DECONSTRUCTING AND RECALIBRATING THE *VALLEY DRUG* ANALYSIS OF REVERSE PAYMENTS

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INTRODUCTION

A patent litigation suit, like any other suit, can be resolved by either a final judgment on the merits or by settlement. Since Congress passed the Hatch-Waxman Act in 1984, parties involved in pharmaceutical patent litigation have increasingly opted to settle their disputes with reverse payments,[1] where the brand-name manufacturer pays the accused infringing generic manufacturer to exit or delay from entering the market.[2] In response, the Federal Trade Commission ("FTC") and generic competitors not party to the settlements have, in some cases, initiated antitrust suits against the settling parties, claiming that reverse payments are unreasonable restraints of trade in violation of Section 1 of the Sherman Act.[3]

Antitrust analysis of reverse payments from a patent holder to an accused infringer strains the concurrent application of antitrust law and patent law. Whereas antitrust law prohibits market-allocation agreements between competi-

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1 FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 25 (2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

2 *Cf.* Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698, 698–99 (2004) (describing reverse payments as settlement payments from patentee-plaintiffs to allegedly infringing defendants to prohibit the use of the patented invention).

3 *See*, *e.g.*, Joblove v. Barr Labs. Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 190 (2d Cir. 2006); Schering-Plough Corp. v. Fed. Trade Comm'n., 402 F.3d 1056, 1058 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1295–96 (11th Cir. 2003); La. Wholesale Drug. Co. v. Hoescht Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896, 899–900 (6th Cir. 2003); *In re* Ciprofloxacin Hydrochloride Antitrust Litig. (*In re Ciprofloxacin Hydrochloride III*), 363 F. Supp. 2d 514, 516–17 (E.D.N.Y. 2005).

tors,[4] patent law grants to a patent holder the right to exclude others from capitalizing on the patented invention.[5] To balance the conflicting policies of antitrust law and patent law, the Eleventh Circuit in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc*. formulated an analytical approach that considers the exclusionary power of patents, a determination of the extent to which an agreement exceeds the scope of a patent's protection, and the anticompetitive effects thereof, to determine whether reverse payments should be subject to antitrust liability.[6]

Courts that have applied the *Valley Drug* analysis[7] have done so in contravention of patent law and thus have undermined the interests of antitrust law. While the exclusionary power of a patent cannot be ignored, the courts have improperly presumed infringement and overextended the presumption of validity of a patent merely because one exists. The result is that some agreements are inappropriately deemed immune from antitrust liability.

The *Valley Drug* analysis should be modified to better accord with antitrust law and patent law. In determining the scope of a patent's protection and the extent to which an agreement exceeds that scope, the legal positions of the parties and the procedural posture of the underlying patent litigation on the issues of infringement and invalidity at the time of settlement should be considered.

Section I of this paper provides a background on reverse payments and how they have thrived under the Hatch-Waxman Act.[8] Section II compares the policies of antitrust law and patent law and discusses how the courts have mitigated the tension between the two in general and specifically with respect to reverse payments. Section III examines how the Second and Eleventh Circuits, the only circuit courts that have applied the *Valley Drug* analysis thus far,[9] have misapplied patent law to the detriment of antitrust law in utilizing the *Valley Drug* analysis. Finally, Section IV explores various approaches to appropriately determine the scope of a patent's protection and the extent to which reverse

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4 United States v. Topco Assocs., Inc., 405 U.S. 596, 607–08 (1972) (holding that agreements to allocate territories between competitors at the same level of the market structure are "conclusively presumed to be unreasonable and therefore illegal") (quoting N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958)).

5 Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980).

6 *Valley Drug*, 344 F.3d at 1312. *See Schering-Plough*, 402 F.3d at 1076.

7 *E.g.*, *Schering-Plough*, 402 F.3d at 1066–76; *In re Tamoxifen Citrate*, 466 F.3d at 212.

8 Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355(j) (2006); 35 U.S.C. § 271(e) (2006)).

9 *E.g.*, *Schering-Plough*, 402 F.3d at 1066–76; *In re Tamoxifen Citrate*, 466 F.3d at 212.

payment agreements may exceed that scope and offers a modification to the *Valley Drug* analysis that better achieves a state of equilibrium between antitrust law and patent law.

I. REVERSE PAYMENTS AND THE HATCH-WAXMAN ACT

Typically, in the settlement of patent infringement cases, the alleged infringer makes settlement payments to the patent holder. Reverse payments, which are also known as exclusion payments,[10] occur when the payments flow in the opposite direction and are made in exchange for the alleged infringer's exit or delay from entering the market.[11] Such reverse payments have gained popularity, particularly in the settlement of pharmaceutical patent disputes with the passing of the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act.[12]

The drafters of the Hatch-Waxman Act sought to encourage the availability of low-cost generic drugs by facilitating challenges to patent validity and infringement by drug manufacturers wishing to market generic versions of patented drugs.[13] The Hatch-Waxman Act created the abbreviated new drug application ("ANDA"), which allows a generic drug manufacturer to piggyback off the safety and efficacy studies of a patented drug.[14] In order to protect the interests of patent holders, an ANDA filer must make certain certifications with respect to any patents claiming the pioneer (brand-name) drug.[15] If the ANDA filer certifies that a patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug ("a paragraph IV certification"), the patent holder may bring suit against the ANDA filer for patent infringement.[16] Thus, under the Hatch-Waxman Act, a brand-name drug manufacturer holding a patent may sue a generic manufacturer for patent infringement merely for submitting an ANDA with a paragraph IV certification. The litigation then proceeds as

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10 Crane, *supra* note 2, at 698–99.

