[24] Noting that a patent provides a lawful right to exclude and that the exclusionary right may be exercised in many ways, the Eleventh Circuit held that the district court

19. U.S. Food and Drug Administration, Abbreviated New Drug Application (ANDA): Generics, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm (last visited Mar. 23, 2010).

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

21. *Id.* at 900.

22. *Id.* at 908.

23. Holman, *supra* note 7, at 545–46 (2007).

24. Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1304 (11th Cir. 2003).

erred in failing to consider the "exclusionary power" of the patent at issue.[25]

Two cases in 2005 provided further traction for the "exclusionary zone" analysis. In *In re Tamoxifen Citrate Antitrust Litigation*, the Second Circuit professed to apply a rule of reason analysis to balance (1) the adverse effect on competition; (2) the pro-competitive "redeeming virtues" of the action; and (3) whether the same pro-competitive benefit could have been achieved through other means.[26] Although the trial court that heard the initial stage of the underlying patent litigation held Astra-Zeneca's patent invalid,[27] the Second Circuit refused to presume invalidity and afforded great deference to the power of the patent throughout its analysis.[28] Noting that the settlement agreement had not exceeded the "exclusionary zone" of the patent by affecting other products, foreclosing completely competition in the tamoxifen market, or barring other generics from seeking to enter the market, the court attributed any adverse effects to the power of the patent, rather than to an anticompetitive agreement between Astra-Zeneca and Barr.[29] On that basis, it upheld the decision of the trial court dismissing the case.

In *Schering-Plough Corp. v. Federal Trade Commission*, the Eleventh Circuit declined to apply a traditional per se or rule of reason analysis, opting to follow *Valley Drug* by examining "(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."[30] Once again, the court paid great deference to the power of the patent, and justified each term of the settlement on those grounds.

The "exclusionary zone" analysis was most recently adopted by the Federal Circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*.[31] In that case, plaintiffs

25. *Id.* at 1306.

26. *See In re* Tamoxifen Citrate Antitrust Litig., 429 F.3d 370, 385 n.13 (2d Cir. 2005), *amended by* 466 F.3d 187 (2d Cir. 2006).

27. *Id.* at 386.

28. *Id.* at 392–93 & n.22.

29. *See id.* at 403.

30. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005) (citing Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003)).

31. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323,

argued on appeal that the district court had failed to apply a proper rule of reason analysis because of its emphasis on the "exclusionary zone" of the patent.[32] In response, the Federal Circuit stated that "the plaintiffs had failed to demonstrate that the Agreements had an anti-competitive effect on the market for ciprofloxacin beyond that permitted by the patent."[33] It therefore concluded that it was unnecessary to proceed to the second and third steps of the rule of reason analysis, because plaintiffs failed to meet their burden in showing anti-competitive effects.[34] The court rejected plaintiffs' assertion that a proper rule of reason analysis should focus on the amount of the reverse payment and the strength of the underlying patent, and adopted the "exclusionary zone" reasoning espoused by the Second and Eleventh Circuits.[35] On that basis, it affirmed the district court's dismissal of plaintiffs' claims.

Most recently, however, the Second Circuit has indicated a possible willingness to revisit its holding in *Tamoxifen*. In *Arkansas Carpenters Health & Welfare Fund v. Bayer* (a companion case to the *Cipro* litigation in the Federal Circuit),[36] the court requested briefing by DOJ.[37] DOJ responded by suggesting that the court revisit its earlier holding, and quoted extensively from that holding. In particular, DOJ noted that in *Tamoxifen*, the Court had observed that if the patent is found invalid, "the *total* profits of the patent holder and the generic manufacturer on the drug in the competitive market will be *lower* than the total profits of the patent holder alone under a patent-conferred monopoly."[38] Accordingly, it is "therefore likely to be in the patent holder's economic interest 'to pay some portion of that difference to the generic manufacturer to maintain the patent monopoly market for itself,'" particularly if the payment is "larger than the generic drug firm's expected

1327 (Fed. Cir. 2008).

32. *Id.* at 1331.

33. *Id.* at 1332.

34. *Id.*

35. *Id.* at 1334–1335.

36. No. 05-2851-cv(L), 2010 WL 1710683 (2d Cir. Apr. 29, 2010).

37. *See* DOJ Brief, *supra* note 5.

38. *Id.* at 5 (quoting *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 209 (2d Cir. 2006)).

gain from litigating the validity issue."[39]

DOJ then proposed that all reverse payment settlements be considered presumptively unlawful, but that the parties be permitted to overcome the presumption by showing "a reasonable explanation of the payment, so that there is no reason to find that the settlement does not provide a degree of competition reasonably consistent with the parties' contemporaneous evaluations of their prospects of litigation success."[40] DOJ characterized this as just the straightforward application of a rule of reason analysis of competitive impacts.[41] But because, under DOJ's formulation, the analysis would be tied to "the parties' contemporaneous evaluations of their prospects of litigation success,"[42] it presents a conundrum for how it could best be applied.

