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**Rational Antitrust Policy and Reverse Payment
Settlements in Hatch-Waxman Patent Litigation**

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Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation

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This Article examines the problem of "reverse payment" settlements in patent litigation under the Hatch-Waxman Act. A reverse payment settlement involves a payment from a branded pharmaceutical company to a generic manufacturer, usually in return for the generic manufacturer's agreement to delay market entry. Federal appellate courts, regulatory agencies, and commentators are divided about the legality of such agreements under antitrust law. This Article argues that the importance of product market definition has been overlooked in existing treatments of the issue. The Article develops an empirically based "Settlement Competition Index" that could be used by courts and regulatory agencies to evaluate reverse payment settlements. A formula to calculate the Settlement Competition Index is provided and tested with hypothetical and real-world examples.

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INTRODUCTION

"Reverse payment" settlements present important problems for debates over intellectual property policy concerning pharmaceutical products. A reverse payment settlement involves a payment from a branded pharmaceutical company to a generic manufacturer, usually in return for the generic manufacturer's agreement to delay market entry.¹ The context of these settlements is patent infringe-

1. See *infra* section I.B. Reverse payment settlements are also called "exclusion settlements" and "pay-to-delay settlements." See also Daniel A. Crane, *Ease over Accuracy in Assessing Patent Settlements*, 88 *MINN. L. REV.* 698, 698-99 (2004) ("I have argued that such 'reverse payments' (also known as 'exit payments' or 'exclusion payments') should not be accorded *per se* treatment under the antitrust laws and should be approved so long as the patentee has a strong *ex ante* likelihood of succeeding on the merits of its infringement claim and thereby excluding the infringing use from the market."); John B. Reiss et al., *Your Business in Court: 2008-2009*, 64 *FOOD & DRUG L.J.* 755, 774 (2009) ("On June 3, 2009, in a sixteen-to-ten vote, the Commerce, Trade, and Consumer Protection Subcommittee cleared the bill for a 'full markup.' The chairman of the FTC argued that, by passing a bill banning pay-to-delay settlements, consumers would save \$35 billion over ten years.") (footnote omitted).

ment litigation under the Hatch-Waxman Act.² The Hatch-Waxman Act allows a generic manufacturer to challenge a branded pharmaceutical company's patent claims without incurring the risk of damages.³ This provision was designed to help weed out weak patents and facilitate competition with generics. Reverse payment settlements arguably frustrate this design by enabling the branded manufacturer to buy off the generic company's challenge.

The Federal Trade Commission (FTC), in the wake of an aggressive anti-trust enforcement program, recently suggested that this issue is "a matter of pressing national concern."⁴ Four federal circuit courts of appeals have weighed in with dramatically conflicting results.⁵ The Sixth Circuit, for example, has ruled that most reverse payment settlements are *per se* unlawful,⁶ while the Federal Circuit, in a somewhat terse opinion, recently ruled that reverse payment settlements simply represent a valid exercise of the patent owner's exclusionary rights and, therefore, present no competitive concerns.⁷ The Department of Justice (DOJ) sat on the sidelines during the Bush administration but recently offered a confusing and highly nuanced proposal.⁸ Congress is considering severe legislation that has attracted major lobbying attention from the branded and generic pharmaceutical industries.⁹ In addition, most academic commentators have argued in favor of significant restrictions on reverse payments.¹⁰

This Article argues that existing proposals have overlooked the importance of product market definition. As a result, existing proposals threaten to overdeter potentially beneficial settlements, underdeter deleterious settlements, or fail to supply meaningful guidance about which agreements might be permissible. This Article offers a new approach that is consistent with how courts and regulatory agencies currently assess analogous agreements between competitors, including exclusive intellectual property licenses and mergers. This approach results in an empirically based "Settlement Competition Index," which can be used to establish antitrust safety zones, zones of *per se* illegality, and zones in which a complete rule of reason analysis should be applied.¹¹

2. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68b-68c, 70b (2006); 21 U.S.C. §§ 301 note, 355, 360cc (2006); 28 U.S.C. § 2201 (2006); 35 U.S.C. §§ 156, 271, 282 (2006) [hereinafter Hatch-Waxman Act]).

3. See *infra* section I.A.

4. *Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs: Hearing on H.R. 1706 Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary*, 110th Cong. 1 (2009) (prepared statement of Richard A. Feinstein, Director, Bureau of Competition, Federal Trade Commission), available at <http://www.ftc.gov/os/2009/06/P859910payfordelay.pdf>.

5. See *infra* section I.C.

6. See *infra* section I.C.4.

7. See *infra* section I.C.2.

8. See *infra* section I.D.

9. See *infra* section I.E.

10. See *infra* Part II.

11. Under a rule of reason analysis, "antitrust plaintiffs must demonstrate that a particular contract or combination is in fact unreasonable and anticompetitive before it will be found unlawful." *Texaco Inc.*

version in exchange for a monetary payment from the patent owner.²⁸ The length of the marketing restriction can vary. In early examples, it ran for the entire remaining patent term, but in more recent settlements, the parties agreed to some division of the remaining patent term.²⁹ Many settlements also involve licenses from the generic company to the patent owner of other technology, and other ancillary provisions.³⁰ Settlements also differ concerning whether a first Paragraph IV filer retains its 180-day market exclusivity.³¹ Thus, most of these settlements address the following four fundamental points: (1) amount of reverse payment; (2) length of generic marketing restriction; (3) retention of generic market exclusivity; and (4) ancillary licenses.³²

C. CASE LAW

Reverse payment settlements have been the subject of antitrust litigation in various federal courts, resulting in conflicting opinions from four different circuit courts of appeals. Some of these opinions stem from enforcement actions brought by the FTC. Others result from consolidated multidistrict private antitrust actions brought by third-party payors, employee unions, and other interested parties, often following on the heels of FTC enforcement action. As discussed in detail below, the Second Circuit has adopted a deferential general policy in favor of settlement; the Federal Circuit has held that reverse payment settlements are presumptively lawful because of the legitimate exclusionary power of patents; the Eleventh Circuit, in a series of cases, has developed a test intended to reflect the legitimate exclusionary zone of the patent; and the Sixth Circuit has held reverse payments per se unlawful.

1. Second Circuit: Presumptively Lawful with Settlement Policy Rationale

The Second Circuit's current view is expressed in *In re Tamoxifen Citrate Antitrust Litigation*, which involved the patent covering tamoxifen, a blockbuster cancer drug.³³ In the infringement litigation following the generic manu-

28. See Matthew Avery, Note, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 191-94 (2008) (describing varieties of settlements); Hemphill, *supra* note 24, at 647-56 (describing typology of settlements); Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 494-500 (2007) (describing nature and typology of reverse payment settlements).

29. See Holman, *supra* note 28, at 495-97.

30. See *id.* at 498-500.

31. See Avery, *supra* note 28, at 191-94; Hemphill, *supra* note 24, at 651-55.

32. See Avery, *supra* note 28, at 191-94; Hemphill, *supra* note 24, at 647-56; Holman, *supra* note 28, at 494-500. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") requires that, as of 2004, all patent litigation settlement agreements between brand-name drug manufacturers and generic drug applicants be filed with the FTC and DOJ. Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461-63. Recent filings are available on the FTC's website at <http://ftc.gov/bc/healthcare/drug/index.htm> (last visited June 30, 2009).

33. 466 F.3d 187, 193 (2d Cir. 2006). At the time of the settlement, the patent was owned by Zeneca. *Id.*

facturer Barr's Paragraph IV filing, the district court found the patent invalid based on fraud when the patent holder withheld testing information from the patent office.³⁴ While an appeal of the ruling was pending, the parties agreed to a settlement, in which Barr would receive a \$21 million payment and a non-exclusive license to sell an off-brand version of the patented drug, and Barr's supplier would receive payments of over \$45 million.³⁵ In return, Barr agreed to delay generic entry until after the expiration of the patent, unless the patent was subsequently declared invalid in litigation brought by another challenger.³⁶ The parties also agreed to move to vacate the district court's judgment.³⁷

The settlement was challenged by various consumers, medical benefit providers, and advocacy groups on antitrust and other grounds in multiple lawsuits, which were eventually consolidated.³⁸ The plaintiffs alleged that, in addition to the formal settlement terms, Barr and Zeneca had reached an informal "understanding" that, if any other generic manufacturer attempted to market a generic version of tamoxifen, Barr would revert to a Paragraph IV certification and seek to invoke the 180-day exclusivity period.³⁹ Indeed, Barr claimed the exclusivity period as the first Paragraph IV filer against subsequent filers.⁴⁰ Regardless, the other generic manufacturers were not able to enter the market because they were held to have infringed Zeneca's patent.⁴¹

The district court rejected the challenges to the settlement and granted a motion to dismiss the claims under Federal Rule of Civil Procedure 12(b)(6).⁴² The Second Circuit affirmed.⁴³ The Second Circuit noted long-standing policy in favor of settlement, including in patent and other intellectual property cases.⁴⁴ In fact, the court stated, settlement promotes the goals of patent law by facilitating certainty, which encourages innovation.⁴⁵ The court rejected the

34. *Id.*

35. *Id.* at 193-94.

36. *Id.*

37. *Id.* at 194. The settlement, in fact, was contingent on the court's granting of this motion, which the court eventually granted. *Id.* In three subsequent Paragraph IV cases involving tamoxifen and other generic manufacturers, different courts held that the judgment of invalidity in the Barr litigation was not issue preclusive because it had been vacated. *Id.* at 194-95. In an unrelated case, the practice of vacating judgments pursuant to settlement subsequently was invalidated in almost all cases by the Supreme Court, but that holding was not retroactive. See *id.* at 194 & n.8 (citing U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship, 513 U.S. 18, 27-29 (1994)).

38. *Id.* at 196; *In re Tamoxifen Citrate Antitrust Litig. (Tamoxifen II)*, 277 F. Supp. 2d 121, 123 (E.D.N.Y. 2003).

39. *Tamoxifen II*, 277 F. Supp. 2d at 125.

40. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 195. Barr was able to make this claim because the FDA's a priori "successful defense" rule, under which the 180-day exclusivity period was only available to a filer that successfully defended an infringement lawsuit, was held invalid by several courts, and subsequently was modified by the FDA. See *id.* A labyrinthine procedural history followed, until the patent eventually expired. See *id.* at 196.

41. See *id.* at 196.

42. *Id.* at 197.

43. *Id.* at 198-99.

44. *Id.* at 202-03.

45. *Id.* at 203.

argument that the settlement allowed a "weak" patent to remain in force because that argument requires an impermissible, and impossible, post hoc review of how an inherently risky and uncertain litigation process would have concluded.⁴⁶

The court further rejected the argument that reverse payment settlements are inherently anticompetitive.⁴⁷ Instead, the court concluded that reverse payments make sense in the Hatch-Waxman Paragraph IV context because most of the risk in the infringement litigation is borne by the patent holder rather than the alleged infringer.⁴⁸ Moreover, the court rejected the claim that reverse payments automatically cross the threshold of legality if the value of the reverse payment far exceeds what the generic manufacturer could earn by selling a generic version of the product.⁴⁹ The patent holder presumably is making a payment based on the value of the patent grant.⁵⁰ Thus, "the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."⁵¹ Although such settlements might protect weak patents, a truly weak patent is likely to face challenges from multiple would-be generic entrants, and the patent holder is unlikely to buy out all potential challengers.⁵² Finally, the court held that the terms of the settlement did not unlawfully exceed the scope of the tamoxifen patent.⁵³ The settlement, the court noted, permitted other manufacturers to challenge the patent and did not restrict access to unrelated or non-infringing products.⁵⁴

The Second Circuit's *Tamoxifen* opinion represents one of the most pro-settlement approaches to the reverse payment problem. There are signs, however, that the Second Circuit might reconsider its views. Another reverse payment appeal is currently pending before the Second Circuit, which involves challenges by labor unions and pharmacy chains to the \$350 million settlement between Bayer AG and various generic manufacturers concerning the anti-bacterial drug ciprofloxacin hydrochloride ("Cipro").⁵⁵ On April 6, 2009, the Second Circuit invited the Department of Justice to submit an amicus brief

46. See *id.* at 204, 212.

47. *Id.* at 206.

48. See *id.* at 207.

49. *Id.* at 208-09.

50. *Id.* at 209.

51. *Id.* at 208-09.

52. *Id.* at 212. The court noted that "[t]he point will come when there are simply no monopoly profits with which to pay the new generic challengers." *Id.*

53. *Id.* at 213.

54. *Id.* at 213-14. In a dissenting opinion, Judge Pooler argued that the plaintiffs had adequately alleged a claim that the settlement agreement should have been subject to a full rule of reason analysis. *Id.* at 221, 228 (Pooler, J., dissenting).

55. Ark. Carpenters Health & Welfare Fund v. Bayer, AG, No. 05-2851-cv(L) (2d Cir. July 6, 2009), summary available at <http://www.scotusblog.com/2009/07/summary-stand-on-pay-for-delay-on-drugs/> (July 6, 2009, 19:54 EST).

detailing the Department's views on the case.⁵⁶ This move seems to signal that the Second Circuit might reconsider the position it took in *Tamoxifen*.