11 *In re* Tamoxifen Citrate, 466 F.3d at 205 (citing David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 335 (2000)). Throughout this paper, "reverse payments" will refer to the payments themselves, as well as the agreements providing for reverse payments.

12 98 Stat. 1585.

13 H.R. REP. NO. 98-857, pt. I, at 14–15 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2647–48.

14 21 U.S.C. § 355(j)(2)(A); H.R. REP. NO. 98-857, pt. I, at 16.

15 21 U.S.C. § 355(j)(2)(A)(vii); H.R. REP. NO. 98-857, pt. I, at 28.

16 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2) (2006) (providing that the submission of an ANDA with a paragraph IV certification is an act of infringement).

any other normal patent infringement suit, and the parties may choose to litigate to adjudication or to settle.

An FTC study of patent infringement suits initiated under the Hatch-Waxman Act revealed the considerable use of reverse payments in settling disputes.[17] In fifty-three cases studied by the FTC where the brand-name manufacturer sued the first ANDA filer for patent infringement, 57% of the cases resulted in a final judgment on the merits, while 38% of the cases settled.[18] Of the twenty settlements observed in the study, nine involved payments from the brand-name manufacturer to the generic manufacturer.[19] In exchange for the payments, the generic manufacturer agreed not to market its generic version of the patented drug until the patent expired or until some other specified date.[20] The reverse payments ranged from $1.75 million to $132.5 million, and the delays ranged from four months to ten years.[21] Parties have also engaged in the use of reverse payments even after a final judgment on the merits. In two cases in which a district court had held the patent invalid and the brand-name manufacturer filed for an appeal, the parties implemented interim settlements that provided for reverse payments.[22] Such interim settlements did not resolve the patent litigation but hinged on the outcome of the litigation.[23]

Reverse payments are particularly prone to use in the context of generic drugs because the Hatch-Waxman Act inadvertently created incentives for the brand-name manufacturer to settle challenges to its patent by making payments to the generic manufacturer.[24] Because the ANDA process permits a generic manufacturer to dispute a patent prior to entering the market with its product,[25] the generic manufacturer's risk in the litigation is substantially reduced. No

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17 FED. TRADE COMM'N, *supra* note 1, at i–ii. In 2002 the FTC studied all ANDA applications from 1992 to 2000 and the effects of the Hatch-Waxman Act on the market and patent litigation. *Id.*

18 *Id.* at 16. In the thirty cases in which a judgment was issued, the generic manufacturer prevailed 73% of the time. Nine of the cases in which the generic manufacturer won resulted in a decision of non-infringement, while another nine resulted in an invalidation of the patent. *Id.* at 13, 17.

19 *Id*. at 31.

20 *Id.*

21 *Id*.

22 *Id.* at 17.

23 *Id.* at 34.

24 *See In re* Ciprofloxacin Hydrochloride Antitrust Litig. (*In re Ciprofloxacin Hydrochloride II*), 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) ("[R]everse payments are a natural by-product of the Hatch-Waxman process. . . .").

25 H.R. REP. NO. 98-857, pt. I, at 28 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2661.

actual infringement has occurred, and, thus, there is no potential for damages, and the generic manufacturer simply has to incur the costs of litigation. Additionally, the potential gain is high: not only is the generic manufacturer potentially entitled to a 180-day period of generic marketing exclusivity,[26] but successful litigation will allow the generic manufacturer to enter the market and earn profits without having substantially invested in the research and development of the drug.[27]

In contrast, the brand-name manufacturer has much to lose in a patent suit and little to gain.[28] If the brand-name manufacturer loses its infringement suit, it faces the loss of market share and possibly its patent. Even if the patent holder prevails in the litigation and maintains the validity of its patent, without actual infringement, the brand-name manufacturer cannot recover damages.[29] The "Hatch-Waxman [Act] essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, [the generic manufacturer] gain[s] considerable leverage in patent litigation."[30] Due to this loss of leverage, the brand-name manufacturer is much more inclined to resort to settlement by reverse payment. Therefore, although Congress may have intended to increase the availability of generic drugs by generating opportunities for generic manufacturers to challenge the validity and infringement of patents with greater ease, the Hatch-Waxman Act also serves to encourage the settlement of patent disputes via reverse payments.[31]

After realization of the growing practice of reverse payments,[32] Congress amended the Hatch-Waxman Act with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").[33] The MMA requires notice to the Assistant Attorney General and the FTC of any agreements entered into between brand-name drug manufacturers and generic drug manufacturers

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26 The first ANDA filer to request FDA approval for a particular generic drug is entitled to a 180-day period of generic marketing exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

27 Joblove v. Barr Labs. Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 207 (2d Cir. 2006).

28 *Id.*

29 35 U.S.C. § 271(e)(4)(C) (2006).

30 Schering-Plough Corp. v. Fed. Trade Comm'n, 402 F.3d 1056, 1074 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006) (citation omitted).

31 *See In re Tamoxifen Citrate*, 466 F.3d at 206.