After receiving the input from DOJ, the Second Circuit recently affirmed the reverse payment settlement at issue in *Bayer*, proclaiming itself bound by the analysis in *Tamoxifen*.[43] However, it expressly invited the plaintiffs to seek review *en banc*, in light of the "exceptional importance" of the antitrust implications of "reverse exclusionary payment settlements."[44] Hinting that further reshaping of the law may be required, the panel suggested there were "compelling reasons to revisit *Tamoxifen*."[45] Thus, weaknesses in the prevailing "exclusionary zone" analysis may yet auger some further evolution of the law, and if the Second Circuit does change course en banc, the issue may well reach the Supreme Court.[46]

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39. *Id.* at 5–6 (quoting *Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 209).

40. *Id.* at 10.

41. *Id.* at 9–10.

42. *Id.* at 10.

43. Ark. Carpenters Health & Welfare Fund v. Bayer, AG, No. 05-2851-cv(L), 2010 WL 1710683, at *5, *7–8 (2d. Cir. Apr. 29, 2010).

44. *Id.* at *1.

45. *Id.* at *8.

46. *Bayer* was a companion case to the Federal Circuit's decision in *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1327 (Fed. Cir. 2008), and a new direction by the Second Circuit would could well trigger a conflict between the circuits that would be appropriate for Supreme Court review.

IV. WEAKNESSES OF THE "EXCLUSIONARY ZONE" ANALYSIS

As an analytic tool, the "exclusionary zone" analysis suffers from numerous drawbacks. First, it tends to be almost entirely circular. There is no "exclusionary zone" of an invalid patent. Rather, the "exclusionary zone" of a patent is by definition dependent upon whether the patent is valid—the very issue *disputed* in the underlying infringement case but *assumed* in an "exclusionary zone" analysis.

Moreover, at issue in an antitrust challenge to a reverse payment settlement are not the rights arising from the patent but the rights arising from a private settlement agreement. That agreement is a contract, a typical object of antitrust scrutiny. Contract law does not allow parties to resurrect an otherwise invalid patent and make it valid. As the DOJ explained in its brief to the Second Circuit in *Bayer*, the Patent Act "offers the patentee a choice between exercising its statutory privilege to protect its interests through litigation to enforce the patent—with the attendant risk that the patent may be invalidated—and relying on private measures that avoid the risk of patent invalidation but provide no antitrust immunity."[47] By essentially presuming patent validity, courts applying an "exclusionary zone" analysis are saying that if there is any possibility that the settlement is justified by patent rights, then the whole antitrust inquiry must be scuttled.

Despite its weaknesses, it is not difficult to understand why courts have embraced the "exclusionary zone" analysis as a lesser of evils. Nearly all courts and scholars acknowledge that because settlement agreements are generally to be encouraged in litigation, it would be inappropriate always to deem them per se unlawful under the antitrust laws.[48]

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47. DOJ Brief, *supra* note 5, at 14.

48. *See*, *e.g.*, *In re* Tamoxifen Citrate Antitrust Litig., 429 F.3d 370, 390–391 (2d Cir. 2005), *amended by* 466 F.3d 187 (2d Cir. 2006); Erica N. Anderson, Note, Schering *the Market: Analyzing the Debate over Reverse-Payment Settlements in the Wake of the Medicare Modernization Act of 2003 and* In re Tamoxifen Citrate Litigation, 93 IOWA L. REV. 1015, 1028–30 (2008) (discussing different scholarly approaches for dealing with reverse payment settlements). Moreover, even a rule of reason analysis is problematic, as some of these same commentators suggest. *See*, *e.g.,* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1065 (11th Cir. 2005). Just as importantly, a rule of reason analysis could implicate the "trial within a trial" problem that so fundamentally is driving the courts toward the exclusionary zone approach.

However, when courts reject the black and white litmus test of a per se rule, they have found little to fall back on. The specter of a rule of reason analysis applied to highly technical patent litigation has proved daunting. Expressly or implicitly, courts have recoiled at the prospect that after a settlement meant to *resolve* complex patent litigation, they must oversee a process in which a jury wades back into the underlying merits of the same dispute (in a "trial within a trial"), and then proceeds to a further level of complexity analyzing antitrust concerns. At some level, the courts seem to be saying that considerations of practicality must play a role.

The FTC and DOJ have even recognized these worries as legitimate, at least up to a point. The DOJ has specifically foresworn the need for a trial within a trial to determine patent validity: "Requiring a court to determine whether the patentee would have prevailed . . . would unduly complicate the litigation by requiring at least a mini-trial of the patent issue in the antitrust case, and likely more."[49] And yet, even DOJ offers no suggestions for how this "mini-trial" might be avoided. Rather, DOJ acknowledges that in most cases, the presumption that reverse payment settlements are invalid can be overcome only "by showing that the settlement preserved a degree of competition reasonably consistent with what had been expected if the infringement litigation went to judgment."[50] How this might be determined, however, is for the most part not addressed.