2. Federal Circuit: Presumptively Lawful with Patent Exclusionary Zone Rationale

The most recent appellate decision is the Federal Circuit's ruling in the *Ciprofloxacin* litigation.⁵⁷ In the *Ciprofloxacin* settlement, the generic manufacturer, Barr, agreed to delay generic entry until six months prior to patent expiration in exchange for a \$49.1 million payment.⁵⁸ In addition, the patent owner, Bayer, agreed to supply Barr with Cipro for resale or to make quarterly payments to Barr over a seven-year period, for a total of \$349 million in quarterly payments.⁵⁹ In subsequent Paragraph IV litigation against other generic manufacturers, Bayer successfully defended the '444 Patent.⁶⁰ The settlement was challenged on antitrust and other grounds by Cipro purchasers and advocacy groups.⁶¹ The district court granted summary judgment against the plaintiffs, and the Federal Circuit affirmed.⁶²

The Federal Circuit held that the settlement agreements did not exceed the "exclusionary zone" of the '444 Patent.⁶³ According to the Federal Circuit, "the essence of the Agreements was to exclude the defendants from profiting from the patented invention. This is well within Bayer's rights as the patentee."⁶⁴ In addition, the court cited public policy in favor of settlement and the common practice of settlements in patent litigation whereby the alleged infringer agrees not to challenge the patent's validity.⁶⁵ The Federal Circuit distinguished the *Ciprofloxacin* settlement from the settlement invalidated by the Sixth Circuit in *In re Cardizem*⁶⁶ because the *Cardizem* settlement entailed restraints on the generic manufacturer that exceeded the patent's exclusionary zone.⁶⁷

56. See Brief for the United States in Response to the Court's Invitation at 1, Ark. Carpenters Health & Welfare Fund, No. 05-2851-cv(L), available at <http://www.justice.gov/atr/cases/747700247708.pdf>. On October 15, 2008, the Federal Circuit issued an opinion upholding the reverse payment settlement in one of the Cipro cases that had been severed from the litigation in the Second Circuit. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1327 (Fed. Cir. 2008), discussed *infra* section I.C.2.

57. *In re Ciprofloxacin*, 544 F.3d at 1327-28. The litigation concerned U.S. Patent No. 4,670,444 (the "'444 Patent") owned by Bayer AG and Bayer Corp. ("Bayer"), which is directed to ciprofloxacin hydrochloride ("Cipro"), an antibacterial compound. *Id.*

58. *Id.* at 1328-32 & n.5.

59. See *id.* at 1329 & n.5.

60. *Id.* at 1329. The '444 Patent had been amended after reexamination in the Patent Office. *Id.*

61. *Id.* at 1329-30.

62. *Id.* at 1330, 1341.

63. *Id.* at 1332-33.

64. *Id.* at 1333.

65. *Id.* at 1333-34.

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

67. *In re Ciprofloxacin*, 544 F.3d at 1335. These included the generic manufacturer's agreement not to relinquish its statutory 180-day exclusivity period, which would have delayed other generic entrants,

3. Eleventh Circuit: Exclusionary Zone Test with Mixed Signals About Presumptive Legality

The Eleventh Circuit has visited the question of reverse payment settlements several times, with somewhat different results. In the first case, *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, the court reviewed settlements between branded manufacturer Abbott Laboratories and generic manufacturers Geneva Pharmaceuticals and Zenith Goldline Pharmaceuticals concerning the hypertension and prostate drug Hytrin.⁶⁸ Both Geneva and Zenith had filed Paragraph IV certifications with respect to various Hytrin-related patents held by Abbott; Geneva was the first filer.⁶⁹ Abbott sued Geneva for infringement.⁷⁰

In the Abbott-Zenith agreement, Zenith admitted validity and infringement, and agreed not to produce an infringing drug, in return for \$6 million in guaranteed payments and further payments of up to \$6 million each quarter, with various contingencies.⁷¹

In the Abbott-Geneva agreement, Geneva agreed not to sell any product containing the patented compound until the patent expired, another party introduced a generic version, or Geneva prevailed in infringement litigation.⁷² Geneva further agreed not to sell or transfer its 180-day exclusivity period.⁷³ In return, Abbott agreed to pay Geneva \$4.5 million per month until another party marketed a generic version or Geneva prevailed in infringement litigation.⁷⁴ Abbott's patent for the crystalline form of the drug was invalidated by the district court under the on sale bar.⁷⁵ This decision was affirmed by the Federal Circuit.⁷⁶

While Abbott's petition for certiorari to the Supreme Court was pending, the FTC issued an order following an investigation of the Abbott-Geneva settlement.⁷⁷ Pursuant to a consent order with Abbott, the FTC prohibited any settlement provision under which the ANDA first filer would relinquish its 180-day exclusivity period or that would prohibit research on a drug that is not

and its agreement not to manufacture competing non-infringing versions of the drug covered by the patent. *Id.*

68. 344 F.3d 1294, 1296, 1298 (11th Cir. 2003).

69. *Id.* at 1298-99.

70. *Id.* However, Abbott failed to file an infringement suit with respect to an alternate formulation for which Geneva had also filed a Paragraph IV certification. *Id.* at 1299. Zenith instituted court action against Abbott seeking delisting of the challenged patents, and Abbott counterclaimed for infringement. *Id.*

71. *Id.* at 1300.

72. *Id.*

73. *Id.*

74. *Id.* at 1300.

75. See *id.* at 1301. Under the "on sale" bar, that patent is invalid if the patented product was on sale in the United States more than one year prior to the date of the patent application. 35 U.S.C. § 102(b).

76. *Id.*

77. *In re Abbott Labs.*, No. C-3945 (Fed. Trade Comm'n May 22, 2000) (decision and order), available at <http://www.ftc.gov/os/2000/05/c3945.do.htm>.

the subject of a patent infringement action.⁷⁸ The FTC further prohibited any settlement agreement entered *pendente lite*, unless accompanied by a stipulated preliminary injunction that included a provision for FTC review.⁷⁹

Following the FTC's Order, a variety of plaintiffs filed private antitrust actions, which were consolidated before a multidistrict litigation panel.⁸⁰ The district court granted summary judgment in plaintiffs' favor, finding that the settlements constituted unlawful market allocation agreements.⁸¹ The Eleventh Circuit reversed.⁸²

According to the Eleventh Circuit, an agreement to refrain from infringing a patent cannot constitute an illegal market allocation because such an agreement would be coextensive with the patent's lawful exclusionary zone.⁸³ The fact that a patent conceivably could be held invalid does not nullify this principle.⁸⁴ The court noted that "[p]atent litigation is too complex and the results too uncertain for parties to accurately forecast" the outcome with any precision.⁸⁵ Even a large reverse payment does not necessarily suggest a weak patent because, "[g]iven the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement."⁸⁶ However, the court noted that if the agreement goes beyond the legitimate exclusionary potential of the patent—for example, by restricting sales of compounds not subject to the patent claims—those provisions might raise antitrust concerns.⁸⁷ The case was remanded for consideration of this question.⁸⁸

The Eleventh Circuit next faced the issue in *Schering-Plough Corp. v. Federal Trade Commission*.⁸⁹ Procedurally, this case involved a challenge by the settling parties to an FTC order invalidating settlements in two situations.⁹⁰ In the first case, the generic manufacturer, Upsher, agreed to delay generic entry of the challenged patent for blood pressure medication.⁹¹ Under the settlement, Schering-Plough received an exclusive license to market a cholesterol-reducing product and other products owned by Upsher for royalty fees of \$60 million plus milestone and percentage payments.⁹² The record contained evidence that, prior to the settlement, Schering-Plough had investigated and obtained substan-

78. *Id.* pt. II.

79. *Id.* pt. III.

80. *Valley Drug Co.*, 344 F.3d at 1295-96.

81. *Id.* at 1301.

82. *Id.* at 1306.

83. *Id.* at 1305-06.

84. See *id.* at 1306-07.

85. *Id.* at 1308.

86. *Id.* at 1310.

87. See *id.* at 1311-12.

88. *Id.* at 1313.

89. 402 F.3d 1056 (11th Cir. 2005).

90. *Id.* at 1058.

91. *Id.* at 1059.

92. *Id.* at 1059-60.

tial valuations of the Upsher cholesterol product.⁹³ However, the Upsher product proved to be unprofitable.⁹⁴

In the second case, Schering-Plough agreed to split the remaining patent life with another generic manufacturer, ESI, which facilitated generic entry three years before patent expiration.⁹⁵ Schering-Plough further agreed to pay ESI \$5 million for legal fees, another \$10 million if ESI obtained FDA approval to market the product by a certain date, and \$15 million for licenses of unrelated products owned by ESI.⁹⁶

These agreements were challenged by the FTC several years after they were concluded.⁹⁷ The FTC ruled that settlements in which "the generic receives anything of value and agrees to defer its own research, development, production or sales activities" are unlawful restraints of trade, unless the payment is \$2 million or less, used solely for litigation costs, and the FTC is notified of the settlement.⁹⁸

The Eleventh Circuit rejected the FTC's approach.⁹⁹ According to the court, neither rule of reason nor per se analysis is appropriate in antitrust cases involving patents because, "[b]y their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present."¹⁰⁰ Instead of traditional antitrust analysis, the court created a three-part test, which "requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."¹⁰¹ Applied to the settlements at issue, the court noted that Schering-Plough's patent appeared to be strong, the license payments by Schering-Plough for unrelated products were not sham "reverse payments," and the settlement agreements had no improper anticompetitive effects.¹⁰²

Concerning anticompetitive effects, the court rejected the FTC's antipathy towards reverse payments in Hatch-Waxman cases. The court reasoned that reverse payments should be expected in Paragraph IV cases—indeed, that "[r]everse payments are a natural by-product of the Hatch-Waxman process"—

because the statute permits generic manufacturers to challenge patent validity without incurring any significant risk.¹⁰³ In fact, the court suggested that "Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude."¹⁰⁴ Under these circumstances, settlements usually are procompetitive, and pro-innovation, because they facilitate certainty.¹⁰⁵

Later that same year, however, a different Eleventh Circuit panel applied the *Schering-Plough* test to permit a challenge to a reverse payment settlement. In *Andrx Pharmaceuticals v. Elan Corp.*, the Eleventh Circuit considered a challenge by generic manufacturer Andrx to a settlement entered into by the patent holder and a different generic company, SkyePharma.¹⁰⁶ SkyePharma was the first Paragraph IV filer with respect to naproxen, an anti-inflammatory medication, which was covered by a patent owned by Elan.¹⁰⁷ In the settlement agreement, SkyePharma admitted infringement and received a license to manufacture controlled release naproxen.¹⁰⁸ Andrx claimed that SkyePharma did not intend to market the product, in which case the 180-day exclusivity period would not begin to run, thereby preventing generic competition prior to patent expiration.¹⁰⁹ The Eleventh Circuit held that these facts supplied an adequate basis for an antitrust claim at the pleading stage.¹¹⁰ According to the court, if the facts as pled were true, "this dynamic would exceed the scope of [the] exclusion intended by the . . . patent."¹¹¹

4. Sixth Circuit: Per Se Unlawful

The Sixth Circuit addressed reverse settlements in *In re Cardizem CD Antitrust Litigation*.¹¹² This case involved an agreement under which the generic manufacturer, Andrx, refrained from marketing a generic version of the drug in question in return for interim payments of \$10 million per quarter while the underlying patent infringement litigation was pending.¹¹³ The agreement further provided that Andrx would receive a final payment of \$100 million, less any interim payments, if the litigation terminated without a finding of infringement.¹¹⁴ The litigation finally settled nearly two years after the companies

93. *Id.* at 1059–60.

94. *Id.* at 1060.

95. *Id.*

96. *See id.* at 1060–61 & n.8.

97. *Id.* at 1061.

98. *Id.* at 1062. The FTC's decision reversed an earlier opinion by an administrative law judge (ALJ) that the settlements were lawful. *Id.* at 1061–62.

99. *Id.* at 1065–66.

100. *Id.*

101. *Id.* at 1066 (citing *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003)).

102. *Id.* at 1072–76. Concerning the Upsher settlement, the court cited the extensive record developed before the ALJ, which suggested the licenses from Upsher represented bona fide business decisions. *Id.* at 1068–71. Concerning the ESI settlement, the court was persuaded by the general policy in favor of settlements, the district court's mediation, and subsequent approval of the settlement. *Id.* at 1076.

103. *Id.* at 1074 (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003)).

104. *Id.*

105. *See id.* at 1075.

106. 421 F.3d 1227, 1230–31 (11th Cir. 2005).

107. *Id.* at 1231.

108. *Id.*

109. *Id.*

110. *Id.* at 1234–36.

111. *Id.* at 1235. However, the court affirmed the dismissal of Andrx's claims that Elan had engaged in sham litigation by filing patent infringement suits against Andrx. *See id.* at 1234.

112. 332 F.3d 896 (6th Cir. 2003).

113. *Id.* at 902.

114. *Id.* at 903.

reached this agreement.¹¹⁵ Pursuant to the final settlement, Andrx received a \$50.7 million payment (for a total of \$89.83 million in interim and final payments) and began to market a generic version, with the benefit of the 180-day exclusivity period under the Hatch-Waxman Act.¹¹⁶ In short, Andrx was paid to delay generic entry while the litigation was pending, without sacrificing the exclusivity period once the litigation terminated.