32 S. REP. NO. 107-167, at 4 (2002).

33 Pub. L. No. 108-173, §§ 1101–1123, 117 Stat. 2066, 2448–2469 (codified as amended at 21 U.S.C. § 355(j)).

that have submitted ANDAs relating to the manufacture, marketing, or sale of the generic drug.[34] The MMA did not prohibit the use of reverse payments.[35]

II. ACCOMMODATING THE COMPETING POLICIES OF ANTITRUST LAW AND PATENT LAW THROUGH THE *VALLEY DRUG* ANALYSIS

Reverse payments in patent litigation implicate both antitrust law and patent law. Because reverse payments involve an agreement to allocate the drug market, reverse payments raise antitrust concerns under the Sherman Act and thus subject the settling parties to antitrust suits by the FTC and generic competitors not involved in the settlement, yet nonetheless affected by it.[36] However, antitrust analysis, which focuses on the anticompetitive effects of an agreement, is complicated by the fact that one of the settling parties owns a patent and has a right to exclude others from using its patent. Because patents are inherently anticompetitive,[37] in *Valley Drug*, the Eleventh Circuit set forth a method of analysis to accommodate the competing policies of antitrust law and patent law.[38] By requiring a determination of the extent to which an agreement exceeds the scope of a patent's protection and the anticompetitive effects thereof,[39] the *Valley Drug* analysis properly considers the exclusionary power of patents in ascertaining whether reverse payments should be subject to antitrust liability.

Reverse payments raise antitrust concerns because they are essentially market-allocation agreements in which the brand-name manufacturer is allotted all of the market for a specified period of time in exchange for making payments to the generic competitor, who agrees to stay out of the market.[40] To promote competition, the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States"[41] and "monopoliz[ation], or attempt[s] to monopolize, or combin[ations] or conspir[acies] . . . to monopolize any part of the trade or

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34 § 1112, 117 Stat. at 2462 (codified as amended at 21 U.S.C.A. § 355(j)(5)(D)(i)(V)).

35 *See* §§ 1101–1123, 117 Stat. at 2448–2469.

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

37 *See* Schering-Plough Corp. v. Fed. Trade Comm'n., 402 F.3d 1056, 1065–66 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

38 *Valley Drug*, 344 F.3d at 1311.

39 *See id.* at 1312.

40 *See id.* at 1304.

41 15 U.S.C. § 1 (2006).

commerce among the several States."[42] Because market allocation eliminates competition between competitors, market allocation agreements unreasonably restrain trade and have been held to be per se illegal by the Supreme Court.[43] Thus there is little disagreement that, in any case where neither party owns a patent, an agreement which involves one party paying the other to exit or refrain from entering the market would readily be deemed an unlawful restraint of trade.[44]

The policy of restraining anticompetitive behavior under antitrust law competes with the policy of granting patent monopolies under patent law.[45] Patent law grants patent owners "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a limited term of years.[46] Patent law carves out a limited monopoly for patent holders in order to promote innovation and invention disclosure.[47]

In recognition of the competing objectives of antitrust law and patent law, the Supreme Court has recognized that patents are an exception to the general rule against monopolies and for a competitive market[48] but that the scope of the exclusionary right of a patent holder is not boundless.[49] Once the patent holder extends his monopoly beyond what was statutorily granted in the patent

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42 15 U.S.C. § 2.

43 United States v. Topco Assocs., Inc., 405 U.S. 596, 608 (1972). Conduct may be considered per se illegal if it has "such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit." State Oil Co. v. Khan, 522 U.S. 3, 10 (1997). Per se analysis generally has been applied in limited circumstances where experience has established that a particular type of conduct is clearly anticompetitive and further examination is not necessary. *See* Broad. Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1, 9 (1979).

44 *Valley Drug*, 344 F.3d at 1304; Schering-Plough Corp. v. Fed. Trade Comm'n, 402 F.3d 1056, 1064 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

45 Joblove v. Barr Labs. Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 202 (2d Cir. 2006).

46 35 U.S.C. §§ 154(a)(1)–(2) (2006); *See* Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention.").

47 Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974).

48 Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965) ("A patent by its very nature is affected with a public interest. (It) is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.") (citing Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945)).

49 United States v. Singer Mfg. Co., 374 U.S. 174, 196–97 (1963).

through agreement, that agreement will be subject to the general law, including Section 1 of the Sherman Act.[50] For example, as Judge Posner illustrated in *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.*,[51] if a company acquires a patent that it knows to be "almost certainly invalid (that is, almost certain not to survive a judicial challenge)," sues it competitors for infringement, and then settles the suit by licensing the patent on the condition that the accused infringer not sell below a certain price, then the patent, suit, and settlement are all merely devices to restrain competition and are in violation of antitrust law.[52]

Because patents grant to their owners the right to exclude and thus inherently have adverse effects on competition,[53] the Eleventh Circuit in *Valley Drug* sought "a suitable accommodation between the differing policies" of the patent and antitrust laws and deployed a new framework of analysis to determine whether reverse payments should be subject to antitrust liability.[54] The Eleventh Circuit in *Valley Drug* held that reverse payments were not subject to either of the traditional modes of Sherman Act Section 1 analysis of per se[55] or rule of reason.[56] Instead, the exclusionary power of the patent was to be consid-

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50 *Id.*

51 289 F. Supp. 2d 986 (N.D. Ill. 2003).

52 *Id.* at 991.

53 Schering-Plough Corp. v. Fed. Trade Comm'n., 402 F.3d 1056, 1065–66 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006) ("By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present.").

54 Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1311 (11th Cir. 2003) (quoting *Walker Process Equip.*, 382 U.S. at 179 (Harlan, J., concurring)).

55 *Id.* The decision of the Eleventh Circuit created a split in the circuit courts on the proper antitrust treatment of reverse payments. The Sixth Circuit held that reverse payments were "a classic example of a *per se* illegal restraint of trade," regardless of the fact that one of the parties held a patent, because reverse payments impermissibly provide for a division of markets between the parties. La. Wholesale Drug. Co. v. Hoescht Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896, 908 (6th Cir. 2003).