There is a need for some procedural framework to assess the "but for" world avoided by the settlement, i.e., the issue of what would have been "expected if the infringement litigation went to judgment."[51] We believe there are established tools available for this task. Before analyzing these tools, however, we must first look more closely at what analysis should actually be required in order to properly assess the legality of a reverse payment settlement under the antitrust laws.

See infra text accompanying notes 56–58.

49. DOJ Brief, *supra* note 5, at 25–26 (internal citation omitted).

50. *Id.* at 30.

51. *See id.*

V. THE ANALYTIC TEST FOR EVALUATING REVERSE PAYMENT SETTLEMENTS

While a complete ban of reverse payment settlements might appeal to antitrust purists, such a drastic measure is both unnecessary and undesirable. A complete ban would frustrate the general policy of courts to encourage settlements of protracted litigation. Reverse payment settlements help to manage legal costs and mitigate risk associated with jury trials in patent cases, while potentially bridging the gap in settlements that, particularly if made in the context of some broader arrangement, could offer pro-competitive benefits when considered overall. However, courts have found it extremely difficult to identify any suitable procedure by which reverse payment settlements could be effectively analyzed. Although the potential for antitrust abuse is recognized, the lack of a practical means for assessing this potential has stymied most courts to date. The problem has been noted, but the remedy has proven elusive.

The comprehensive itemization of all factors that might affect a proper antitrust analysis of reverse payment settlements is beyond the scope of this article. Suffice it to say that at least at a general level, rule of reason standards are well developed, and we are confident that courts could refine them with more specificity in the particular context of reverse payments as the cases progressed. The central difficulty, however, is that challenging a reverse payment settlement necessarily requires an analysis of the bona fides of that settlement. It is therefore worth at least some brief analysis of the kinds of issues that might be implicated in this environment.

The touchstone of any rule of reason analysis is impact on competition. If courts, in response to the demands of government regulators, begin to look more closely at reverse payment settlements, touchstones may develop to facilitate the rule of reason analysis. A reverse payment in excess of the total profits the generic might have achieved if market entry had occurred might, for example, require particularly close scrutiny. Where the full terms and impact of settlement are less clear, however, courts have recognized the potential need to analyze the probability that extended litigation would have produced a more pro-competitive outcome (i.e., beneficial to

consumers) than the proposed settlement.[52] This necessarily requires at least some evaluation of the parties' potential prospects in the litigation, because it is the projected outcome of that litigation which defines the "but for" world to which the settlement must be compared.

In addition, there must be some market and profitability analysis. A sensible rule of reason analysis would consider not only the scope of the patent rights, but also the profitability of the market in which those rights could be exercised. Both of these are facts that the parties would have considered themselves when they negotiated the settlement. Parties would not enter into a reverse payment settlement without assessing: (1) the strength of the patent; (2) the profit the generic would have earned had it entered the market; (3) the size of the reverse payment; and (4) any other terms of the settlement or conditions of the negotiation that would tend to affect the balance.[53]

At least as a theoretical matter, the evaluation of these factors should permit a court to determine whether a reverse payment settlement was a reasonable conclusion to the underlying patent litigation, or whether it is indicative of a "pay-for-delay" agreement not justified by the merits of the patent. DOJ, for example, has stated that the presumption of unlawfulness would be overcome if the settlement provides "a degree of competition reasonably consistent with the parties' contemporaneous evaluations of their prospects of litigation success."[54]

While seemingly straightforward, however, DOJ's formulation masks hidden difficulties. These difficulties vary depending upon whether the generic's market entry is completely prohibited or only delayed under the terms of settlement. A threshold question, for example, is whether a reverse payment settlement should ever be deemed reasonable if it allows no generic competition until the patent term has expired. One could imagine some limited circumstances where rule of reason standards might be satisfied—e.g., where both parties believed there was overwhelming evidence that the patent was valid and infringed and the reverse payment was

52. *See Tamoxifen Citrate Antitrust Litigation*, 429 F.3d at 386.
53. *See*, *e.g.*, *id.* at 391–392; Anderson, *supra* note 48, at 1028–31.
54. DOJ Brief, *supra* note 5, at 10.

very low—but this would probably be the unusual case.

We believe that in most cases, courts confronting reverse payment settlements will be able to identify at least some pro-competitive features. Eventual entry by the generic may be permitted, or at minimum, the generic may be cross-licensed to sell some "generic" version of the branded firm's product. In such circumstances, the inquiry will turn on the size of the reverse payment, the terms of market entry by the generic, and the likely litigation outcome had no settlement been reached. A sliding scale might be envisioned. At one end of that scale are cases involving perceptions by the parties of a high likelihood of patent validity, and relatively low reverse payment amounts. At the other end are weak patent rights, high monetary payments, and substantial foreclosure of market entry by the generic.