The agreements were challenged on antitrust and other grounds in various consolidated cases by indirect purchasers and other putative class representatives.¹¹⁷ The case reached the Sixth Circuit on interlocutory appeal from the district court's grant of summary judgment finding that the interim agreement was a *per se* illegal horizontal restraint of trade.¹¹⁸ The Sixth Circuit emphatically agreed: "There is simply no escaping the conclusion that the Agreement . . . was, at its core, a horizontal agreement to eliminate competition in the market for Caritzem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade."¹¹⁹ According to the court, "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor \$40 million per year to stay out of the market."¹²⁰

5. Summary of Case Law

The common thread in the case law is that any evaluation of reverse payment settlements must account for the exclusionary power of the patent. These opinions represent a significant split among circuit courts, however, about how to weight patent rights against the public policy interest in generic drug competition. Many law professors and economists are concerned about this split, particularly insofar as some of the case law suggests that reverse payment settlements are shielded from scrutiny by the patent laws, as evidenced by an amicus brief filed in support of the plaintiffs' petition for certiorari in the Federal Circuit *Ciprofloxacin* case.¹²¹ The Supreme Court thus far, however, has not taken up the question.¹²²

115. *Id.*

116. *Id.*

117. *Id.* at 903 n.7.

118. *Id.* at 905.

119. *Id.* at 908.

120. *Id.* (footnote omitted). The Sixth Circuit also rejected defendants' arguments concerning antitrust injury. *Id.* at 912. Accordingly, the court affirmed the district court's grant of summary judgment in plaintiffs' favor. *Id.* at 915.

121. See Brief Amici Curiae of 54 Intellectual Prop. Law, Antitrust Law, Econ., and Bus. Professors et al. in Support of Petitioner at 2-3, *Ark. Carpenters Health & Welfare Fund v. Boyer AG*, 129 S. Ct. 2828 (2009) (mem.) (No. 08-1194).

122. Most recently, the Court declined to grant certiorari in the *Ciprofloxacin* litigation before the Federal Circuit. See *Ark. Carpenters Health & Welfare Fund*, 129 S. Ct. 2828.

D. ENFORCEMENT AGENCY VIEWS

The key antitrust enforcement agencies, the Federal Trade Commission and Department of Justice, also have taken somewhat contradictory positions on reverse payment settlements.

As reflected in the *Schering-Plough* case discussed above, the FTC believes reverse payment settlements in the Hatch-Waxman context are presumptively anticompetitive.¹²³ Indeed, the FTC considers the social costs imposed by such settlements "a matter of pressing national concern."¹²⁴ The FTC claims that its enforcement actions had deterred "pay for delay" settlements until the appellate court rulings from the Second, Eleventh, and Federal Circuits once again opened the door to this practice.¹²⁵ The FTC, therefore, supports federal legislation that would generally prohibit settlements where the generic manufacturer receives value in exchange for an agreement to refrain from selling the generic product.¹²⁶

The Department of Justice initially took a less dogmatic stance than the FTC. In an amicus brief relating to a certiorari petition filed in *Schering-Plough*, the DOJ stated that "[i]n the patent context . . . a settlement involving restrictions on the sale of the products in question is not necessarily impermissible."¹²⁷ The DOJ noted that reverse payments in Hatch-Waxman cases implicate compelling policy concerns: the statutory right to exclude afforded by a patent and the Hatch-Waxman policy facilitating challenges to weak patents.¹²⁸ The DOJ did not articulate a precise standard under which these competing concerns could be balanced. Rather, it argued that the FTC's proposed standard was unclear and that the complex procedural history of *Schering-Plough* rendered it an inappropriate vehicle for deciding broad policy questions.¹²⁹

Recently, however, perhaps reflecting a change in philosophy under the Obama administration, the DOJ has taken a more critical stance that would require a complete rule of reason analysis of most reverse payment settlements. In response to an invitation from the Second Circuit in *Arkansas Carpenters Health & Welfare Fund v. Boyer AG*, the DOJ submitted a brief in which it asserted that "[s]ettlements [i]nvolving [a] [p]ayment [i]n [e]xchange for [a]n [a]greement [t]o [w]ithdraw [a] [v]alidity [c]hallenge [a]nd [l]imit [c]ompetition

123. See Appeal Brief of Counsel Supporting the Complaint, *In re Schering-Plough Corp.*, No. 9297 (Fed. Trade Comm'n Aug. 9, 2002), available at <http://www.ftc.gov/os/2002/08/scheringplaintbrief.pdf>.

124. *Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry*, supra note 4, at 1 (prepared statement of Richard A. Feinstein, Director, Bureau of Competition, Federal Trade Commission).

125. *Id.* at 9.

126. *Id.* at 19.

127. Brief for the United States as Amicus Curiae at 8, *Fed. Trade Comm'n v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), available at http://www.usdoj.gov/aipr/cases/02163009_216358.pdf.

128. *Id.* at 10-11.

129. *Id.* at 14-16.

[a]re [p]resumptively [u]nlawful."¹³⁰ Nevertheless, the DOJ noted that this presumption could be rebutted if "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."¹³¹

The DOJ argued that it is "neither necessary nor appropriate" for the court to assess the likelihood of success in the underlying patent litigation because that "determination would be based on information available to the parties when they entered into the settlement."¹³² Nevertheless, the DOJ suggested that "[l]iability properly turns on whether, in avoiding the prospect of invalidation that accompanies infringement litigation, the parties have by contract obtained more exclusion than warranted in light of that prospect."¹³³

The presumption of illegality would be rebutted if the payment to the alleged infringer does not exceed litigation costs.¹³⁴ If the payment is "greatly in excess of avoided litigation costs," the focus would turn to the "nature and extent of the generic competition permitted."¹³⁵ According to the DOJ, settlements that preclude generic entry prior to patent expiration would necessarily fail to carry this burden.¹³⁶

If the settlement provides for generic entry prior to patent expiration, the presumption could be rebutted if "the settlement preserved a degree of competition reasonably consistent with what had been expected if the infringement litigation went to judgment."¹³⁷ The parties would be required to show that the settlement terms "reasonably reflected their contemporaneous evaluations of the likelihood that a judgment in the patent litigation would have resulted in generic competition before patent expiration."¹³⁸ However, even if the parties were highly certain that the patent would be upheld, "a reverse payment settlement permitting significantly less generic competition than would be consistent with that likelihood would be an unreasonable restraint on competition."¹³⁹

E. PENDING LEGISLATION

Bills pending in the Senate and House would prohibit or limit most reverse payment settlements.¹⁴⁰ The House bill and the original Senate bill would amend the Federal Trade Commission Act by prohibiting an ANDA filer from

130. Brief for the United States in Response to Court's Invitation, *supra* note 56, at 21.

131. *Id.* at 10.

132. *Id.* at 24 & n.8.

133. *Id.* at 25. The DOJ acknowledged that this view was at odds with its prior views. *Id.* at 26 n.9.

134. *Id.* at 28.

135. *Id.* at 29.

136. *Id.*

137. *Id.* at 30.

138. *Id.* at 30-31.

139. *Id.* at 31.

140. See Preserve Access to Affordable Generics Act, S. 369, 111th Cong. § 2(b) (as reported and amended by S. Comm. on the Judiciary, Oct. 15, 2009); Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. § 2(a) (2009).

receiving anything of value in exchange for an agreement "not to research, develop, manufacture, market, or sell [the ANDA product] . . . for any period of time."¹⁴¹ The Senate bill would also add the penalty of forfeiture of the 180-day Hatch-Waxman exclusivity period for violation of this provision.¹⁴² The House bill contains a similar prohibition and penalty provision.¹⁴³

The revised Senate bill includes a finding that reverse payment settlements "have unduly delayed the marketing of low-cost generic drugs contrary to free competition, the interests of consumers, and the principles underlying antitrust law."¹⁴⁴ The revised bill, however, provides only a rebuttable presumption of illegality where the ANDA filer receives value or agrees to limit its activities with respect to the ANDA product.¹⁴⁵ The presumption can be rebutted "if the parties to such agreement demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement."¹⁴⁶ The bill includes a list of factors that can be considered under this rule of reason analysis.¹⁴⁷ In addition, the bill would provide a safe harbor for settlements in which the ANDA filer is permitted early market entry and is reimbursed for "reasonable litigation expenses not to exceed \$7,500,000."¹⁴⁸ Finally, the bill would permit the FTC to impose civil penalties for violations of up to three times the value received in the settlement.¹⁴⁹

141. H.R. 1706 § 2(a)(2); S. 369 § 3. Section 28 of the Federal Trade Commission Act, as proposed, will allow the Federal Trade Commission to initiate enforcement proceedings against parties to a patent settlement agreement. S. 369 § 3. In addition, the proposed section 28 allows for the agreement to be presumed anticompetitive if the "ANDA filer receives anything of value; and . . . the [] filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time." S. 369 § 3.

142. S. 369 § 5.

143. H.R. 1706 §§ 2(a), 4.

144. S. 369 § 2(a)(6)(B).

145. *Id.* § 3(a).

146. *Id.*

147. *Id.* The factors are:

- (1) the length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product;
- (2) the value to consumers of the competition from the ANDA product allowed under the agreement;
- (3) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim;
- (4) the revenue the ANDA filer would have received by winning the patent litigation;
- (5) the reduction in the NDA holder's revenues if it had lost the patent litigation;
- (6) the time period between the date of the agreement conveying value to the ANDA filer and the date of the settlement of the patent infringement claim; and
- (7) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection.

Id.

148. See *id.*

149. *Id.*

II. EFFORTS TO THEORIZE THE REVERSE PAYMENT PROBLEM

A. CURRENT PROPOSALS

Reverse payment settlements have attracted attention from a number of prominent intellectual property and competition law scholars. As discussed below, the various proposals these scholars have offered focus on efforts to balance the legitimate exclusionary power of patents against the benefits of generic competition, while at the same time affording some certainty to litigants. Herbert Hovenkamp, Mark Janis, and Mark Lemley, for example, suggest that cases in which the antitrust analysis is unclear "should be decided on IP grounds."¹⁵⁰ By way of comparison, cases in the "clear" category are those in which "(1) the agreement would be lawful under the antitrust laws even in the absence of any IP dispute, or (2) the agreement would be unlawful under the antitrust laws even if all the IP claims that are made were fully sustained."¹⁵¹ The first category includes, for example, settlements by which the parties give each other unrestricted, non-exclusive licenses.¹⁵² The second category includes cases in which there is a horizontal market division or other anticompetitive arrangement "that goes beyond the scope of the disputed patent," such as an agreement to restrict sales of products unrelated to the patent claims.¹⁵³ The antitrust analysis would be unclear where "the settlement agreement would constitute lawful use of the claimed IP right if an infringement claim was valid, but not if there were no valid IP right."¹⁵⁴

Hovenkamp, Janis, and Lemley suggest that rule of reason analysis is inappropriate in disputed cases because "[t]he issue in such cases is not so much the economic consequences of the agreement as whether those consequences are deemed acceptable as a matter of IP policy."¹⁵⁵ However, they acknowledge that the high costs of adjudicating the validity of an intellectual property claim might in some cases favor rule of reason analysis over a full assessment of the intellectual property rights.¹⁵⁶ When it is clear that neither of the parties possesses market power in any relevant market, for example, the authors suggest that a court could dispose of the case under the rule of reason instead of assessing the strength of the intellectual property rights.¹⁵⁷

Hovenkamp, Janis, and Lemley argue that reverse payments should be "presumptively unlawful, shifting the burden of proof to the infringement plaintiff."¹⁵⁸ The infringement plaintiff would then need to show "(1) that the ex ante

likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit."¹⁵⁹ They suggest, however, that the inquiry into the underlying intellectual property suit "need not be particularly searching" because "[t]he goal is merely to ensure that there is a legitimate dispute being settled."¹⁶⁰

Daniel Crane also argues that the question of reverse payment settlements is at heart an intellectual property issue, but is more solicitous of patent rights.¹⁶¹ He notes that "restrictive rules regarding patent infringement settlements may create super-optimal uncertainty regarding patent rights leading to sub-optimal inventive activity or delays in the marketing of non-infringing substitutes."¹⁶² Crane argues that "the optimal rule would permit exit payment settlements when the ex ante likelihood of success of the patentee's infringement suit is high and prohibit them when the ex ante probability of success is low."¹⁶³

In contrast, Thomas Cotter suggests that it is impractical to assess patent strength ex ante.¹⁶⁴ In a commentary on Hovenkamp, Janis, and Lemley's proposal, Cotter suggests that their three-part test is helpful, but that "requiring antitrust tribunals to scrutinize the merits of a settled IP dispute threatens to unravel the substantial private and social benefits to which the settlement gives rise, including the reduction in litigation costs that settlement generally promotes."¹⁶⁵ Cotter argues that, in some cases, settlement payments that exceed the value of litigation costs could be procompetitive.¹⁶⁶ Where the "amount of the reverse payment is higher than the saved litigation expenses but less than the defendant's potential loss at trial," Cotter concludes that the agreement probably represents the parties' judgment that the patent claim likely would have succeeded on the merits, even if there is less than absolute certainty about the outcome.¹⁶⁷ If the settlement payment approaches or exceeds the litigation expenses plus the amount the defendant could have made selling the allegedly infringing product—and, thus, the amount the plaintiff could potentially have obtained in damages in the infringement suit—stricter antitrust scrutiny is justified.¹⁶⁸

159. *Id.*

160. *Id.* at 1760.

161. Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 *FLA. L. REV.* 747, 750 (2002); see also ROBIN FELDMAN, *THE ROLE OF SCIENCE IN LAW* 160-69 (2009) (suggesting that courts evaluating reverse payment settlements are better equipped to determine the likelihood of success on the merits of the patent litigation than they are to evaluate a settlement's effect on consumer surplus).

162. Crane, *supra* note 161, at 749.

163. *Id.* at 750.

164. Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 *MINN. L. REV.* 1789, 1815 (2003).

165. *Id.* at 1795.

166. *Id.* at 1802-09 (stating that "per se treatment of reverse payment settlements is inappropriate, because these agreements also have some potential to enhance rather than impede efficiency").

167. *Id.* at 1814.

168. *Id.* at 1814-15.

150. See Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 *MINN. L. REV.* 1719, 1725 (2003).

151. *Id.*

152. *Id.*

153. *Id.* at 1726.

154. *Id.*

155. *Id.* at 1729.

156. See *id.* at 1732.

157. *Id.* at 1733.

158. *Id.* at 1759.

Christopher M. Holman takes a somewhat different track after examining the diversity and complexity of Paragraph IV litigation settlements.¹⁶⁹ Holman notes that very few reverse payment settlements involve simple payments in return for total generic exclusion prior to patent expiration.¹⁷⁰ He suggests that where barriers to generic entry are low and there are numerous potential generic challengers, reverse payment settlements will not pose a significant problem because the iterative process of resolving multiple Paragraph IV challenges would become counterproductive.¹⁷¹ Holman suggests that removing the 180-day exclusivity period for Paragraph IV first filers, or at least the ability to "park" exclusivity during a period of negotiated delayed entry, would solve many of the generic entry problems that can make reverse payment settlements problematic.¹⁷²

Scott Hemphill agrees that reverse payments are a problem because of faulty regulatory design and that the typology of reverse payment settlements is varied and complex.¹⁷³ However, Hemphill is less sanguine than Holman about the competitive benefits of such settlements and sees much of the complexity as an effort by the parties to hide the anticompetitive potential of such settlements in the face of stronger FTC enforcement.¹⁷⁴ Although strict antitrust rules could overdeter potentially beneficial settlements, Hemphill is far more concerned about underdeterrence, particularly where the public interest in access to medicine is at stake.¹⁷⁵ Therefore, Hemphill concludes that "a settlement should be accorded a presumption of illegality as an unreasonable restraint of trade if the settlement both restricts the generic firm's ability to market a competing drug and includes compensation from the innovator to the generic firm."¹⁷⁶

Finally, Michael Carrier argues that reverse payment agreements should be considered presumptively unlawful in light of Hatch-Waxman's regulatory structure.¹⁷⁷ Carrier supports his analysis with reference to the Supreme Court's opinion in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*.¹⁷⁸ There, the Court stated that the existence of a pervasive regulatory

169. See Holman, *supra* note 28.

170. *Id.* at 494-95 (stating that "a closer look at the facts of individual cases reveals that few, if any, reverse payment settlements are as simple as that or as blatantly anti-competitive").

171. *Id.* at 506. Holman argues that, if generic entry is relatively easy, "the branded company would be expected to experience a parade of subsequent third party generic companies challenging the patent and threatening to enter the market. Eventually, the cost of paying off all the potential competitors would outstrip the profits of even the most lucrative blockbuster drug." *Id.*

172. See *id.* at 516-19. Holman also argues that existing ANDA filing requirements remain overly costly and cumbersome. See *id.* at 519-23.

173. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1561 (2006); see Hemphill, *supra* note 24, at 663-70.

174. See Hemphill, *supra* note 24, at 685.

175. See Hemphill, *supra* note 173, at 1616.

176. *Id.* at 1561.

177. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. Rev. 37, 67-70 (2009).

178. *Id.* at 68-69 (citing *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004)).

regime must be considered when evaluating conduct under the antitrust laws.¹⁷⁹ Carrier suggests that the Hatch-Waxman regime reflects a policy in favor of patent challenges, that the regulatory regime is relatively ineffective in achieving this purpose, and that reverse payments are "uniquely concerning" because they allow branded and generic manufacturers to limit competition.¹⁸⁰

B. TOWARDS A SETTLEMENT COMPETITION INDEX?

The approach outlined in this Article, which is discussed in detail in Part III below, would require a more refined inquiry into the actual anticompetitive effects of any particular reverse payment agreement. A number of the proposals outlined above seek to avoid this sort of searching inquiry into market structure. This section explains why existing proposals are inadequate and why a thorough analysis of market power is necessary.

1. Under and Overdeterrence

Proposals that would limit settlement amounts to litigation costs, use the settlement amount as a proxy for patent strength, or hold reverse payment settlements presumptively unlawful, are problematic because they threaten to overdeter potentially beneficial settlements. As Scott Hemphill notes, such a restrictive policy choice runs the risk of "false positives."¹⁸¹ In Hemphill's judgment, "false positives" are far less damaging than "false negatives" because of the large deadweight losses resulting from many pharmaceutical patents.¹⁸² The Hovenkamp-Lemley-Janis test, Michael Carrier's *Trinko* approach, the legislation currently pending before Congress, and the enforcement agencies' current policies likewise seem to reflect far more concern about underdeterrence than overdeterrence.

On the surface, this stance seems appropriate given the public interest in drug price competition and the purposes of the Hatch-Waxman Act. However, an overly aggressive regulatory posture ignores another key factor in most Paragraph IV settlements: the length of the bargained-for restriction on generic competition.

Using settlement amounts as the sole measure of validity threatens to turn the Paragraph IV process into an all-or-nothing proposition: either the patent is upheld and there is no generic competition during the remaining patent term, or the patent is invalidated. Most Paragraph IV settlements, however, permit generic entry at some point prior to patent expiration. A reverse payment settlement that results in a reduced patent term often will benefit the public more than a trial on the merits and subsequent appeals, even if the patent ultimately is invalidated. As the Justice Department noted in its brief recently

179. See *id.*

180. See *id.* at 67-76.

181. See Hemphill, *supra* note 24, at 669-70.

182. See *id.*

filed in *Arkansas Carpenters Health & Welfare Fund* (the Barr litigation),

[a]t least as a general matter, a settlement dividing the remaining life of the patent into a period of exclusion and a period of competition, based on the parties' expectations as to the likelihood of the patent being invalidated (and therefore their understanding of the value of a litigated outcome, on average), will adequately accommodate the public interest in freeing the market from undeserved monopolies.¹⁸³

The Justice Department's brief, however, incorrectly assumes that any reverse payment connected to an agreement to divide the remaining patent term must "naturally [be] viewed as consideration for the generic's agreement to delay entry beyond the point that would otherwise reflect the parties' shared view of the likelihood that the patentee would ultimately prevail in the litigation."¹⁸⁴ If the Paragraph IV challenger cannot receive more than its litigation costs in settlement, or if the amount of the settlement payment is the key determinant of antitrust exposure, the incentive to settle before trial is greatly diminished, and this important benefit could be lost.

It is true that a settlement without any reverse payment could include other important benefits, including early entry. It is unclear, however, whether cases would settle if early entry, without any reverse payment, is the only option on the table. In such cases, the entry date bargained for by the generic manufacturer presumably would be significantly earlier than an early entry date that is coupled with a payment. At some point, the branded manufacturer will choose to litigate rather than to sacrifice most of its remaining patent life in settlement.

For example, consider a patent with six years remaining on its term that produces rents of \$1 billion per year, against which one potential generic entrant files a Paragraph IV certification. If the subsequent infringement litigation takes four years from filing until a decision is issued on appeal, and the generic company prevails, the public will benefit from two years of early generic competition and up to a \$2 billion increase in consumer surplus, less any externalities and transaction costs imposed by four years of costly litigation.¹⁸⁵ If the patent challenge is unsuccessful, there is zero increase in consumer surplus and consumers must still bear the externalities imposed by the litigation

process. By comparison, if the litigation settles within one year of filing, and the parties agree to split the remaining patent term, the public will benefit from three years of early generic competition and up to a \$3 billion increase in consumer surplus, less the amount of the reverse payment to the generic challenger.¹⁸⁶ It is easy to see that, under a wide variety of similar scenarios, the overall increase in consumer surplus resulting from a reverse payment settlement can be greater than that resulting from a successful patent challenge. The Settlement Competition Index avoids the potentially inefficient results of the Justice Department's test by requiring a more complete evaluation of the agreement's actual competitive effects.

2. Settlement Amount as a Proxy for Patent Strength

Another significant question about my approach is whether it does more work than existing proposals that use the amount of the settlement payment as a gauge of the parties' beliefs about patent strength.¹⁸⁷ There are at least three reasons why the amount of the settlement payment alone often is not an adequate measure.

First, many reverse payment settlements involve unrelated licenses, authorized generic sales, and other side deals, in addition to or in lieu of monetary payments.¹⁸⁸ As Scott Hemphill has noted, "[v]iewed in isolation, it is difficult to tell whether a side deal represents payment for value or disguised payment for delayed generic entry."¹⁸⁹ Hemphill concludes that the rarity of such deals between branded and generic companies outside the Paragraph IV settlement context renders the inclusion of such deals in settlements suspicious and presumptively unlawful.¹⁹⁰ It is not clear, however, that such a presumption is always warranted. In *Schering-Plough*, for example, the Eleventh Circuit concluded that a side deal, which had been explored by the branded company prior to the Paragraph IV litigation, had significant independent business merit.¹⁹¹ In any event, even if Hemphill's general suspicions are correct, the complicated, multilayered nature of the typical settlement package belies any simple correspondence between risk and payment size.

Second, and perhaps most importantly, unlike an ordinary patent case, the generic challenger faces no risk in the Paragraph IV infringement case beyond litigation expenses. The pharmaceutical patent holder, in contrast, risks losing

183. Brief for the United States in Response to the Court's Invitation, *supra* note 56, at 22.

184. *Id.*

185. These include the consumption of judicial resources and, perhaps more importantly, the diversion of time and human resources away from the core business of product innovation. See Albert W. Alschuler, *Mediation with a Mugging: The Shortage of Adjudicative Services and the Need for a Two-Tier Trial System in Civil Cases*, 99 HARV. L. REV. 1808, 1812 (1986) ("Although litigation commonly proves expensive to the litigating parties, these parties pay only a fraction of the cost of operating the courts. In that sense, governments subsidize civil litigation, and the subsidy is substantial."); Thomas D. Rowe, Jr., *American Law Institute Study on Paths to a "Better Way": Litigation, Alternatives, and Accommodation: Background Paper*, 1989 DUKE L.J. 824, 868-73 (discussing positive and negative externalities and transaction costs of litigation).

186. Of course, if the parties were certain of the outcome and timing of the litigation, they would not rationally settle the case for any entry date prior to that which the generic could achieve through the litigation. The primary reason for settlement, however, is that the timing of an outcome of the litigation is uncertain. The point here is that the parties' adjustment of this uncertainty through a reverse payment settlement can often create a better net social welfare outcome than litigation.

187. See, e.g., Cotter, *supra* note 164, at 1814-15.

188. See Hemphill, *supra* note 24, at 663-69.

189. *Id.* at 668.

190. *Id.* at 668-69.

191. See 402 F.3d 1056, 1070 (2005).

an asset that might produce billions of dollars in rent each year.¹⁹² As the Eleventh Circuit stated in *Schering-Plough*, "Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude."¹⁹³

In this regard, it should be noted that Hatch-Waxman is not, or at least was not designed to be, merely a simplification of existing declaratory judgment procedures. First, the 180-day exclusivity period for first filers provides an additional incentive over the declaratory judgment context.¹⁹⁴ Even without the 180-day exclusivity period, however, in the context in which the Paragraph IV procedures were originally crafted, generic manufacturers retain significant incentives to challenge patents without incurring substantial risk.¹⁹⁵

Prior to the Supreme Court's recent decision in *MedImmune, Inc. v. Genentech, Inc.*,¹⁹⁶ the Federal Circuit employed the "reasonable apprehension of suit" test, under which a declaratory judgment plaintiff in a patent case had to show "both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity."¹⁹⁷ Under this test, the generic manufacturer would have to incur the risk of a significant damages suit before it could file an action for a declaratory judgment of invalidity or non-infringement. In fact, the Federal Circuit held in *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.* that even the filing of an ANDA with a Paragraph IV certification is insufficient to confer a generic manufacturer with standing to file a declaratory judgment action against the patent holder (although, in determining whether there is a "reasonable apprehension of suit," it is a factor to be considered in the totality of the circumstances).¹⁹⁸ Therefore, prior to *MedImmune*, the Hatch-Waxman Paragraph IV framework represented a significant reallocation of risk over ordinary declaratory judgment procedures.¹⁹⁹

In *MedImmune*, the Supreme Court called into question the Federal Circuit's "reasonable apprehension of suit" test.²⁰⁰ However, the Federal Circuit has generally interpreted *MedImmune* narrowly as relating primarily to cases in which there is an existing licensing relationship.²⁰¹ According to the Federal Circuit, "[i]n the context of conduct prior to the existence of a license, declaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement without some affirmative act by the patentee."²⁰²

However, the Federal Circuit demonstrated its willingness to follow *MedImmune* in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, where the Federal Circuit recognized the abrogation of *Teva Pharmaceuticals USA, Inc. v. Pfizer Inc.*²⁰³ According to the *Novartis* panel, the filing of an ANDA entitles the filer to bring a declaratory judgment action against the patent owner.²⁰⁴ Because an ANDA filing is an act of infringement, which gives the patent owner a right to sue, "[i]t logically follows that if such an action creates a justiciable controversy for one party, the same action should create a justiciable declaratory judgment controversy for the opposing party."²⁰⁵

It is now possible, then, for an ANDA filer to bring a declaratory judgment action if the patent owner fails to sue within the 45-day Paragraph IV window. It remains true, however, that the Hatch-Waxman procedures significantly alter the balance of risks in comparison to ordinary patent litigation. Under the Federal Circuit's jurisprudence after *MedImmune*, unless there is an ongoing licensing relationship, a declaratory judgment action for non-infringement or invalidity ordinarily is only possible when the declaratory judgment plaintiff is engaging in activity that exposes it to a real risk of a claim for damages. The ANDA context is an exception because an ANDA filing is a technical act of infringement that, by itself, does not give rise to a claim for damages. In fact, the Federal Circuit's decision in *Novartis* tips the playing field even further in favor of the generic manufacturer. Now the generic manufacturer can place a patent at risk, without any threat of a damages claim, even if the patent owner chooses not to sue for infringement as permitted under the Paragraph IV framework.

the *Glaxo* court notes, the Hatch-Waxman Act was amended in 2003 to allow a Paragraph IV filer not sued for infringement by the patent holder within the 45-day window to file a declaratory judgment action. *Id.* at 507-08 (citing 35 U.S.C. § 271(e)(5) (2006)). However, the *Glaxo* court held that this provision did not modify the "reasonable apprehension of suit" test, which it believed was rooted in the constitutional "case and controversy" requirement. *See id.*

200. *See MedImmune, Inc.*, 549 U.S. at 132 n.11.

