NOTE

PHARMACEUTICAL PATENT LITIGATION SETTLEMENTS: BALANCING PATENT & ANTITRUST POLICY THROUGH INSTITUTIONAL CHOICE

*Timothy A. Cook**

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Should a branded pharmaceutical company be allowed to pay a generic competitor to stay out of the market for a drug? Antitrust policy implies that such a deal should be prohibited, but the answer becomes less clear when the transaction is packaged as a patent-litigation settlement. Since Congress passed the Hatch-Waxman Act, which encourages generic manufacturers to challenge pharmaceutical patent validity, settlements of this kind have been on the rise. Congress, the Department of Justice, and the Federal Trade Commission have condemned these agreements as anticompetitive and costly to American consumers, but none of these bodies has been able to craft a regulatory solution. Several circuit courts have recently heard challenges to these settlements under existing antitrust law, but they have all adopted different approaches to balancing the drug patent holder's right to settle litigation against the pro-competitive policies enshrined in the antitrust statutes.

Drawing on the tools of comparative institutional analysis, this Note questions the wisdom of the single-branch regulatory reforms that have been proposed thus far, and it advocates a return to common-sense administrative regulation for this technically complex legal problem. This Note calls for (1) Congress to begin the regulatory effort by articulating its policy goals, (2) the FTC to promulgate rules, including safe harbors, that further Congress's policies, and (3) courts to use both Congress's

* University of Virginia School of Law, J.D. 2011; Columbia University, M.A. 2007; Harvard College, A.B. 2006. An earlier version of this Note was selected as the winner of the 2010 Virginia State Bar IP Section Student Writing Competition. I would like to thank Professor Margo Bagley, from whose seminar this Note arose, for her dedicated instruction and invaluable guidance during my time at Virginia Law. Thanks also to Professors John Duffy, John Harrison, Liz Magill, and Sai Prakash for the many stimulating classroom discussions that influenced this Note, as well as my parents for their unwavering support. All errors remain my own.

pronouncements and the FTC's regulations as a basis for ultimately evaluating settlement agreements. By respecting institutional competencies, regulators can overcome the current political hurdles and bring clarity to this ambiguous nexus between patent and antitrust law.

INTRODUCTION

In January of 1997, Bayer paid Barr Laboratories nearly $400 million for Barr's promise to refrain from producing ciprofloxacin hydrochloride ("Cipro"), an antibiotic, until December 2003. Consumer advocates and purchasers of Cipro promptly filed suits against Bayer and Barr, alleging that this agreement was an illegal contract in restraint of trade.[1] At first blush, this case appears open-and-shut: the parties executed a market-sharing agreement in contravention of Section 1 of the Sherman Act.[2] Yet, a federal district court and two courts of appeals concluded that this agreement was valid.[3]

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1. *See In re* Ciprofloxacin Hydrochloride Antitrust Litig. (*Ciprofloxacin II*), 363 F. Supp. 2d 514 (E.D.N.Y. 2005), *aff'd in part*, 544 F.3d 1323 (Fed. Cir. 2008), *aff'd in part sub nom.* Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir.), *reh'g en banc denied*, 625 F.3d 779 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1606 (2011).

2. 15 U.S.C. § 1 (2006).

3. *See* Ark. Carpenters Health & Welfare Fund v. Bayer AG (*Ark. Carpenters I*), 604 F.3d 98, 110 (2d Cir. 2010), *aff'g in part Ciprofloxacin II*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005), *reh'g en banc denied*, 625 F.3d 779 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1606

The agreement between the companies was not the corrupt, back-of-the-limo sort of deal that the Sherman Act originally sought to curtail; rather, it was the settlement of a patent-infringement suit that Bayer launched pursuant to the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("Hatch-Waxman Act").[4] While courts generally encourage settlement,[5] these settlements in which a patent holder pays a potential challenger to drop its claims of patent invalidity—so-called reverse-payment settlements—are peculiar because the plaintiff in the original action is paying the defendant to end the suit.[6] These settlements prompt a number of questions: is the patent holder paying off the competition to maintain its monopoly profits on a patent that the holder knows to be invalid?[7] Does the litigation reflect a legitimate patent dispute, or is it simply a sham to cover an otherwise blatant violation of antitrust laws? And finally, at the most fundamental level, is the purpose of the settlement to avoid litigation costs or to stifle competition?