Concrete examples help to illustrate. Assume for example that a settlement was premised on the conclusion, shared by both parties, that the underlying patent had a substantial likelihood (i.e., 75% or greater) of being upheld as valid. So long as any reverse payment was small relative to the projected profitability of the pioneer and generic, a settlement might seem justified. The generic under these facts was very unlikely to have achieved market entry through litigation, and the reverse payment amount might be found reasonable when considered in this context and against the fact that it offsets some potential litigation costs and business uncertainty risks associated with "irrational" litigation outcomes. This latter factor is frequently overlooked. Patent jury trials are often criticized for their unreliability,[55] and settlements that overcome that unreliability when the parties have a shared view of the likely outcome should be respected.

If, on the other hand, the pioneer came to the conclusion that the patent in all likelihood would be found invalid, and the pioneer then simply proceeded to buy the generic out of the market by paying it something close to what the generic would have obtained in profit by entering the market, antitrust review does seem appropriate. In that case, a hefty reverse payment would be tantamount to an acknowledgement that the pioneer had no real patent rights but rather could keep the

55. *See, e.g.*, Brad Stone, *Blackberry Smackdown; Wrangling Over Patents Is Worrying Users and Investors*, NEWSWEEK, Dec. 12, 2005, at 48.

generic out of the market only by paying the full value of the generic's likely gain by entering the market. A court could conclude that this was not a reasonable settlement, but a straightforward "pay-for-delay" arrangement, and therefore, an antitrust violation.

Analyzing specific examples is one thing. The texture and complexity of all possible reverse payment scenarios is quite another. It will not be unusual, for example, for the parties to have very different estimations of success, with perhaps each party believing it would be likely to prevail if the case ultimately went to trial. Profit estimates extending into the future might also be highly variable and disputed. There is no "formula" that will adequately measure all possibilities under all circumstances. Nor will courts ever be able to predict with certainty either the likely litigation outcome or the future market behavior.

However, these precise factors will have been analyzed by both parties in reaching their settlement. Even though exact outcomes could not be known, the probabilities of all likely outcomes should have been assessed. As a matter of theory, it therefore seems neither unfair nor particularly difficult to compare the choices made in the settlement agreement with the actual beliefs that drove those choices. In fact, the subjective assessments of the parties, driven by detailed evaluation of the facts and law by knowledgeable counsel, may offer the most reliable tools for assessing the antitrust impacts of the agreement.

While difficulties will remain under any approach, the courts should aspire to some solution to the largely unworkable "exclusionary zone" standard that most courts currently follow. The risks of reverse payment settlements are evident. The severe weaknesses of the "exclusionary zone" test are also evident. A new and better construct needs to be crafted.

VI. AN ALTERNATIVE PROPOSAL

Courts following the "exclusionary zone" rule have imagined that in the absence of a per se approach, analysis of the reasonableness of any particular settlement would necessarily mean becoming bogged down in a "trial within a trial." Under such an imagined approach, the whole issue of whether the patent is valid has to be litigated (despite the settlement) in order to determine if the settlement was

reasonable.[56] This would require claim construction, assessment of all prior art, evaluation of the range of other invalidating defenses, and potentially opening the issue of inequitable conduct before the United States Patent and Trademark Office (USPTO) as well. Most importantly, it would permit a jury to reach its own determination of these issues, thereby potentially second-guessing how *either* party to the litigation actually evaluated them in fact. This "trial within a trial" approach disregards entirely the benefits of settlement and the rights of parties to make their own judgments about which settlements are reasonable, and requires a full-scale vindication of those judgments before a lay jury.

On closer analysis, however, we believe the real problem is not what to analyze, but how to make the analysis. Under our approach, the focus of the rule of reason analysis would be limited to how the parties themselves perceived and evaluated the underlying dispute, and determined the terms of settlement. A key benefit to this approach is that it would take into account a much smaller and potentially more reliable set of facts—namely, what the parties themselves believed and how they evaluated the settlement.[57]

From an analytic perspective, the focus on the parties' own assessments seems entirely appropriate. Litigants analyze their litigation positions in far more detail than any court could do in the span of a trial. In patent litigation, including the months leading up to the litigation, it is not uncommon for millions of dollars in legal and expert fees to be expended. This

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56. "In its decision that led to the Eleventh Circuit appeal in *Schering-Plough*, the FTC concluded that 'it would not be necessary, practical, or particularly useful for the Commission to embark on an inquiry into the merits of the underlying patent dispute when resolving antitrust issues in patent settlements.'" *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1336 (Fed. Cir. 2008) (citing Schering-Plough Corp., No. 9297, 2003 WL 22989651, slip op. at 19 (F.T.C. Dec. 8, 2003)).