56 344 F.3d at 1311 n.27. The rule of reason tests "whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition." Bd. of Trade of Chi. v. United States, 246 U.S. 231, 238 (1918). The rule of reason analysis is a three-step process: (1) the plaintiff must prove that "the challenged action has had an *actual* adverse effect on competition as a whole in the relevant market," (2) if the plaintiff succeeds in satisfying his burden, "the burden shifts to the defendant to establish the 'pro-competitive redeeming virtues' of the action," and (3) if the defendant succeeds, the plaintiff then has the burden to "show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition." K.M.B. Warehouse Distribs., Inc. v. Walker Mfg. Co., 61 F.3d 123, 127 (2d Cir. 1995) (citations omitted). The Eastern District of New York employed a rule of reason analysis in *In re Ciprofloxacin Hydrochloride III* and held that, without evidence that the agreement involving

ered in an analysis that required consideration of the scope of the exclusionary potential of the patent,[57] the extent to which the agreement exceeds that scope, and the resulting anticompetitive effects.[58] Nearly two years later, in *Schering-Plough Corp. v. Federal Trade Commission*, the Eleventh Circuit collapsed the *Valley Drug* analysis into one that focused on the extent to which the exclusionary effects of the agreement exceeds the scope of the patent's protection and the anticompetitive effects thereof.[59]

III. PATENT LAW AND ITS MISAPPLICATION IN THE *VALLEY DRUG* ANALYSIS

In considering the exclusionary power of a patent and its impact on the antitrust analysis of reverse payments, courts applying the *Valley Drug* analysis have misconstrued patent law and accorded undue presumptions of validity and infringement merely due to the existence of a patent. In *Schering-Plough*, the Eleventh Circuit essentially contorted the presumption of validity of a patent into a presumption of infringement by finding that the patent in question read on the alleged infringing products without performing claim construction.[60] In *In re Tamoxifen Citrate Antitrust Litigation*, the Second Circuit abused the presumption of validity by continuing to presume the validity of a patent even after the accused infringer had satisfied its burden in obtaining a final judgment of patent invalidity.[61] The courts' misapplication of patent law improperly shields reverse

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a reverse payment exceeded the scope of the claims of the patent, the reverse payment was insufficient to subject settling parties in a patent litigation suit to antitrust liability. 363 F. Supp. 2d 514, 548 (E.D.N.Y. 2005).

57 *Valley Drug*, 344 F.3d at 1312 (although providing little guidance as to what is meant by "the exclusionary potential of [a] patent"). The court used the phrases "exclusionary potential of a patent," "potential exclusionary effect," "potential exclusionary power," and "exclusionary power" interchangeably, *see*, *e.g.*, *id.* at 1305–06, 1309–12, indicating that the phrases have the same meaning. In the Second and Eleventh Circuits' application of the *Valley Drug* analysis in *In re Tamoxifen Citrate* and *Schering-Plough*, respectively, the courts avoided the troubling phrase of "the exclusionary potential of a patent" and instead subtly adopted one that was better-recognized, "a patent's protection." *See* Joblove v. Barr Labs. Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 212 (2d Cir. 2006); *Schering-Plough*, 402 F.3d at 1076.

58 *Valley Drug*, 344 F.3d at 1312.

59 402 F.3d at 1076.

60 Brief of States as Amici Curiae in Support of Fed. Trade Comm'n. at 16–17, Fed. Trade Comm'n v. Schering-Plough Corp., No. 05-273 (Sept. 30, 2005), 2005 WL 2454839 [hereinafter Brief for States].

61 *See In re Tamoxifen Citrate*, 429 F.3d at 388, 397–400; Imperial Chem. Indus., PLC v. Barr Labs., Inc., 795 F. Supp. 619, 626–27 (S.D.N.Y. 1992).

payments from antitrust liability and thus undermines the interests of antitrust law.

Precluded from performing a post hoc analysis of validity or infringement, [62] courts have heavily relied on the presumption of validity present at the time the agreement was made. Under statutory patent law, a patent is presumed valid.[63] As such, "[p]atents are born valid and remain so until proven otherwise."[64] The presumption is a procedural device, imposing the burden of proving invalidity on the party asserting invalidity.[65] Thus, until the challenger successfully carries its burden to a final decision on the issue of invalidity, a patent holder may exercise its patent rights, including the right to exclude. The right to exclude, however, is not automatic. Although patent law provides a remedy by civil action for infringement,[66] the patent holder must first prove infringement before the court will issue a permanent injunction.[67] Consequently, the right to exclude has been characterized as "a right to *try* to exclude."[68]

In applying the *Valley Drug* analysis in *Schering-Plough*, the Eleventh Circuit paid little heed to the patent holder's burden to prove infringement.[69] The court not only improperly partook in a post hoc analysis of infringement, it erroneously presumed infringement.[70] The brand-name manufacturer owned a formulation patent on an extended-release coating for a drug used to treat high blood pressure or congestive heart disease.[71] During the underlying patent infringement suit, the two generic manufacturers solely asserted non-infringement.[72] In assessing the legality of the reverse payments used to settle the patent dispute, the court reaffirmed the use of the *Valley Drug* analysis.[73] Without undergoing claim construction, and despite its own admonition in *Valley Drug* against performing post hoc analysis on the merits of the underlying

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62 *See infra* Section IV. A.

63 35 U.S.C. § 282 (2006).

64 Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549, 1555 n.1 (Fed. Cir. 1985).

65 35 U.S.C. § 282; Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983).

66 35 U.S.C. § 281.

67 Lemelson v. United States, 752 F.2d 1538, 1547 (Fed. Cir. 1985).

68 Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 395 (2003).