201. *See, e.g., SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1384 (Fed. Cir. 2007).

202. *See id.* at 1380-81.

203. *See Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1339-40 (Fed. Cir. 2007).

204. *See id.* at 1342.

205. *Id.* The court also was persuaded that 35 U.S.C. § 271(e)(5), the ANDA declaratory judgment provision, supports the generic manufacturers' right to file a declaratory judgment action. *Id.* at 1342-43.

192. *See Hemphill, supra* note 24, at 648-49 (noting that the average U.S. annual sales of drugs implicated in reverse payment settlements was \$1.3 billion, and that some had annual sales as high as \$7 and \$3 billion).

193. 402 F.3d at 1074.

194. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

195. *See* 35 U.S.C. 271(e)(4) (2006).

196. 549 U.S. 118 (2007).

197. *See Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1343-44 (Fed. Cir. 2007) (quoting *B.P. Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993), *abrogated by Benitec Austl., Ltd.*, 495 F.3d 1340).

198. *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333-37 (Fed. Cir. 2005) (stating that the business disadvantage to the second generic manufacturer—the plaintiff—created by the first generic manufacturer's 180-day exclusivity period is "the product of the Hatch-Waxman scheme and the fact that [defendant] has acted in a manner permitted under that scheme. It is not the product of a threat of suit by [defendant]" and, therefore, does not amount to an actual controversy between plaintiff and defendant), *abrogated by MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 132 (2007).

199. *See, e.g., Glaxo Group Ltd. v. Dr. Reddy's Labs., Ltd.*, 325 F. Supp. 2d 502, 508 (D.N.J. 2004) (holding that ANDA filing alone is insufficient to satisfy the "reasonable apprehension of suit" test). As

A final reason why the amount of payment for any one settlement might not provide an accurate gauge of patent strength is the possibility of multiple Paragraph IV challenges by different ANDA filers. In deciding whether to settle any given challenge, the patent owner must consider (a) what signals the settlement will send to other existing or potential ANDA filers and (b) the costs of subsequent settlements.

In this regard, the ANDA settlement process bears some similarity to multidistrict mass tort litigation, where there are multiple cases proceeding on different timetables.²⁰⁶ In such circumstances, the defendant must engage in an iterative bargaining game with various different plaintiffs. The settlement price paid to any individual plaintiff might be higher or lower than the true value of the claim, depending on the defendant's assessment of the value of all the related claims in the aggregate and the plaintiff's beliefs about the payoffs available to the defendant for settling at any given point during the life of the broader litigation.²⁰⁷ In similar fashion, viewing any one Paragraph IV settlement in isolation will likely provide a distorted image of the actual value of that claim.

When the stakes are so high, and the risks so unbalanced, the patent holder likely will pay a significant settlement premium even if the risk of losing the infringement case is very small. By statutory design, the Paragraph IV filer has the patent owner "over a barrel" regardless of whether the patent is strong or weak. A reverse payment may represent the patent holder's belief that the patent is weak, but it may instead represent a risk-averse decision to buy off even a slim risk that a strong patent claim will fail in the courts. The latter decision would help to achieve certainty about rents that represent many multiples of that amount or it may reflect something about where that individual settlement falls in the process of bargaining with all potential filers. The value of an individual settlement, therefore, cannot be used as a reliable proxy for patent strength.

III. A PROPOSED "SETTLEMENT COMPETITION INDEX"

As discussed in the previous Part, existing proposals in scholarship revolve around the same central concern that has been addressed by the courts: what is the legitimate exclusionary power of a patent? None of these authorities, however, have focused on how patents function in *particularized product markets*. In this Part, I suggest what is, in effect, a significant elaboration of the Hovenkamp-Janis-Lemley test. This new test can be developed into a "safe harbor" framework that focuses on patent strength in connection with product market structure. Under this test, the court or regulatory agency first would consider the following criteria:

- (1) The difference in product market concentration that would likely result from the agreement; and
- (2) The probability that the patent will be held to be valid and infringed.

These criteria would be used to create a Settlement Competition Index ("SCI"), which provides a rough empirical gauge of the potential anticompetitive effects of the settlement. As discussed in detail in section III.C below, the SCI formula is the market concentration (derived from the Herfindahl-Hirschman Index ("HHI")) prior to generic entry, less the likely market concentration after generic entry, divided by the probability of enforcement, or otherwise represented as:

$$SCI = \frac{\Delta HHI}{pE}$$

Settlements at the lower and upper ranges of this Index would be presumptively valid or invalid, respectively. Settlements in the middle range would be further evaluated according to a balancing test under the rule of reason. This approach would establish antitrust "safety zones" and zones of per se illegality, consistent with antitrust policy concerning intellectual property licensing and mergers generally. This would promote greater certainty and efficiency in the settlement bargaining process.

Each element of my proposal is unpacked in the next section. Some possible objections to my approach are discussed in the following sections. The final section provides details about the calculation and application of the SCI.

A. THE IMPORTANCE OF ASSESSING PRODUCT MARKET CONCENTRATION

The first prong of my proposed test involves assessment of market concentration before and after the agreement. None of the courts, legal commentators, or regulatory agencies that have considered the reverse payment settlement problem thus far has paid sufficient attention to the importance of product market definition.²⁰⁸ This is surprising because a patent's impact on market concentration is a key determinant of the patent's power.

All of the authorities agree that valid patents provide a legitimate zone of exclusion and that reverse payment settlements are problematic to the extent they expand the patentee's exclusionary power beyond that inherent in the patent. The *scope* of a patent's legitimate exclusionary zone is defined by the

206. For a description of the multidistrict litigation and settlement process, see generally Howard M. Erichson, *A Typology of Aggregate Settlements*, 80 NOTRE DAME L. REV. 1769 (2005).

207. See generally *id.* at 1786-95 (describing how aggregate settlements are distributed).

208. As noted *infra* in notes 231-44 and their accompanying text, most economists who have attempted to model responses to the reverse payment settlement problem define a relevant product market, but oversimplify their models by assuming the market is either a monopoly or a duopoly.

scope of the claims, including the range of covered equivalents.²⁰⁹ The power of a patent's legitimate exclusionary zone, however, cannot be defined without reference to product market definition.²¹⁰ The definition of a patent's exclusionary zone must encompass both scope and power.

Scope and power are complementary, but not identical, concepts. It is true that scope and power usually involve a proportional relationship: as the scope of a patent's claim expands, its potential market power expands. A patent claim for "pharmaceutical compounds to treat depression" obviously would confer greater market power than a patent claim for the chemical formulation of the active ingredient in Prozac, fluoxetine hydrochloride.²¹¹ The doctrines that limit claim scope—novelty, non-obviousness, and the rules regarding claim construction and the range of equivalents—therefore also serve to constrain patent power. But these doctrines do not fully circumscribe the range of a patent's power. If fluoxetine hydrochloride is the only compound capable of treating depression, a patent claiming that compound confers greater market power than is the case when there are multiple non-infringing compounds that can be used to treat depression with similar clinical results.

More generally, product market definition is fundamental to antitrust analysis under the rule of reason. As one leading treatise notes, "The determination of the relevant market is inextricably related to the question of whether the defendant's competitors have been or will be foreclosed from the market by virtue of the challenged acts."²¹² Only in the context of per se liability, where the conduct is deemed inherently anticompetitive, is the question of market definition set aside.²¹³ The authorities that seek some kind of per se rule concerning reverse payment settlements, however, do not explain why such agreements are inherently anticompetitive except in a circular fashion that inevitably points back to the need for product market definition.

A response to this view might be that any agreement that expands a patent's scope should be considered an unlawful restraint of trade. This closely resembles arguments concerning tying arrangements involving patents, which were recently resolved by the Supreme Court in *Illinois Tool Works, Inc. v. Independent Ink, Inc.*²¹⁴

In *Illinois Tool Works*, the Court reversed the precedent rule that tying arrangements involving the tie of patented and unpatented products are per se

unlawful.²¹⁵ According to the Court, the conclusion that a particular tying arrangement involving a patent is unlawful "must be supported by proof of power in the relevant market rather than by a mere presumption thereof."²¹⁶ The Court based this conclusion, in part, on Congress's distinction between patent rights and market power in the Patent Act.²¹⁷

The *Illinois Tool Works* Court essentially adopted Justice O'Connor's reasoning in her concurrence to *Jefferson Parish Hospital District No. 2 v. Hyde*, a patent tying case abrogated by *Illinois Tool Works*.²¹⁸ Justice O'Connor there stated:

A common misconception has been that a patent or copyright, a high market share, or a unique product that competitors are not able to offer suffice to demonstrate market power. While each of these three factors might help to give market power to a seller, it is also possible that a seller in these situations will have no market power: for example, a patent holder has no market power in any relevant sense if there are close substitutes for the patented product. Similarly, a high market share indicates market power only if the market is properly defined to include all reasonable substitutes for the product.²¹⁹

Justice O'Connor's reasoning is consistent with antitrust policy concerning intellectual property generally, including the Federal Trade Commission and Department of Justice guidelines for intellectual property licenses.²²⁰ A reverse payment settlement is not, of course, a license agreement. However, the antitrust concern over reverse payment settlements is the same as the concern over exclusive licenses: will the agreement result in an unacceptable degree of market concentration? A license agreement can allow the parties to aggregate the legitimate exclusionary power of multiple intellectual property rights in a way that illegitimately concentrates market power.²²¹ In a transaction that involves a sale or exclusive transfer of intellectual property rights, the agencies apply a merger analysis to determine the agreement's competitive effects.²²²

This approach rests on a sound theoretical foundation. Patent rights are

215. See *id.* at 45-46.

216. *Id.* at 43.

217. *Id.* at 41-42 (citing 35 U.S.C. § 271(d)(5) (2006)).

218. *Id.* at 37-38.

219. *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 37 n.7 (1984) (O'Connor, J., concurring), abrogated by *Ill. Tool Works Inc.*, 547 U.S. at 28.

220. See U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY (1995), available at <http://www.usdoj.gov/atr/public/guidelines/0558.htm>.

221. See *id.* § 2.1 ("As with other forms of private property, certain types of conduct with respect to intellectual property may have anticompetitive effects against which the antitrust laws can and do protect. Intellectual property is thus neither particularly free from scrutiny under the antitrust laws, nor particularly suspect under them."); *id.* § 3.1 ("[A]ntitrust concerns may arise when a licensing arrangement harms competition among entities that would have been actual or likely potential competitors . . .").

222. *Id.* § 5.7

209. See, e.g., *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 732 (2002) ("The scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described.")

210. See, e.g., *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 36 (2006).

211. Fluoxetine hydrochloride is the generic name for a selective serotonin reuptake inhibitor originally sold under the brand name Prozac. See ELI LILLY & CO., PROZAC PRESCRIBING INFORMATION 1 (2009), available at <http://www.prozac.com/Pages/index.aspx>.

212. 1 LOUIS ALTMAN & MALLA POLLACK, CALLMANN ON UNFAIR COMPETITION, TRADEMARKS AND MONOPOLIES § 4:31, at 4-308 (4th ed. 2009).

213. See *id.* § 4:31, at 4-306.

214. 547 U.S. 28 (2006).

probabilistic, not certain, because validity and infringement are always decided after the alleged infringement through litigation.²²³ This means that it is impossible to determine patent scope with certainty *ex ante*. As noted in section III.C below, it is possible to assess with some degree of confidence the *probability* that an infringement claim will succeed. This alone, however, does not answer the question whether the parties' adjustment of this probability through settlement should be held unlawful as an impermissible restraint of trade. That question must circle back to the likely effects of the restraint in the particular product market in which this probabilistic right is being asserted. Both the product market and the probability of enforcement must be considered to assess the reasonableness of the restraint under all the circumstances.