57. We do not intend to suggest that probing the parties' settlement evaluations will be a simple exercise. Indeed, once it was understood that settlement intent could be evaluated in some circumstances, we would expect parties to adopt counter-measures to protect against potential discovery probes. Exchanges during the course of some settlement discussions may be guarded, and parties might be expected in any event to avoid incriminating statements in their documentation. But judicial procedures provide mechanisms for deciding upon appropriate discovery in these circumstances, and while some complexity will still be involved, we believe our approach offers enormous savings in both time and effectiveness.

purposely intensive analysis provides the most secure baseline for analyzing the real merits of the dispute.

Although there is little doubt that the most thorough understanding of the facts of any particular dispute is often held by the litigants themselves, when the litigants settle, there ordinarily is a cloak of confidentiality that the litigants are entitled to rely upon to shield their settlement discussions from further scrutiny. In the reverse payment scenario, the trick then is to find a way that respects the legitimate rights of confidentiality, while still permitting some outside scrutiny where appropriate.

Luckily, there is an already established set of tools in our court system that can provide this middle ground. In the approach outlined below, an antitrust plaintiff challenging a reverse payment settlement would proceed in a three-step fashion. First, it could gather publicly available information. Second, it could invoke the principles of Federal Rule of Evidence 408 during discovery, to obtain information about the settlement agreement.[58] Finally, if the court had strong suspicions that there had indeed been an antitrust violation, it could allow the plaintiff to pursue privileged information about the settlement by invoking the crime-fraud exception to privilege. This would have to be done with care, however, and only in extraordinary circumstances, as discussed below.

These steps should proceed seriatim. The Rule 408 inquiry would be best undertaken after the challenge to the reverse payment settlement had been framed by publicly available information, when the exact purpose for the Rule 408 inquiry could be defined on the basis of such information. Similarly, invocation of the crime-fraud exception to attorney-client privilege would require a prima facie showing of wrongdoing (in this case, an alleged antitrust violation) that could be made out only if sufficiently probative facts had been uncovered from public information and the court-supervised Rule 408 inquiry. We analyze each of the three steps below.

58. Rule 408 allows admission of evidence of compromise or offers to compromise when the evidence is offered for a purpose other than to prove "liability for, invalidity of, or amount of a claim that was disputed as to validity or amount, or to impeach through a prior inconsistent statement or contradiction." FED. R. EVID. 408.

A. PUBLICLY AVAILABLE INFORMATION

To learn more about the patent at the center of a settlement, plaintiffs in an antitrust challenge should first be required to look at public information available from several sources. First, the FDA publishes all approved generic and pioneer drugs in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the Orange Book.[59] Pioneer drug entries identify relevant patents. The complaint in the underlying patent infringement case would also identify the patents alleged to have been infringed. Copies of the patents are obtained from the USPTO.[60]

Evidence related to the strength of the patents is available in the prosecution histories of the patents. A prosecution history includes all of the papers filed by the Applicants and the USPTO during prosecution of the patent application. Importantly, the prosecution history includes all Office Actions issued by the USPTO and all amendments and responses to Office Actions filed by the Applicants. Office Actions could provide a basis upon which a patent could potentially be found invalid. Using this source, an antitrust plaintiff could ascertain at least some important facts concerning the likelihood of a patent's validity and proffer evidence of patent invalidity.

Depending on the point at which the pioneer and the generic settled, court filings in the underlying patent infringement case might also provide an antitrust plaintiff with detailed analysis regarding the validity of the patents at issue. This would be particularly true for cases that progressed to the point of summary judgment; motions at that phase of trial could present the best arguments for invalidity and validity, respectively. Thus, depending upon the progress of the case prior to settlement, an antitrust plaintiff might be able to access very useful evidence regarding the strength of the patents at issue.

While a reverse payment settlement agreement is typically confidential, an antitrust plaintiff might also obtain details regarding the settlement agreement in annual reports filed by

59. *See* OFFICE OF GENERIC DRUGS, U.S. DEP'T OF HEALTH & HUMAN SERVS., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2010), *available at* http://www.accessdata.fda.gov/scripts/cder/ob/eclink.cfm.