69 Brief for States, *supra* note 60, at 16–17.

70 *Id.*

71 Schering-Plough Corp. v. Fed. Trade Comm'n, 402 F.3d 1056, 1058 (11th Cir. 2005), *cert. denied*, 126 S.Ct. 2929 (2006).

72 Although the generic manufacturers certified in their ANDAs that the patent was either invalid or their products did not infringe the patent, *id.* at 1059 n.2, neither generic competitor alleged that the patent was invalid during the patent infringement suit, *id.* at 1068.

73 *Id.* at 1066.

patent litigation,[74] the court found that the generic products restricted by the reverse payments "cover[ed] the identical reach of the . . . patent."[75] The court provided no basis for concluding that the agreement was within the scope of the patent's protection or that the accused products would have infringed the patent.[76] Instead, the court presumed infringement merely "[b]y virtue of . . . [the] patent" and because the alleged infringers had not proven invalidity or noninfringement.[77] The court misinterpreted the burdens of the parties in a patent infringement suit[78] and ignored well-settled patent law that the patent holder bears the burden of proving infringement and, until the patent holder satisfies that burden, a patent cannot be held to be infringed.[79]

In *In re Tamoxifen Citrate*, the Second Circuit misapplied patent law similarly by ignoring the legal consequences of an accused infringer satisfying its burden of proving invalidity.[80] There, a brand-name manufacturer held a patent on the active ingredient in a prescription drug widely used for the treatment of breast cancer.[81] After the district court held the patent invalid, the brand-name manufacturer appealed the district court's judgment.[82] While the appeal was pending, the parties entered into an interim settlement providing for reverse payments contingent on the district court vacating its judgment.[83] As a result, the district court granted the motion to vacate the judgment.[84] In the subsequent antitrust suit challenging the legality of the reverse payments, the Second Circuit applied the *Valley Drug* analysis and held that the agreement did not violate antitrust law.[85] That the district court had already held the patent invalid had no bearing on the Second Circuit's determination of the scope of the patent's protection.[86] The court considered the patent presumptively valid even

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74 Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1308 (11th Cir. 2003).

75 *Schering-Plough Corp.*, 402 F.3d at 1073.

76 *Id.* at 1066–67, 73.

77 *Id.* at 1066–67.

78 *See* Brief for States, *supra* note 60, at 16–17.

79 *See supra* notes 63–68 and accompanying text.

80 *See* 466 F.3d 187, 204 (2d Cir. 2006).

81 *Id*. at 193.

82 *Id*.

83 *Id*. at 193–94.

84 *Id*. at 194. Although the use of such a *vacatur* has since been overruled by *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18, 27–29 (1994), the ruling did not apply retroactively to *In re Tamixofen Citrate*, 466 F.3d at 194 n.8.

85 *In re Tamixofen Citrate*, 466 F.3d at 212, 216.

86 *See id.* at 205 ("The fact that the settlement here occurred after the district court ruled against [the patent holder] seems to us to be of little moment."), 214 ("[the] patent . . . precludes all

after it had been invalidated by final judgment.[87] Because the presumption of validity is merely a procedural tool allocating the burden of proving invalidity to the alleged infringer,[88] the court clearly and erroneously extended the appropriate usage of the presumption in an antitrust suit where neither party had the burden of proving invalidity.[89]

The *Valley Drug* analysis is intended to subject only those portions of a settlement agreement that are outside the bounds of a patent's protection to traditional antitrust analysis, be it per se or rule of reason analysis.[90] The Second and Eleventh Circuits, in attempting to balance the competing policies of antitrust law and patent law, however, have undercut the interests of antitrust law due to their misapplication of patent law. By presuming infringement[91] and misusing the presumption of invalidity, the courts are improperly broadening the scope of a patent's protection and inappropriately immunizing reverse payments from antitrust liability. Had the courts applied patent law properly,[92] the cases would have resulted differently such that some of the reverse payments would have been subject to antitrust liability.

IV. RECALIBRATING THE *VALLEY DRUG* ANALYSIS

Because the *Valley Drug* analysis has gone astray, it should be adjusted so that the courts determine the scope of a patent's protection and whether a settlement agreement exceeds that scope in light of the legal positions of the parties and the procedural posture of the underlying patent litigation, at the time

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generic versions of tamoxifen, so that any such competing version would, as we understand it, necessarily infringe the patent").

87 *Id.* According to the dissent, the majority placed undue emphasis on *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1377–78 (Fed. Cir. 2002), which was cited for the proposition that patents are presumed valid on appeal even after a judgment of invalidity. *In re Tamoxifen Citrate*, 466 F.3d at 230 (Pooler, J., dissenting). *Rosco* merely cited 35 U.S.C. § 282, which provides for the presumption of validity, to eventually hold that the plaintiffs in the case had failed to overcome that presumption. *In re Tamoxifen Citrate*, 466 F.3d at 230 (Pooler, J., dissenting).

88 35 U.S.C. § 282 (2007); Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983).

89 *See In re Tamixofen Citrate*, 466 F.3d at 203–04.

90 *See* 344 F.3d 1294, 1312 (11th Cir. 2003) ("Any provisions of the Agreements found to have effects beyond the exclusionary effects of [the] patent may then be subjected to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether those provisions violate § 1 of the Sherman Act.").

91 Brief for States, *supra* note 60, at 16–17.

92 *See supra* text accompanying notes 57–63.

of settlement. The parties' legal positions and the procedural posture of invalidity or infringement should guide the *Valley Drug* analysis in particular situations, such as where the generic competitor has conceded infringement or where a judgment of validity of the patent has issued.