Most economists that have attempted to model the effects of reverse payment settlements have recognized the need for objective measurements of product market concentration. For example, in a paper that provides detailed economic models of reverse payment settlements, Carl Shapiro developed a ratio he calls the "'patent competition index' (PCI)."²²⁴ The PCI provides an index of the loss of consumer surplus when firms settle a patent challenge by merging and identifies the amount of efficiencies the merger must generate in order to promote consumer welfare.²²⁵ Shapiro suggests that the PCI could be integrated with the DOJ-FTC Horizontal Merger Guidelines because "[t]he safe-harbor provisions in merger enforcement can reasonably be viewed as indicating the magnitude of efficiencies that are credited to merging parties as a matter of course."²²⁶ He notes that "a somewhat greater increase in concentration would be permitted if the acquired firm is operating under a patent cloud."²²⁷

My proposal suggests some expansion of, complications to, and simplifications of economic models such as Shapiro's. The expansion is that Shapiro's basic insight about merger analysis should apply even when the settlement will not result in a merger. This is consistent with the way in which enforcement agencies currently evaluate exclusive horizontal intellectual property licenses.²²⁸ An exclusive horizontal license functions like a merger in that it

allows potential competitors to aggregate existing or potential market shares in a given product market. The licensee in such a transaction often contributes nothing other than monetary consideration and an agreement not to challenge the licensed intellectual property rights.

A reverse payment settlement, in turn, is similar to an exclusive license in that competition that might have resulted from a challenge to the intellectual property right is limited by agreement.²²⁹ Of course, the potential efficiency justifications differ because, in an ordinary exclusive license, the monetary consideration paid to the licensor presumably reflects an efficient allocation of resources and the exchange of technology may involve spillover benefits resulting from the acquisition of ancillary knowledge by the licensee.²³⁰ The potential efficiency justifications differ when one party to the transaction is being paid *not* to develop a technology. Nevertheless, the initial question of anti-competitive effects remains similar: will the merger, exclusive license, or reverse payment settlement result in a harmful aggregation of market power? Thus, the merger analysis model can also apply to "ordinary" reverse payment settlements.

A way in which I propose to complicate Shapiro's model (and other similar economic models) concerns the structure of the product market after consummation of the settlement. Most existing economic models assume only duopolistic competition if the settlement is not consummated and the patent is held valid but not infringed.²³¹ This assumption, however, is unrealistic in many pharmaceutical product markets. My proposal includes an assessment of the product market as it actually exists for the drug subject to the settlement. Again, this is consistent with existing DOJ-FTC intellectual property licensing and merger guidelines and other sources of antitrust policy.

In antitrust cases, the relevant market "is composed of products that have reasonable interchangeability for the purposes for which they are produced—

sale by an intellectual property owner of all of its rights to that intellectual property and to a transaction in which a person obtains through grant, sale, or other transfer an exclusive license for intellectual property (i.e., a license that precludes all other persons, including the licensor, from using the licensed intellectual property)." U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, *supra* note 220, § 5.7.

229. An exclusive license is different in that it does not exclude the licensed party from the market. However, the exclusive license does, by definition, exclude other potential licensees, and may preclude or limit challenges to the patent by the licensee. *Cf. MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126-37 (2007) (discussing circumstances under which a patent licensee can seek a declaratory judgment of patent invalidity).

230. *See, e.g.*, U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, *supra* note 220, § 2.3 (noting procompetitive benefits of licensing).

231. *See, e.g., id.* Other modelers have made similar simplifying assumptions. *See* Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, in 4 NAT'L BUREAU OF ECON. RESEARCH, INNOVATION POLICY AND THE ECONOMY 145, 159-60 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2004) (modeling "monopoly days, triopoly days, and duopoly days" resulting from Paragraph IV litigation settlements); Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 656 n.2 (2004) (recognizing that the patent holder might not have monopoly power in real markets but adopting assumption of market power to simplify modeling).

223. *See* Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, J. ECON. PERSP., Spring 2005, at 75, 75 ("[E]conomists have increasingly recognized that a patent does not confer upon its owner the right to exclude but rather a right to *try* to exclude by asserting the patent in court." (citation omitted)); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 395 (2003) ("[A] patent is best viewed as a *probabilistic* property right. What the patent grant actually gives the patentholder is the right to sue to prevent others from infringing the patent. Nothing in the patent grant guarantees that the patent will be declared valid, or that the defendant in the patent suit will be found to have infringed. In other words, all real patents are *less strong* than the idealized patent grant usually imagined in economic theory.")

224. Shapiro, *supra* note 223, at 403.

225. *Id.*

226. *See id.* (implicating the DOJ-FTC Horizontal Merger Guidelines by stating that "[a]n extension to this article would be to integrate this analysis with traditional structural merger analysis based on measures of market concentration").

227. *Id.*

228. As the joint Department of Justice-Federal Trade Commission *Antitrust Guidelines for the Licensing of Intellectual Property* note, the FTC and DOJ "will apply a merger analysis to an outright

price, use and qualities considered."²³² For pharmaceutical products, "the only logical place from which to determine the relevant product market is from the array of therapeutically substitutable choices available to the doctor."²³³ Expert testimony from physicians, pharmacists, third-party payors, and other sources can help establish which products are therapeutic substitutes.²³⁴ It is also possible to quantify the cross-price elasticity of demand for branded and generic products in the same therapeutic class.²³⁵

Often, a significant variety of competing patented and generic products exist in the same class to treat the same condition. In fact, there has been significant policy debate over whether patents perversely incentivize second generation "me too" drugs in a blockbuster class that yields little or no marginal increase in therapeutic value.²³⁶ For example, at least five variations of selective serotonin reuptake inhibitors (SSRIs) have been approved by the FDA to treat depression.²³⁷ These are sold under at least seven brand names by three different branded manufacturers.²³⁸ Four of the patents relating to these compounds have expired and generic versions of these drugs are sold by generic manufacturers.²³⁹ In such a product market, the loss of generic competition with respect to one compound would not result in a true monopoly, nor would the presence of generic competition with respect to one patent result in a duopoly. In other words, the scope of the patent claims for any one compound does not define the boundaries of the relevant product market.

Notwithstanding this criticism of Shapiro's model, the definition of a product

market for pharmaceuticals is complicated by the need for a therapeutic fit between a given compound within a drug class and the patient. It is quite possible, for example, that a patient suffering from depression might respond only to one particular compound within the class of SSRIs. Moreover, some patients being treated with certain types of drugs—including psychiatric drugs—report better results from the branded version of a particular compound than from a generic, even though the FDA has found the products to be bioequivalent.²⁴⁰ It is unclear why this discrepancy occurs—whether because of some subtleties of the formulation process,²⁴¹ or a simple placebo effect. Thus, for any given patient, the product market might not be as broad as the total range of potential treatments.

Pharmaceutical product markets are also complicated by the effects of advertising and the role of the prescribing physician. Some commentators suggest that the branded pharmaceutical industry and prescribing physicians effectively collude to direct patients towards "newer," more expensive treatments that might prove no more effective than cheaper alternatives.²⁴² At the very least, there is evidence that perceptions about the safety or efficacy of older versions of a drug within a therapeutic class can be influenced by the introduction of new versions, even if the new version might not be materially safer or more effective.²⁴³

Even with these caveats, however, it seems reasonable to reject the assumption that all pharmaceutical product markets in which a Paragraph IV validity challenge has been mounted to a patent are only either potential monopolies or duopolies.²⁴⁴ Therefore, at least as a first rough measure of competitive effect, it is reasonable to define the relevant product market to include all potentially competing drugs in the same class.

232. *United States v. E.I. duPont de Nemours & Co.*, 351 U.S. 377, 404 (1956). The joint DOJ-FTC Merger Guidelines indicate that a product market can be defined by examining whether buyers likely would shift to a substitute product in response to a "small but significant and nontransitory" increase in price—in other words, by the cross-price elasticity of demand. U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 1.1 (rev. ed. 1997), available at <http://www.justice.gov/fta/public/guidelines/hmg.htm>.

233. *In re Schering-Plough Corp.*, No. 9297, at 88 (Fed. Trade Comm'n June 27, 2002), available at <http://www.ftc.gov/os/2002/07/scheringinitialdecision2.pdf>.

234. *See id.* at 88–89.

235. *See, e.g.*, Sara Fisher Ellison et al., *Characteristics of Demand for Pharmaceutical Products: An Examination of Four Cephalosporins*, 28 RAND J. ECON. 426 (1997) (examining cross-price elasticities of cephalosporins in a product market that included four different branded compounds); *see also* Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & ECON. 311, 312 (2000) ("[P]atent-protected drugs may face competition from 'therapeutic substitutes'—drugs with different active ingredients but similar therapeutic effects.")

236. *See, e.g.*, Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 538 (2009) ("[T]he patent system is largely incapable of distinguishing unimportant me-too drugs from drugs of significant medicinal value, and there is little reason to trust that the drugs deemed 'obvious' under current law would not provide great benefit to society.")

237. These include citalopram, escitalopram, fluoxetine, paroxetine, and sertraline. *See* Mayo Clinic, *Selective Serotonin Reuptake Inhibitors (SSRIs)*, <http://www.mayoclinic.com/health/ssris/MH00066> (last visited Mar. 22, 2010).

238. *See* Haiden A. Huskamp et al., *Generic Entry, Reformulations and Promotion of SSRIs in the US*, 26 PHARMACOECONOMICS 603, 604, 607 (2008) (noting that branded SSRIs include Prozac, Paxil, Zoloft, Celexa, Paxil CR, Prozac Weekly, and Lexapro).

239. *Id.* at 607.

240. *See* Giuseppe Borgherini, *The Bioequivalence and Therapeutic Efficacy of Generic Versus Brand-Name Psychoactive Drugs*, 25 CLINICAL THERAPEUTICS 1578, 1578 (2003).

241. *See, e.g., id.* at 1588–89 (discussing different excipients between brand-name and generic compounds).

242. *See, e.g.*, Arielle Levin Becker, *No More Free Lunches? Fierce Fight Underway Over Physician Gifts*, HARTFORD COURANT, May 25, 2009, at A1 ("On one side: consumer advocates, health care watchdogs and some doctors who say industry gifts, no matter how small, can influence doctors to prescribe expensive, new drugs instead of less-costly generics. This drives up health care costs and potentially harms patients . . ."); Gardiner Harris, *Document Details Plan To Promote Costly Drug*, N.Y. TIMES, Sept. 2, 2009, at B1 ("The pharmaceutical industry has developed thousands of medicines that have saved millions of lives, but it has also used its marketing muscle to successfully peddle expensive pills that are no more effective than older drugs sold at a fraction of the cost."); *Small Drug Promo Items May Influence Young Doctors: Exposure to Brand-Name Pads, Pens and the Like Bears Closer Monitoring, Study Suggests*, U.S. NEWS & WORLD REP., May 11, 2009, <http://health.usnews.com/articles/health/healthday/2009/05/11/small-drug-promo-items-may-influence-young-doctors.html>.

243. *See, e.g.*, Ernst R. Berndt, Robert S. Pindyck & Pierre Azoulay, *Consumption Externalities and Diffusion in Pharmaceutical Markets: Antulcer Drugs*, 51 J. INDUS. ECON. 243, 244 (2003) ("Consumption externalities arise when the use of a drug by others influences perceptions about its efficacy, safety, and 'acceptability,' and thus affects its valuation and rate of adoption.")

244. Danzon and Chao note some of these sorts of complications but conclude that "there is evidence of competition between therapeutic substitutes in the form of lower prices for successive entrants." Danzon & Chao, *supra* note 235, at 344–45.

B. ASSESSING THE PROBABILITY OF PATENT ENFORCEMENT

The second prong of my proposed test involves an assessment of the probability that the patent would have been held to be valid and infringed—in other words, an assessment of the patent's scope.²⁴⁵

The litigation probability factor might, somewhat surprisingly, be one of the most controversial aspects of my proposal. In the *Tamoxifen* litigation, for example, the Second Circuit refused to engage in speculation about the outcome of the infringement litigation in the event it had not been settled.²⁴⁶ However, the likelihood that the patent will be held invalid or not infringed is key to evaluating whether a settlement violates antitrust law. If the patent is strong and likely to be enforced against the challenger, there is little social welfare benefit in prolonged litigation, and there are potentially significant negative externalities resulting from the parties' use of judicial resources.²⁴⁷ If the patent is weak, in contrast, the competitive effects of a settlement are likely to be more deleterious.

The Justice Department and some commentators argue that the parties' beliefs about patent strength at the time of the settlement can serve as a proxy for an actual, objective evaluation of the patent's exclusionary power.²⁴⁸ The settling parties' beliefs, however, cannot by themselves substitute for an objective evaluation of patent scope.

First, as the DOJ acknowledges in passing in its Barr brief, at least some of the reverse payment amount might reflect the parties' adjustment of information asymmetries concerning patent strength.²⁴⁹ In fact, the DOJ's Barr brief grossly underestimates the extent to which information asymmetries and information biases can distort the settlement process.²⁵⁰ Particularly where there are significant information asymmetries, the parties' respective assessments of patent

strength might diverge widely. The amount of the payment will then reflect substantial differences in the parties' respective assessments of patent strength rather than a reasonable proxy for actual patent strength.