60. United States Patent and Trademark Office, Patent Full-Text and Full-Image Databases, http://patft.uspto.gov/ (last visited Feb. 17, 2009).

public companies with the SEC. Such reports sometimes include the amount and frequency of payments from the pioneer drug company to the generic manufacturer, terms agreed to by the generic manufacturer in consideration for payment, and other ancillary agreements entered into at the time of the reverse payment settlement agreement. For example, in one of its annual reports, Barr Laboratories, Inc. ("Barr") discussed its reverse payment settlement agreement with Bayer AG and Bayer Corporation (collectively "Bayer"), including the amount of the payment and the terms of a related supply agreement.[61]

Court filings in a civil action initiated by the FTC or DOJ could also provide an antitrust plaintiff with evidence pertaining to the terms of the settlement, the beliefs of settlement participants regarding the settlement, product revenues and projections, the anticompetitive effects of the settlement, and other information. Although government regulators generally initiate non-public investigations in the first instance, if the pioneer drug company and generic manufacturer refuse to sign a consent order, the FTC has been willing to file an action in a U.S. district court seeking injunctive relief. In that case, some fruits of the non-public investigation become public. The FTC recently initiated such an action after a non-public investigation of a reverse payment settlement.[62]

There may be a variety of additional information available as well, especially for important drugs.[63] This might include press releases, trade publications, financial analyst reports, analyst calls with management, FDA dockets, and FTC reports.[64]

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61. Barr Labs., Inc., Annual Report (Form 10-K405) (Sept. 29, 1997), *available at* http://www.sec.gov/Archives/edgar/data/10081/0000950123-97-008183.txt.

62. Complaint for Injunctive Relief, FTC v. Cephalon, Inc., No. 08-cv-2141-RBS (D.D.C. Feb. 13, 2008), *available at* ttp://www.ftc.gov/os/caselist/0610182/080213complaint.pdf.

63. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 646–47 (2009).

64. *Id.*

B. INVOKING FEDERAL RULE OF EVIDENCE 408 DURING DISCOVERY

Although a significant amount of information about a given settlement may be available in the public domain, it may be that this information by itself will be insufficient in many cases to fully resolve antitrust concerns. However, publicly available information should provide an appropriate baseline for seeking court approval of further discovery directed at the reasonableness of the settlement. This would be supervised under the strictures of the Federal Rules of Civil Procedure, and Federal Rules of Evidence 402 and 408. Two sorts of materials could be sought—i.e., the settlement agreement documents themselves and communications between the parties concerning the settlement, including negotiations.

Federal Rule of Evidence 408 allows for the admissibility of evidence of compromise negotiations, so long as the evidence is not offered to prove "liability for, invalidity of, or amount of a claim" that was the subject of the negotiations.[65] The purpose of this stricture is to ensure that evidence of compromise cannot be admitted to prove the validity or invalidity of the underlying claim in a follow-on action to reassert or rely upon that claim.[66] In a follow-on antitrust action, however, it is not the validity or invalidity of the underlying claim that is at issue, but only the parties' subjective perceptions of that claim. Those perceptions may be entirely in error, but the bona fides of the settlement for antitrust purposes would nevertheless turn on those perceptions, rather than the real merits, of the underlying claims. Discovery could therefore properly be limited to facts concerning the settlement agreement and negotiations bearing on whether or not the parties intended to affect an illegal restraint on trade.[67] Discovery directed strictly toward whether there was a patent infringement would generally not be allowed. As one court has stated, evidence of compromise negotiations is likely to be admissible where "the settlement

65. FED. R. EVID. 408.

66. *See* FED. R. EVID. 408 advisory committee's note.

67. *See id.* The advisory committee provides examples of courts admitting evidence of an insurer's settlement offer to prove the insurer's bad faith, *id.* (citing Athey v. Farmers Ins. Exch., 234 F.3d 357, 362 (8th Cir. 2000)), and finding Rule 408 "inapplicable when the claim is based upon a wrong . . . committed during the course of settlement negotiations," *id.* (citing Uforma/Shelby Bus. Forms, Inc. v. NLRB, 111 F.3d 1284, 1293 (6th Cir. 1997).

communications at issue arise out of a dispute distinct from the one for which the evidence is being offered."[68]

The court would nevertheless retain a gate-keeping role in assessing this issue. Thus, an antitrust plaintiff should be required, based on public information, to demonstrate some reasonable basis for its antitrust theory, and be able to explain the specific features of the settlement negotiations that require discovery in order to substantiate that claim. Courts evaluating the admissibility of evidence under Rule 408, for example, often examine not only the purpose for which the party seeks to admit the evidence, but whether admission of the evidence would undermine the policy behind Rule 408, which is to avoid chilling settlement negotiations.[69] In a case in which one party sought to admit evidence from a mediation to establish the amount in controversy for federal jurisdiction purposes, the court admitted such evidence.[70] The court reasoned that "concern that one's adversary will use statements during negotiation as proof of liability or wrongdoing, not concern that it will use them as proof of the amount in controversy, is the primary obstacle to forthright negotiation discussions."[71] Similarly, admitting evidence of a settlement agreement between a pioneer and a generic manufacturer for purposes of an antitrust analysis of the settlement would be unlikely to chill settlement negotiations in an underlying patent infringement case. To the extent there was a chilling effect, it would most likely be manifested in extra care by the drug companies to avoid the kind of discussion that might raise antitrust concerns. Only companies that intended to effect an anti-competitive agreement would need to worry about such "chilling effects." For this reason, admitting evidence of the settlement negotiations should be permissible under Rule 408.