Cases where infringement is challenged but a court has not ruled on the patent's validity present a more difficult issue and do not fall easily within the *Valley Drug* analysis. In these cases, the scope of the patent's protection cannot be determined readily; thus, the analysis must resort to a traditional rule of reason analysis where the fact finder takes into account a variety of factors.[93] Because antitrust law requires that the legality of an agreement between competitors be determined from the time the agreement was made,[94] a post hoc analysis of validity and infringement, which both involve claim construction,[95] would not be appropriate to ascertain the extent to which an agreement exceeds the scope of a patent's protection. It would also be inappropriate for a court to determine the legality of a settlement based on the parties' estimation of the patent's scope and validity as measured by the use and size of reverse payments.

A. Claim construction and adjudication of invalidity and infringement are inappropriate in antitrust cases

In patent litigation suits, the scope of a patent's protection is determined by claim construction.[96] Claim construction is a highly-involved process that focuses on analyzing the claims, the specification, and the prosecution history to ascertain the meaning of the claims.[97] The process requires giving the claim terms the meaning they would have had to a person of ordinary skill in the art at the time of the effective filing date of the patent.[98] Determining the extent to which an agreement exceeds the scope of a patent thus entails ascertaining the

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93 *See supra* note 56.

94 Polk Bros. v. Forest City Enters., Inc., 776 F.2d 185, 189 (7th Cir. 1985); SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1207 (2d Cir. 1981).

95 Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd.*, 517 U.S. 370 (1996).

96 *Id.*

97 *See* Phillips v. AWH Corp., 415 F.3d 1303, 1314, 1317 (Fed. Cir. 2005) (en banc). Extrinsic evidence, such as expert testimony, dictionaries, and learned treatises, may also be used but cannot be relied upon to change the meaning of the claims as defined by the claims, specification, and prosecution history. *Id.* at 1317–18.

98 *Id.* at 1312–13.

degree to which the allegedly infringing product falls outside the scope of the construed claims.[99]

Courts, however, in reviewing the legality of reverse payments, have avoided claim construction[100] and, essentially, a determination on the merits of the underlying patent litigation,[101] and rightly so. Under antitrust law, the legality of an agreement between competitors should be judged at the time the agreement was reached.[102] Exposing settling parties to antitrust liability merely because the patent was subsequently invalidated would undermine the incentives of patent law.[103] Patent litigation is too complex and unpredictable to determine whether a patent would later be deemed invalid.[104]

Although claim construction is normally post hoc in that it is performed after the grant of the patent and the alleged infringement,[105] post hoc analysis in which the claims are construed after an agreement was made would be inappropriate in antitrust cases. The consequences of an antitrust violation are much more severe than those imposed upon any party in a standard patent infringement suit. Antitrust violations ordinarily result in criminal sanctions or treble damages.[106] In contrast, patent infringement suits cannot result in criminal sanctions,[107] and treble damages may only be imposed upon a showing of willful infringement or bad faith of the accused infringer.[108]

Thus, courts have noted only a few circumstances under which the enforcement of a patent, including litigation and settlement, may be subject to

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99 *See supra* notes 50, 90 and accompanying text.

100 *See*, *e.g.*, Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1308 (11th Cir. 2003).

101 *See id.*; *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213 (2d Cir. 2005); Schering-Plough Corp. v. Fed. Trade Comm'n, 402 F.3d 1056, 1068 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

102 Polk Bros. v. Forest City Enters., Inc., 776 F.2d 185, 189 (7th Cir. 1985); SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1207 (2d Cir. 1981).

103 Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 179–80 (1965) (Harlan, J., concurring); *Valley Drug.*, 344 F.3d at 1308; *In re* Ciprofloxacin Hydrochloride Antitrust Litig. (*In re Ciprofloxacin Hydrochloride III*), 363 F. Supp. 2d 514, 530 (E.D.N.Y. 2005).

104 *See Valley Drug*, 344 F.3d at 1308.

105 *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd.*, 517 U.S. 370 (1996).

106 15 U.S.C. §§ 1, 15a (2006).

107 *See* 35 U.S.C. §§ 283–285 (2006) (providing for the civil and equitable remedies of damages, attorney fees, and injunctions in patent infringement suits).

108 Lam, Inc. v. Johns-Manville Corp., 668 F.2d 462, 474 (10th Cir. 1982); Deere & Co. v. Int'l Harvester Co., 658 F.2d 1137, 1146 (7th Cir. 1981); *see* 35 U.S.C. § 284 (providing for treble damages at the court's discretion).

antitrust liability. These circumstances include where the patent was procured by fraud;[109] the patent holder knew that the patent was invalid[110] or not infringed;[111] and the underlying infringement lawsuit was a "sham."[112] Although courts have focused on the inappropriateness of performing post hoc analysis on the issue of invalidity when assessing the legality of reverse payments,[113] much of the same reasoning applies for restricting post hoc analysis of infringement, because a determination of infringement also rests on how the claims are construed.[114]

B. Assessing antitrust liability based on the probable outcome of the underlying patent litigation is problematic

Because all property rights are subject to legal uncertainties, commentators have argued that patent rights are "probabilistic" in nature.[115] Although patent holders have a right to exclude, they must first prove infringement before they can obtain a permanent injunction or damages.[116] Thus, the right to exclude is not guaranteed. In fact, in a study of written, final validity decisions issued by the district courts and the Federal Circuit from 1989 through 1996, nearly 46% of patents challenged in litigation were found invalid.[117] In the 2002 FTC study on Hatch-Waxman litigation, nearly a third of the judgments issued invalidated the patent.[118] Under a "probabilistic" approach, the antitrust analysis would incorporate the probable outcomes of the underlying litigation.[119] "[T]he

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109 *Walker Process Equip., Inc.*, 382 U.S. at 176.