Moreover, the DOJ's proposed approach would allow the parties to game the regulatory framework. It would be easy for the parties to pad their files with inflated assessments of patent strength in anticipation of a later challenge to a settlement. Therefore, although the parties' pre-settlement evaluations of patent strength might be relevant to an objective determination, they cannot serve as substitutes for an objective valuation.

The DOJ and other commentators are right to be concerned about the prospect of a "trial within a trial" on patent strength, particularly given the complexity of some patent validity and infringement issues. Courts can establish procedures, however, for obtaining a reasonable estimate of patent strength without the need for a full-blown infringement trial. The purpose here is to develop a reasonable assessment of the probability of litigation success, not a certain, final adjudication of validity and infringement.²⁵¹

Lawyers routinely seek to quantify litigation risks in all sorts of cases, including patent cases. Of course, no experienced lawyer would ever discuss potential litigation outcomes in terms other than probabilities, with varying degrees of confidence. In litigation, the possibility of an unexpected or even seemingly bizarre result remains ever present. But that possibility is simply part of a good lawyer's probability calculus. There is no reason why a capable expert could not offer an opinion about the probability of patent enforcement. Even in litigated patent cases, courts engage in this sort of probabilistic analysis of the likelihood of success on the merits when the plaintiff has requested a preliminary injunction.²⁵²

In the context of settlement, the assessment of litigation risk by courts is nothing extraordinary; indeed, it is routine. For example, federal courts must evaluate the merits of the underlying litigation when deciding whether to approve any class action settlement.²⁵³ Nearly all of the factors the court must consider require the court to assess risks and probabilities attending the prosecution of the underlying litigation.²⁵⁴

245. Here, I disagree with Shapiro and others who suggest that a meaningful model can be developed in which patent strength is an exogenous factor. See Shapiro, *supra* note 223, at 397. Yet, even Shapiro notes this weakness in his model. *Id.*

246. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 203 (2d Cir. 2006) ("We cannot judge this post-trial, pre-appeal settlement on the basis of the likelihood *vel non* of Zeneca's success had it not settled but rather pursued its appeal.")

247. See Alschuler, *supra* note 185, at 1812; see also Willig & Bigelow, *supra* note 231, at 657 ("[T]here are likely to exist voluntary mutually beneficial settlements between the patent holder who claims infringement and the firm seeking to enter that are favorable to consumer and social welfare. Under such socially desirable settlements, entry is permitted at an intermediate date that is consonant with and reflects the relative odds of the parties' success in the patent litigation that would ensue absent settlement.")

248. See Brief for the United States in Response to the Court's Invitation, *supra* note 56, at 21.

249. *Id.* at 29 ("[A] modest reverse payment to 'bridge the gap' between parties with different expectations about litigation outcomes may be a legitimate cost of settlement.")

250. See, e.g., Robert H. Gertner, *Asymmetric Information, Uncertainty, and Selection Bias in Litigation*, 1993 U. CHI. L. SCH. ROUNDTABLE 75, 76 (describing "optimism" and "asymmetric information" models of settlement bargaining); George Loewenstein & Don A. Moore, *When Ignorance Is Bliss: Information Exchange and Inefficiency in Bargaining*, 33 J. LEGAL STUD. 37, 53 (2004) ("Information that is complex, or sufficiently ambiguous to allow for different interpretations by the two sides, will increase opportunities for self-serving interpretations of that information. Self-serving interpreta-

tions of fairness encourage biased estimations of the probability of prevailing in court and lead people to hold out too long, fight too hard, and settle too slowly." (citation omitted)).

251. *Cf.* Hovenkamp, Janis & Lemley, *supra* note 150, at 1760 (stating that evaluation of patent strength "need not be particularly searching" because "[t]he goal is merely to ensure that there is a legitimate dispute being settled").

252. See, e.g., *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1379 (Fed. Cir. 2009) ("[W]hen analyzing the likelihood of success factor, the trial court, after considering all the evidence available at this early stage of the litigation, must determine whether it is more likely than not that the challenger will be able to prove at trial, by clear and convincing evidence, that the patent is invalid.")

253. See, e.g., *City of Detroit v. Grinnell Corp.*, 495 F.2d 448, 463 (2d Cir. 1974), *abrogated by* *Goldberger v. Integrated Res., Inc.*, 209 F.3d 43 (2d Cir. 2000).

254. The factors include:

- (1) the complexity, expense and likely duration of the litigation;
- (2) the reaction of the class to the settlement;
- (3) the stage of the proceedings and the amount of discovery completed;
- (4) the risks of establishing liability;
- (5) the risks of establishing damages;
- (6) the risks of maintaining the class action through the trial;
- (7) the ability of the defendants to withstand a

A key purpose of this review is to protect the interests of absent class members on whose behalf the action was brought.²⁵⁵ Derivative suits provide another example in which court approval is required to protect nonparties with an interest in the outcome.²⁵⁶

Similarly, court approval is required for any settlement of a bankruptcy proceeding in order to protect absent claimants.²⁵⁷ In this context, the Supreme Court has noted that "[t]here can be no informed and independent judgment as to whether a proposed compromise is fair and equitable until the bankruptcy judge has apprised himself of all facts necessary for an intelligent and objective opinion of the probabilities of ultimate success should the claim be litigated."²⁵⁸

Under the Tunney Act, court approval is also required for consent decrees in antitrust enforcement actions in order to determine whether the settlement is in the public interest.²⁵⁹ The standard of judicial review in this instance, however, is narrow: an antitrust consent decree can be overturned "only if any of the terms appear ambiguous, if the enforcement mechanism is inadequate, if third parties will be positively injured, or if the decree otherwise makes a 'mockery of judicial power.'"²⁶⁰ This narrower standard protects the constitutional interest in the government's exercise of prosecutorial discretion concerning the enforcement action.²⁶¹

A Paragraph IV case is similar to a class action, a derivative action, or a bankruptcy proceeding in that the Hatch-Waxman procedural framework facilitates the prosecution of private litigation specifically intended to benefit parties beyond those named in the action. There is a sense in which the Paragraph IV filer acts as a representative of the public, which has an interest in the rents accruing to the patent holder if the patent is invalid or unenforceable.²⁶² The complicated issue of prosecutorial discretion underlying the Tunney Act does not apply. It is therefore reasonable that an assessment of the risks of the litigation

greater judgment; (8) the range of reasonableness of the settlement fund in light of the best possible recovery; [and] (9) the range of reasonableness of the settlement fund to a possible recovery in light of all the attendant risks of litigation.

Id. (internal citations omitted)

255. See *United States v. City of Miami*, 614 F.2d 1322, 1330-31 (5th Cir. 1980) ("In the class action and shareholder derivative suit contexts... careful scrutiny is necessary to guard against settlements that may benefit the class representatives or their attorneys at the expense of absent class members or shareholders." (internal citation omitted)).

256. See FED. R. CIV. P. 23.1(b); *United States v. City of Miami*, 614 F.2d at 1330-31.

257. See FED. R. BANKR. P. 9019(a); JONATHAN P. FRIEDLAND, *COMMERCIAL BANKRUPTCY LITIGATION* § 2:20 (2d ed. 2009).

258. Protective Comm. for Indep. Stockholders of TMT Trailer Ferry, Inc. v. Anderson, 390 U.S. 414, 424 (1968).

259. 15 U.S.C. § 16(b), (e)(1) (2006).

260. *Massachusetts v. Microsoft Corp.*, 373 F.3d 1199, 1236 (D.C. Cir. 2004) (quoting *Mass. Sch. of Law at Andover, Inc. v. United States*, 118 F.3d 776, 783 (D.C. Cir. 1997)).

261. *Id.* at 1236-37.

262. Shapiro refers to this as a sort of "property" right accruing to the public. See Shapiro, *supra* note 223, at 395. Even taken in Shapiro's non-literal sense, this characterization is too strong. The point remains, however, that there is a public interest in competition, with a limited exception carved out for patent rights based on the social bargain of reward for innovation and disclosure.

should comprise part of the court's review of any Paragraph IV settlement.

The model presented in this Article treats the probability of enforcement (patent scope) along with market concentration (patent power) as factors in developing the SCI, which could be used by courts and enforcement agencies as a tool for antitrust evaluation of reverse payment settlements. The next section demonstrates how the SCI would operate.

C. CALCULATING THE SETTLEMENT COMPETITION INDEX

Antitrust policy already employs most of the tools required to calculate the SCI. As discussed in sections III.A and B above, the first step is to define the relevant product market. The next step is to measure the proposed settlement's effect on market concentration.

In merger cases, the FTC and DOJ use the Herfindahl-Hirschman Index ("HHI") "[a]s an aid to the interpretation of market data."²⁶³ The HHI is measured "by summing the squares of the individual market shares of all the participants."²⁶⁴ The agencies evaluate the likely competitive effects of mergers by examining the extent to which the proposed merger would increase this measure of market concentration.²⁶⁵

A similar analysis can apply to reverse payment settlement cases. A court or agency can measure the likely HHI if the Paragraph IV filer enters the market, versus the HHI if the Paragraph IV filer cannot, or chooses not to, enter. This figure is the difference in HHI or "ΔHHI."

The difference in HHI, however, is not the only relevant factor. A complete model must also include the likelihood that the difference in market concentration is due to the legitimate exclusionary zone of the patent. Therefore, the probability of patent enforcement must be factored into the equation to create the SCI. The SCI formula, thus, is the HHI prior to generic entry, less the HHI after generic entry, divided by the probability of enforcement:

$$SCI = \frac{\Delta HHI}{pE}$$

Higher SCI values represent an increasing likelihood that the settlement is anticompetitive as a matter of antitrust policy and/or deviates from the purposes of the Hatch-Waxman Act. Such policy concerns can arise either because of inherent market concentration, because the settlement permits the patent holder to capture rents that are outside the legitimate exclusionary zone of the patent, or from some combination of those two factors. The ability to weigh both

263. U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, *supra* note 232, § 1.5.

264. *Id.* For a review and evaluation of the use of the HHI in merger analysis, see Neil B. Cohen & Charles A. Sullivan, *The Herfindahl-Hirschman Index and the New Antitrust Merger Guidelines Concentrating on Concentration*, 62 TEX. L. REV. 453 (1983).

265. U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, *supra* note 232, § 1.51.

product market structure and patent zone is unique to this model.

The next sections provide some hypothetical examples, apply the SCI to a real-world case, and offer some potential safe harbor guidelines.

1. Hypothetical Examples

The following examples illustrate how the SCI could work in a variety of hypothetical product markets. In the first example, there are four competing patented compounds that serve as close therapeutic substitutes, each with an equal market share:

Example 1

Manufacturer	Market Share
Alpha	25%
Beta	25%
Gamma	25%
Delta	25%

The HHI for this market is 2500. Suppose that a generic manufacturer files a Paragraph IV certification with respect to Alpha's compound, successfully challenges the patent, and enters the market, resulting in dilution of each existing competitor's market shares. The respective market shares might appear as follows:

Manufacturer	Market Share
Alpha	20%
Generic	20%
Beta	20%
Gamma	20%
Delta	20%

The HHI for this market is 2000. The Δ HHI therefore is 500. The following table shows the SCI for this potential market, assuming different probabilities of success in the Paragraph IV litigation:

Δ HHI	Prob. Patent Enforcement	Settlement Competition Index
500	.1	5000
500	.25	2000
500	.5	1000
500	.75	666
500	1	500

Notice that the higher the probability of patent enforcement, the lower the resulting SCI.²⁶⁶ This demonstrates that any market concentration likely is not caused by the settlement. Rather, in such cases, the market concentration reflects the market power afforded the inventor under the Patent Act. As courts and antitrust enforcement agencies have repeatedly observed, the market power afforded by a patent is not an antitrust problem in itself. The Hatch-Waxman Act's Paragraph IV procedures are designed to weed out weak patents, which should not have been granted in the first instance, not to destroy valid patent rights.

Example 2 models a less homogeneous market, in which the generic entrant primarily siphons market share from a strong branded competitor:

Example 2

Manufacturer	Market Share
Alpha	50%
Beta	10%
Gamma	10%
Delta	30%
HHI	3600

Manufacturer	Market Share
Alpha	35%
Generic	25%
Beta	8%
Gamma	7%
Delta	25%
HHI	2588
Δ HHI	1012

Δ HHI	Prob. Patent Enforcement	Settlement Competition Index
1012	.1	10120
1012	.25	4048
1012	.5	2024
1012	.75	1349
1012	1	1012

266. In the real world, the probability of patent enforcement is almost never 0 (zero probability of enforcement) or 1 (absolute certainty of enforcement). These probabilities are included for reference.

Notice that a greater change in market concentration results in a higher overall SCI, but that settlements in which there is a high probability of patent enforcement remain at the low to moderate end of the SCI scale.

Example 3 represents a market that is diluted prior to generic entry:

Example 3

Manufacturer	Market Share
Alpha	12.5%
Beta	12.5%
Gamma	12.5%
Delta	12.5%
Kappa	12.5%
Epsilon	12.5%
Iota	12.5%
Omega	12.5%
HHI	1250

Manufacturer	Market Share
Alpha	11.25%
Beta	11.25%
Generic	10.00%
Gamma	11.25%
Delta	11.25%
Kappa	11.25%
Epsilon	11.25%
Iota	11.25%
Omega	11.25%
HHI	1112.5
Δ HHI	137.5

Δ HHI	Prob. Patent Enforcement	Settlement Competition Index
137.5	.1	1375
137.5	.25	550
137.5	.5	275
137.5	.75	183
137.5	1	138

This example illustrates that, where the exclusionary power of the patent is ver limited (that is, the market will not be greatly diluted by the entry of th generic), the SCI will tend to be quite low, meaning there is less reason fo concern over a settlement.