Passing muster under Rule 408 would entitle the antitrust plaintiff to discovery of *non-privileged* communications regarding the settlement. These communications would be a

68. Zurich Am. Ins. Co. v. Watts Indus., Inc., 417 F.3d 682, 689 (7th Cir. 2005).

69. *See, e.g.*, Affiliated Mfrs, Inc. v. Aluminum Co. of Am., 56 F.3d 521, 526 (3d Cir. 1995) ("The policy behind Rule 408 is to encourage freedom of discussion with regard to compromise.").

70. *See* Molina v. Lexmark Int'l, Inc., No. CV 08-04796 MMM (FMx), 2008 WL 4447678 (C.D. Cal. Sept. 30, 2008).

71. *Id.* at *13.

further source of potentially rich information by which the bona fides of the settlement could be evaluated. With the terms of the settlement agreement and underlying, non-privileged discussions exposed to discovery, the parties would be able to develop their arguments about the nature of the settlement, particularly on the basis of the amount of the reverse payment, the stage at which the parties settled, the length of the negotiations, and whether the generic is permitted to license technology or enter the market prior to the expiration of the pioneer's patent. A reasonably rich antitrust analysis could be performed with this information, and an antitrust plaintiff whose case at this juncture was still based only on conjecture and suspicion should be entitled to go no further. However, if discovery of non-privileged settlement materials establishes a prima facie case of a potential antitrust violation, further inquiry will be appropriate, as discussed below.

C. USING THE CRIME-FRAUD EXCEPTION TO PRIVILEGE

Rule 408 itself permits a government prosecutor (such as the DOJ or FTC) to utilize settlement agreements and negotiations for any purpose in connection with a criminal inquiry. Similarly, the law has long permitted confidentiality claims based on attorney-client privilege to be overcome if the communications were in furtherance of a crime or fraud.[72] This "crime-fraud" exception is used sparingly, and should be. Nevertheless, if used with great care, it could hold benefits for evaluating reverse payment cases in which there appears to be prima facie evidence that the antitrust laws have been violated.

The antitrust laws provide for both civil and criminal remedies, and intentional antitrust violations qualify as "criminal" for purposes of the common law crime-fraud exception to privilege.[73] Therefore, an antitrust plaintiff could potentially use the crime-fraud exception to delve even more deeply into what the parties were really intending, by piercing the privilege between the settling companies and their attorneys. This would require some prima facie showing of criminal intent by the challenging party, but should not depend

72. Auburn K. Daily & S. Britta Thornquist, *Has the Exception Outgrown the Privilege?: Exploring the Application of the Crime-Fraud Exception to the Attorney-Client Privilege,* 16 GEO. J. LEGAL ETHICS 583, 584 (2003).

73. *See In re* Burlington N., Inc., 822 F.2d 518, 524–525 (5th Cir. 1987).

upon whether actual criminal charges have in fact been brought by antitrust enforcement authorities. To establish its basis for invocation of crime-fraud, a plaintiff would be required to undertake a two-part showing. First, the plaintiff must convince the court to undertake an in camera review of the documents in question. This requires a factual showing "adequate to support a good faith belief by a reasonable person . . . that in camera review . . . [might] reveal evidence to establish the claim that the crime-fraud exception applies."[74]

Second, the court may order production of otherwise privileged documents on the basis of in camera review, but only if it finds that a prima facie antitrust violation has been made out.[75] Moreover, only those documents found to have been written "in furtherance" of that violation will be ordered to be produced.[76] Under this procedure, therefore, the court retains considerable discretion as to whether the privilege should be pierced, and what specific communications should be produced.

We recognize that the very suggestion that the crime-fraud exception could play a meaningful role here will strike some readers as extreme. But it should not. First, under our proposal, the court would never get to a crime-fraud analysis unless and until the antitrust plaintiff had demonstrated a real basis for its claim. Suspicions or even "possible" inferences would not be enough. The crime-fraud case law requires that the plaintiff demonstrate a prima facie case that, as applied here, the antitrust laws have been violated. Because this violation must be criminal in nature to trigger the crime-fraud exception, it necessarily has an intent element, and the prima facie case would require a demonstration of such intent.[77] We presume that in most cases, this would be an extremely difficult hurdle to surmount.

A plaintiff seeking to invoke the crime-fraud exception

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74. *In re* Ditropan XL Antitrust Litig., No. MDL 06-1761 JSW (EDL), 2007 WL 3256208, at *1 (N.D. Cal. Nov. 5, 2007) (quoting United States v. Zolin, 491 U.S. 554, 572 (1989)).

75. *See* Abbott Labs. v. Andrx Pharm., Inc., 241 F.R.D. 480, 489–490 (N.D. Ill. 2007).