110 Handguards, Inc. v. Ethicon, Inc., 601 F.2d 986, 994–96 (9th Cir. 1979).

111 Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 877 (Fed. Cir. 1985), *overruled on other grounds*, Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1068 (Fed. Cir. 1998).

112 Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 59–60 (1993) (defining "sham" litigation as a lawsuit that is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits").

113 *E.g.*, Valley Drug Co. v. Geneva Pharm, Inc., 344 F.3d 1294, 1308 (11th Cir. 2003).

114 *See Markman*, 52 F.3d at 976.

115 *E.g.*, Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP. 75, Spring 2005; Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND. J. ECON. 391, 395 (2003) [hereinafter *Antitrust Limits*].

116 *See supra* notes 66–68 and accompanying text.

117 John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205–06 (1998).

118 FED. TRADE COMM'N, *supra* note 1, at 19–20.

119 Herbert Hovenkamp et. al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1756–63 (2003).

patent holder's rights are calibrated according to the likelihood that the patent holder would win the patent litigation[] and the extent of exclusion that such a victory would permit."[120]

The problems with the probabilistic approach are apparent. Not only does it contravene the presumption of validity accorded to patents,[121] but accurately measuring the likelihood of the patent litigation's outcome would be nearly impossible. Arguably, a reverse payment in excess of a generic competitor's likely profits might strongly indicate the patent holder's lack of confidence in the patent's validity or infringement. However, as the FTC itself stated, "[t]he anticipated profits of the patent holder in the absence of generic competition are greater than the sum of its profits and the profits of the generic entrant when the two compete."[122] Thus, a patent holder sensibly would be willing to pay up to the difference between its two potential profits, even if the difference were greater than the generic competitor's potential profits, in order to secure its position in the market.[123] Even payments greater than that difference are not necessarily a good indication of the patent holder's confidence in successfully enforcing its patent, however. The patent holder has to consider not only the profits it might lose to the generic competitor with whom it has an agreement but also the profits it might lose to all potential competitors should it lose its patent.[124] Unless the value of a patent can be predicted for the length of its remaining term, in consideration of all potential entrants into the market, measuring the likelihood of the patent litigation's outcome based on the size of the reverse payments should be avoided.

Additionally, subjecting a patent holder to antitrust liability merely because of its fear of losing the patent seems outright unfair. As Judge Posner aptly stated,

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120 *Antitrust Limits*, *supra* note 115, at 395.

121 *See supra* notes 63–68 and accompanying text.

122 *In re* Schering-Plough Corp., No. 9297, slip op. at 27 (F.T.C. Dec. 18, 2003), *available at* 2003 WL 22989651, *vacated*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

123 *See In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 209 (2d Cir. 2005). The total profits would be greater in a market where the patent holder faces no competition than that in a market infiltrated by generic competition presumably because all manufacturers would reduce their prices to gain market share, thereby reducing profits. Thus, if the patent holder's profits totaled $100M in a non-competitive market but dropped down to $80M in a competitive market with a total profit potential of $90M, it would make economic sense for the patent holder to offer up to $20M to the generic manufacturer to stay out of the market even though such an offer would exceed the generic manufacturer's potential profits of $10M.

124 *See id.*

> the private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case. . . . It is not 'bad faith' to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of rights. No one can be *certain* that he will prevail in a patent suit.[125]

C. The Valley Drug *analysis should be modified to consider the legal positions of the parties and the procedural posture of the underlying patent litigation at the time of settlement*

A determination of whether an agreement exceeds the scope of a patent's protection under the *Valley Drug* analysis should be based on the legal positions of the parties and the procedural posture of the underlying patent litigation at the time the agreement was made. The parties should be bound to any assertions or concessions already made on the issues of infringement or invalidity, as well as to any judgments rendered by a court on such issues. At the time of settlement, there should be no uncertainty as to the legal positions of the parties and the procedural posture. Exposing the settling parties to antitrust liability based on what was clearly known to them at the time of the agreement is a much more objective and legally-sound process than performing claim construction, a post hoc analysis of infringement or invalidity, or a probabilistic approach.

Thus, if at the time the agreement was made, infringement had already been admitted by the generic competitor, and no judgment had been issued invalidating the patent, then the agreement is within the scope of the patent's protection and the patent retains its presumption of validity. The parties might agree that the patent would read on the generic drug if the patent were valid; indeed, the patent is presumed valid.[126] With no exclusionary effects of the agreement exceeding the scope of the patent's protection, an agreement to settle a patent dispute with reverse payments, therefore, is insufficient to subject the parties to antitrust liability.

If, on the other hand, a court has already invalidated the patent, as was the case in *In re Tamoxifen Citrate,* then the presumption of validity is lost.[127]

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125 Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 992–93 (N.D. Ill. 2003) (citation omitted).

126 *See supra* notes 63–64 and accompanying text.

127 *See* Shelcore, Inc. v. Durham Indus., Inc., 745 F.2d 621, 624–25 (Fed. Cir. 1984) ("The presumption of validity does not guide our analysis on appeal. Rather, we review the findings and conclusions of a district court under the appropriate standards of review."). Moreover, the court cannot re-adjudicate the validity of a patent in a suit where only antitrust issues are raised.