2. A Real-World Example

The drug LYRICA, sold by Pfizer, provides a helpful real-world example o how the SCI would work. LYRICA is the brand name for pregabalin, which ha been approved by the FDA for the treatment of fibromyalgia.²⁶⁷ It is ofte prescribed for various types of neuropathic pain.²⁶⁸ Teva Pharmaceuticals an several other generic manufacturers, including Sandoz, Actavis, Cobalt Labs Sun Pharma, and Alpharma, filed Paragraph IV certifications with respect to LYRICA, and Pfizer sued for infringement.²⁶⁹ What if the parties decide to settle the resulting litigation?

According to the Merck Manual, other drugs prescribed for neuropathic pain include TEGRETOL (carbamazepine), gabapentin, and phenytoin.²⁷⁰ Novartis sells TEGRETOL.²⁷¹ Pfizer markets Gabapentin as NEURONTIN.²⁷² Gabapentin also is sold by numerous generic manufacturers, including Teva and Glenmark.²⁷³ Phenytoin is sold by Pfizer as DILANTIN and is also sold by numerous generic manufac- turers, including Actavis, Morton Grove, Mylan Pharmaceuticals, Precision Dose, and Taro.²⁷⁴ The following chart shows the market shares for these

267. See Pfizer, LYRICA (pregabalin) Capsules CV Official Website, http://www.lyrica.com/fibro_homepage.aspx (last visited Jan. 20, 2010).

268. PFIZER, MEDICATION GUIDE: LYRICA 2 (2009), available at http://www.lyrica.com/fibro_homepage.aspx.

269. See Complaint at 1, Pfizer, Inc. v. Teva Pharms. USA, Inc., No. 1:09-cv-00307 (D. Del. Apr. 29, 2009), available at <http://www.patentdocs.typepad.com/files/pfizer-v-teva-1.pdf> (last visited July 31, 2009); *Pfizer Lawsuit Against Sun To Block Generic Lyrica*, DANCE WITH SHADOWS: PILLSCRIBE, June 19, 2009, <http://www.dancewithshadows.com/pillscribe/pfizer-bolsters-lawsuit-against-sun-to-block-generic-lyrica-pregabalin/>.

270. Russell K. Portenoy, Merck & Co., Inc., Introduction: Pain: Merck Manual for Healthcare Professionals tbl.4 (Feb. 2007), <http://www.merck.com/mmpe/sec16/ch209/ch209a.html#CACIDG1H>.

271. Novartis Pharms. Corp., Pharmaceutical Products, <http://www.pharma.us.novartis.com/products/index.jsp> (last visited Mar. 11, 2010).

272. Pfizer Inc., NEURONTIN (gabapentin), http://www.pfizer.com/products/rx/rx_product_neurontin.jsp (last visited Mar. 11, 2010).

273. Glenmark Generics Inc., USA, <http://us.glenmark-generics.com/Products/Index> (last visited Mar. 11, 2010); Teva Pharmaceuticals USA, Generic Drug Products—Teva Pharmaceutical Manufacturer, <http://www.tevausa.com/default.aspx?pageid=47&category=ProductName&next=1&letter=G> (last visited Mar. 11, 2010).

274. Actavis US, Product List, Product Search, <http://www.actavis.us/en/products/product+list/default.htm> (last visited Mar. 11, 2010); Mylan Pharmaceuticals: Products: Consumer Product Guide, <http://www.mylanpharma.com/product/productList.aspx> (last visited Mar. 11, 2010); Precision Dose, Inc., <http://www.precisiondose.com/products.html> (last visited Mar. 11, 2010); Taro U.S.A. Rx Products, <http://www.tarousa.com/Products/Rx/ProductsByAlpha.html> (last visited Mar. 11, 2010); Wockhardt USA—Our Other Websites, <http://www.wockhardusa.com/products.html> (last visited Mar. 11, 2010) (listing Morton Grove Pharmaceuticals' products).

drugs in 2008 based on available sales figures and other market data.²⁷⁵

Manufacturer	Drug	Sales (Millions USD)	Market Share
Pfizer	LYRICA	2573	75%
	NEURONTIN	387	
	DILANTIN	30	
Novartis	TEGRETOL	451	11%
Teva	Gabapentin	85	2%
Alpharma	Gabapentin	85	3%
	Phenytoin	30	
Ivax	Gabapentin	85	2%
Glenmark	Gabapentin	85	2%
Morton Grove	Phenytoin	30	1%
Precision Dose	Phenytoin	30	1%
Taro	Phenytoin	30	1%
UDL	Phenytoin	30	1%
Xactdose	Phenytoin	30	1%
Total		3885	100%

The HHI for this market is 5777. This number reflects a highly concentrated product market. Suppose now that the parties do not settle, the generic companies prevail in their respective infringement cases, the generic manufacturers capture 50% of LYRICA's market share, and the market for pregabalin increases somewhat at the expense of older products.²⁷⁶ Based on these assumptions, the market might appear as follows:

275. For sales figures, see PFIZER INC., 2008 FINANCIAL REPORT 21 (2008), available at <http://media.pfizer.com/files/annualreport/2008/financial/financial2008.pdf> and Novartis, Novartis Product Sales, <http://www.novartis.com/investors/sales-results/product-sales.shtml> (last visited Feb. 11, 2010). Sales figures for generic manufacturers are estimated and not publicly reported. Concerning phenytoin, one source indicates that the total U.S. market is approximately \$191 million. See *Taro Receives ANDA Approval for Extended Phenytoin Sodium Capsules, USP 100 mg*, GLOBENEWSWIRE, Sept. 6, 2006, <http://www.globenewswire.com/newsroom/news.html?id=104762>. The total U.S. generic market for gabapentin is approximately \$325 million. See *Glenmark Gets U.S. FDA Nod To Market Generic Gabapentin*, BUS. STANDARD, Aug. 24, 2006, <http://www.business-standard.com/india/news/glenmark-gets-us-fda-nod-to-market-generic-gabapentin/255700/>.

276. These assumptions, of course, could easily be modified to model different scenarios. This is one of the benefits of a flexible index such as the SCI.

Manufacturer	Drug	Sales (Millions USD)	Market Share
Pfizer	LYRICA	1500	42%
	NEURONTIN	385	
	DILANTIN	30	
Novartis	TEGRETOL	450	10%
Teva	Gabapentin	75	7%
	Pregabalin	250	
Alpharma	Gabapentin	75	8%
	Phenytoin	20	
	Pregabalin	250	
Ivax	Gabapentin	75	1%
Glenmark	Gabapentin	75	1%
Morton Grove	Phenytoin	20	1%
Precision Dose	Phenytoin	20	1%
Taro	Phenytoin	20	1%
UDL	Phenytoin	20	1%
Xactdose	Phenytoin	20	1%
Sandoz	Pregabalin	250	6%
Actavis	Pregabalin	250	6%
Cobalt Labs	Pregabalin	250	6%
Sun Pharma	Pregabalin	250	6%
Total		4285	100%

The HHI for this market is 2300. The Δ HHI is 3477. The SCI at various probabilities of patent enforcement is as follows:

Δ HHI	Prob. Patent Enforcement	Settlement Competition Index
3477	.1	34,770
3477	.25	13,908
3477	.5	6954
3477	.75	4636
3477	1	3477

As might be expected in this very concentrated market, the SCI is high regardless of the probability of enforcement, but it is extremely high when the probability of enforcement is low.

3. Establishing Safety Zones and Zones of Illegality

The SCI could be used to establish safety zones, zones of presumptive illegality, and zones in which a full rule of reason analysis should apply. The hypothetical examples and the LYRICA case study set forth above suggest that a range such as the following might be reasonable:

Safety Zone: $SCI < 1500$
 Heightened Scrutiny: $SCI = 1501-5000$
 Per se Illegality: $SCI > 5000$

Of course, this proposed scale, which is based on a limited number of hypothetical examples, should be calibrated based on additional hypothetical and real-world market data. The essential point, for the purpose of this Article, is that a quantifiable scale based on empirical market data could easily be developed using the SCI.²⁷⁷

D. HEIGHTENED SCRUTINY: WEIGHING REASONABLENESS

Under my proposed test, if the SCI suggests heightened scrutiny is required, the court or regulatory agency would inquire into a variety of factors under the rule of reason to determine whether the settlement is reasonable, including, for example:

- the amount of the reverse settlement payment;
- the length of delay in generic entry;
- the existence and nature of any ancillary licenses;
- the existence and nature of any licenses related to products unrelated to the patented compound; and
- any other facts suggesting that the agreement is, or is not, likely to have unreasonable anticompetitive effects.

Given the scope and flexibility of these factors, it is reasonable to ask whether it would be more efficient to proceed directly to this step without the detailed analysis required for the SCI. The existence of an empirically based index with zones of safety and presumptive illegality, however, promotes greater efficiency and certainty and reduces the transaction costs and externalities of litigation.²⁷⁸ The ex ante signal provided by such guidelines will likely reduce the overall number of *problematic* reverse payment settlements. This

277. This approach is consistent with the revised Senate bill concerning reverse payment settlements, which permits the FTC to issue regulations exempting some classes of agreements from enforcement proceedings. See Preserve Access to Affordable Generics Act, S. 369, 111th Cong. § 3 (as reported and amended by S. Comm. on Judiciary, Oct. 15, 2009).

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principle is embedded in other areas of antitrust law, including the general rule about per se violations as well as DOJ and FTC guidelines for mergers,²⁷⁹ intellectual property licenses,²⁸⁰ and specific health care industry transactions.²⁸¹

As all of the courts, commentators, and regulatory agencies that have considered the question agree, a valid pharmaceutical patent affords its owner with legitimate zone of market exclusion.²⁸² A Paragraph IV settlement that exclude generic competition is not problematic if it reflects the legitimate exclusionary power of the patent. Moreover, general antitrust law principles support the idea that the law is only concerned with restraints of trade that *unreasonably* restrain competition and that the threat of an unreasonable restraint rises as market concentration increases.²⁸³

The SCI takes all this into account and signals that settlements below certain threshold should not be considered. But settlements above this threshold are the types we should care about most: those that likely will result in a market degree of market concentration where the patent likely is relatively weak. With a clear, empirically based zone of presumptive illegality, the parties will have guidance to demonstrate that some agreements should not even be attempted. Conversely, the existence of a safety zone for agreements that are highly unlikely to raise serious competition problems will help conserve judicial and administrative resources.

In the middle zone are those ambiguous cases that require a more searching rule of reason analysis. The uncertainty and expense inherent in this process should also result in a decrease in settlement activity likely to fall into this zone. The parties are likely to reach agreements within this zone only when they possess a fair degree of confidence that the agreement will be upheld under heightened scrutiny.

CONCLUSION

Review of reverse payment settlements in Hatch-Waxman litigation require a careful balance between intellectual property and competition policy. Patent legitimately confer a right to exclude. This right is important to the funding mechanisms for new research and development in our present financing system for private applied pharmaceutical research. Hatch-Waxman's Paragraph IV procedures, which were designed to facilitate challenges to weak patents, dramati-

279. U.S. Dep't of Justice & Fed. Trade Comm'n, *supra* note 232, § 0.2.

280. U.S. Dep't of Justice & Fed. Trade Comm'n, *supra* note 220, § 3.4.

281. See, e.g., U.S. Dep't of Justice & Fed. Trade Comm'n, *STANDARDS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE* §§ 1.B, 2.B (1996), available at <http://www.justice.gov/antitrust/guidelines1791.htm>.

282. See *supra* Part I and II.

283. See, e.g., U.S. Dep't of Justice & Fed. Trade Comm'n, *supra* note 220, §§ 2.1-2.2; U.S. Dep't of Justice & Fed. Trade Comm'n, *supra* note 232, § 0.1; U.S. Dep't of Justice & Fed. Trade Comm'n, *supra* note 281, § 9A-B.2.a (discussing the factors that make specific health care industry merger joint ventures unreasonable, relying particularly on market share).

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283. See, e.g., U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, *supra* note 220, §§ 2.1-2.2; U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, *supra* note 232, § 0.1; U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, *supra* note 281, § 9A-B.2.a (discussing the factors that make specific health care industry merger joint ventures unreasonable, relying particularly on market share).

cally alter the risk calculus of ordinary patent litigation. The patentee has everything to lose, while the generic challenger has everything to gain. Under these circumstances, reverse payment settlements should not be outright prohibited.

There is legitimate concern, however, that the anticompetitive effects of some of these settlements might exceed the legitimate exclusionary zone of the patent under challenge. Previous efforts to address this concern have ignored the need to define particular pharmaceutical product markets. Product market definition is essential to other analogous areas of antitrust analysis involving intellectual property. Once the relevant product market is defined, an empirical index can be developed, under which any given settlement can be evaluated. This Settlement Competition Index can be employed to develop antitrust safe harbors and zones of *per se* illegality. Settlements falling into a middle range can be subjected to a full rule of reason analysis. This process will provide useful *ex ante* signals to firms about what sorts of settlements are likely to be approved, resulting in a more rational approach overall to Paragraph IV settlements.