76. Mark A. Thornhill et al., Peering into Lawyers' Files: Prosecutors' Use of the Crime or Fraud Exception 7 (2005) (unpublished paper presented to ABA Section of Natural Res., Envtl. & Energy Law), *available at* http://www.abanet.org/environ/committees/environcrimes/thornhill.pdf.

77. *See Abbott Labs.,* 241 F.R.D. at 490.

thus faces a stiff burden requiring that it both exhausts less intrusive discovery tools and establishes the necessary showing of intent that would be the touchstone for any alleged criminal antitrust violation. A plaintiff seeking to invoke the crime-fraud exception should first be required to review publicly available information and exhaust appropriate discovery tools permitted by Rule 408. Among other things, this may reveal important dimensions of the underlying settlement negotiations. While communications between a party and its attorney are generally privileged, communications between two opposing parties negotiating a settlement agreement generally are not, absent unusual circumstances.[78] Discovery of such information could benefit either party. While a plaintiff will seek evidence of apparently conscious antitrust violations, defendants in many cases will be able to show that their negotiations focused on solutions that should not raise, and were not believed to raise, valid antitrust concerns. In the latter instance, the court would properly deny a plaintiff's request for waiver of attorney-client privilege under the crime-fraud exception.

In the exceptional case where a basis for crime-fraud review does exist, there would be additional protections available by reason of the requirement that a judge first review evidence from the settlement negotiations in camera.[79] Such evidence might include each company's assessment of its litigation risks, advice from counsel about the likelihood of success based on the strength of the patent at issue, and assessments by each party of their potential gains or losses depending on the potential outcomes of the case. All of this evidence would allow a court to assess whether the parties reached a reasonable settlement based on the legitimate factors under consideration at the time, or whether the settlement was simply a veiled agreement by one party to stay out of the market in exchange for an unreasonable reverse payment. If

78. *See* 1 EDNA SELAN EPSTEIN, THE ATTORNEY-CLIENT PRIVILEGE AND WORK PRODUCT DOCTRINE 484 (5th ed. 2007).

79. In camera reviews are sometimes conducted by a judge other than the one presiding over the underlying case, to prevent prejudice to the producing party in the event the evidence does not meet the requirements for admission under the crime-fraud exception. Given that antitrust cases are commonly adjudicated through bench trials, it would be reasonable for a drug company to request that a separate judge review any evidence produced for in camera review.

the court was satisfied that the settlement was reasonable and legitimate, the privileged information submitted for in camera review would never be revealed to plaintiffs, because it would necessarily be insufficient to establish an antitrust crime. If the court were still suspicious of the settlement after reviewing the privileged evidence, and believed that the totality of the evidence was sufficient to establish a prima facie showing of an antitrust violation, it could allow examination of privileged documents deemed to be "in furtherance" of the crime.[80]

The production of such otherwise privileged documents to the party challenging a reverse payment settlement does not resolve that challenge. It simply makes available a broader set of facts for assessing it. What the parties tell each other during settlement discussions is not always (or even often) what they are telling themselves internally. Thus, in order to really understand the true intent of parties to a reverse payment settlement, it might be necessary to discover their internal thought processes. However, the parties to the reverse payment settlement would retain their rights to prove in any way they considered appropriate that their settlement was reasonable or, at a minimum, not an intentional violation of the antitrust laws.

Crime-fraud procedures are well established. They are reserved for exceptional circumstances, and would be here as well. Only where a plaintiff could demonstrate a prima facie case of antitrust violation would the crime-fraud exception be triggered, and only communications "in furtherance of" the violation could be discovered. If used carefully and judiciously as the third step in a multi-step process for analyzing reverse payment settlements, this mechanism would hold real potential for allowing litigants to get to the heart of disputed matters without need of the trial within a trial that has so terrified the courts to date.

VII. CONCLUSION

We believe our proposal responds to an important limitation in the manner in which courts assess reverse payments in the settlement of patent litigation in the drug field. Growing acceptance of a rule premised on the "exclusionary zone" of a patent is based on reasoning that is

80. *See Abbott Labs.*, 241 F.R.D. at 487, 490 (N.D. Ill. 2007).

entirely circular. It presumes the validity of the patent, even though it was the very uncertainty of that issue that drove the reverse payment settlement. Our approach offers a more suitable and thorough analysis, while avoiding the countervailing risks of a "trial within a trial" which seems to have scared off most courts from undertaking any fulsome antitrust evaluation of reverse payment settlements. The approach proceeds in three phases: public data must first be examined; non-privileged, private information may then be examined as determined by the court; and finally, upon a real prima facie showing of potentially criminal behavior, attorney-client privilege may be pierced and the examination permitted to include specific privileged documents that the court selects based on its in camera review. The inquiry can be stopped at any stage, if parties to the settlement make a sufficient showing of the bona fides of their agreement. On balance, this process ensures that principles of both the patent laws and the antitrust laws are considered, and put in harmony.