The brand-name manufacturer no longer has the right to a patent monopoly and cannot exert any exclusionary power. Without the existence of a patent, the *Valley Drug* analysis then yields to a determination of the anticompetitive effects of the agreement, which, under traditional antitrust analysis, would subject the parties to antitrust liability. The case becomes one in which neither party holds a patent, and a market-allocation agreement between the two is readily deemed an unlawful restraint of trade.[128]

Finally, in cases where the generic competitor asserts non-infringement, and the patent has yet to be declared invalid, similar to what occurred in *Schering-Plough*,[129] the *Valley Drug* analysis is simply inappropriate. The open issue of infringement prevents any conclusions as to the scope of the patent's protection and whether the agreement is within that scope. Therefore, the rule of reason must be applied, in which a variety of factors are considered, including, but not limited to, the presumptive validity of the patent, the use and size of the reverse payments, and any legitimate procompetitive benefits the brand-name manufacturer may proffer.[130]

Under this proposed modification of the *Valley Drug* analysis, or, more precisely, the application thereof, reverse payments would no longer be deemed "per se legal."[131] Depending on the course of the patent litigation, some reverse payments might be subject to antitrust liability, while others might survive antitrust scrutiny. That not all reverse payments would be subject to antitrust condemnation comports with patent law and the current provisions of the Hatch-Waxman Act.[132] The Hatch-Waxman Act does not purport to prohibit settlements nor does it require resolution of patent litigation by final, unappealable judgment.[133] It simply facilitates the initiation of patent infringement suits with no directives as to how the suits shall terminate.[134] Congress has been alerted to reverse payments and the capacity of reverse payments to stall the entry of generic drug manufacturers.[135] Congress, however, responded by amending the Hatch-Waxman Act through the MMA to require merely that parties provide

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128 *See supra* note 44 and accompanying text.

129 *See supra* note 72 and accompanying text.

130 *See also supra* note 56.

131 *See* Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1039 (2004) ("The judicial treatment of reverse payments has ranged from per se condemnation to virtual per se legality.").

132 *See supra* text accompanying note 126 and note 133

133 *See* 21 U.S.C. § 355(j) (2006).

134 *See id.*

135 *See* S. REP. NO. 107-167, at 4 (2002).

notice of settlement to the government's antitrust agencies.[136] By mandating notice of settlement, Congress evinced its ability to prohibit reverse payments or settlements of any nature, yet it declined to do so. The absence of action from Congress in this regard is telling of its intent or lack thereof.

Concededly, the possibility of immunity from antitrust liability might motivate parties involved in Hatch-Waxman litigation to collude. Because the proposed modification of the *Valley Drug* analysis does not subject reverse payments to antitrust liability where infringement has already been admitted and a district court has not yet invalidated the patent, a generic competitor interested in receiving reverse payments would be more prone to admit infringement and settle to escape antitrust liability. While such a situation may arise, unless Congress reforms the Hatch-Waxman Act or otherwise legislates against the use of reverse payments, such behavior should be deemed free from antitrust scrutiny under the *Valley Drug* analysis.

Determining the extent to which an agreement exceeds the scope of a patent's protection should rest on the legal positions of the parties and the procedural posture of the underlying patent litigation on the issues of invalidity and infringement at the time the agreement was made. Alternative approaches, such as performing claim construction, adjudicating the issues of invalidity and infringement, and adjusting the right to exclude according to the probable outcome of the litigation, are inappropriate in antitrust cases.

V. CONCLUSION

In order to balance the competing policies of antitrust law and patent law to determine whether reverse payments should be subject to antitrust liability, the Eleventh Circuit in *Valley Drug* promulgated an analytical framework that focuses antitrust scrutiny on the extent to which an agreement exceeds the scope of a patent's protection. Both the Second and the Eleventh Circuits, however, have applied the *Valley Drug* analysis in contravention of patent law and, thus, have undermined the interests of antitrust law. By presuming infringement[137] and misusing the presumption of invalidity, the courts have essentially shielded reverse payments from antitrust liability simply because a patent exists.

Central to the *Valley Drug* analysis is determining the extent to which an agreement exceeds the scope of a patent's protection. While the scope of a patent's protection and whether an alleged infringing product falls within that

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136 *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, 2448–69 (codified as amended at 21 U.S.C. 355(j)(5)(D)(i)(V)).

137 Brief for States, *supra* note 60, at 16–17.

scope are normally determined by claim construction or an adjudication of patent invalidity or infringement, such approaches would not be appropriate in an antitrust case. Antitrust law requires that the legality of an agreement be judged at the time the agreement was reached.[138] Moreover, a patent holder should not be exposed to criminal sanctions and treble damages merely because it sought to enforce, by way of settlement, what was presumed to be a valid patent. Conditioning antitrust liability on the probable outcome of the litigation based on the parties' actions would be inappropriate as well. Using the existence and size of reverse payments to "quantify" a patent holder's confidence in its patent's validity or infringement suit is a dubious process in and of itself. Moreover, simply because a patent holder fears that its patent might be invalid or not infringed does not necessarily mean its fear would be realized in litigation.

Instead, the scope of a patent's protection and the extent to which an agreement exceeds that scope should be ascertained by what is clearly known and binding to the parties at the time of settlement: the legal positions of the parties and the procedural posture of the underlying patent litigation on the issues of infringement and invalidity. Thus, the *Valley Drug* analysis should be modified into the following prongs: (1) where infringement has been admitted and the patent has yet to be declared invalid, the agreement is not subject to antitrust liability; (2) where the patent had already been invalidated, the agreement is subject to antitrust liability; and (3) where infringement was challenged but the patent has yet to be declared invalid, the agreement is analyzed under the rule of reason, where factors such as the presumptive validity of the patent, the use and size of the reverse payments, and any legitimate procompetitive benefits proffered by the brand-name manufacturer are considered.

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[138] Polk Bros. v. Forest City Enters., Inc.,776 F.2d 185, 189 (7th Cir. 1985); SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1207 (2d Cir. 1981).