In recent years, pharmaceutical reverse-payment settlements have drawn the ire of many political-action groups and commentators. Some have attacked them as anticompetitive,[8] costly to American consumers,[9] and even a $35 billion drain on the United States' health-insurance system.[10] The House of Representatives,[11] the Senate,[12] the Federal Trade

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(2011); Ark. Carpenters Health & Welfare Fund v. Bayer AG (*In re* Ciprofloxacin Hydrochloride Antitrust Litig.) (*Ciprofloxacin III*), 544 F.3d 1323, 1333 (Fed. Cir. 2008), *aff'g in part* 363 F. Supp. 2d 514 (E.D.N.Y. 2005); *Ciprofloxacin II*, 363 F. Supp. 2d at 540–41.

4. *See* 21 U.S.C. § 355 (2006).

5. *See, e.g.*, Standard Oil Co. (Ind.) v. United States, 283 U.S. 163, 171 (1931) ("Where there are legitimately conflicting claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act.").

6. For a brief description of this problem, see Steven Seidenberg, *The Flip Side of 'Reverse Payments*,' A.B.A. J., Feb. 2010, at 17, *available at* http://www.abajournal.com/magazine/article/the_flip_side_of_reverse_payments.

7. For a simplified analysis of how reverse-payment settlements may be profitable for both the innovator and generic manufacturer, see C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1588–96 (2006).

8. Editorial, *Pay-for-Delay: Health-Care Reform Should End This Scheme by Drugmakers*, WASH. POST, Jan. 15, 2010, at A24 ("It is difficult to see how this practice is anything but a sham and anticompetitive.").

9. *See* Natasha Singer, *Deals to Restrain Generic Drugs Face a Ban in Health Care Bill*, N.Y. TIMES, Jan. 13, 2010, at B4.

10. Jon Leibowitz, Chairman, Fed. Trade Comm'n, "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution), Address at the Center for American Progress (June 23, 2009), *available at* http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf.

11. Protecting Consumer Access to Generic Drugs Act, H.R. 1706, 111th Cong. (2009).

12. Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009).

Commission ("FTC"),[13] and the U.S. Department of Justice ("DOJ")[14] have all commented on or taken action to eradicate this practice, and they have had the support of the majority of state attorneys general[15] and the American Medical Association.[16] Yet, none of these reform efforts have gained traction. The problem has fallen squarely on the courts, and they have divided sharply over the proper legal standard to adopt in evaluating reverse-payment settlement agreements.[17]

Many scholars have offered solutions. For instance, some have examined whether it would be wise for Congress to enact a per se rule banning these payments,[18] and some proposals suggest adopting a presumption of illegality[19] or quick-look analysis[20] instead. At least one commentator has suggested a larger role for agencies, premising his argument on the FTC's superior position "to collect and synthesize aggregate information, relative to courts."[21] Still others have suggested that reform take place in the judiciary. These scholars argue for standards

13. *See, e.g.*, Petition for Writ of Certiorari, FTC v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273).

14. Brief for the United States in Response to the Court's Invitation, *Ark. Carpenters I*, 604 F.3d 98 (No. 05-2851-cv(L)).

15. Brief of 34 State Attorneys General as Amici Curiae in Support of Petition for Rehearing En Banc Filed by Appellants Louisiana Wholesale Drug Co., Inc. et al., Ark. Carpenters Health & Welfare Fund v. Bayer AG (*Ark. Carpenters II*), 625 F.3d 779 (2d Cir.), *denying reh'g en banc to* 604 F.3d 98 (2d Cir. 2010) (No. 05-2851-cv(L)), *available at* http://www.prescriptionaccess.org/docs/Cipro_2010_May_AG_Amicus.pdf.

16. Brief of Amici Curiae AARP et al. Supporting Appellants' Petition for En Banc Review, *Ark. Carpenters II*, 625 F.3d 779 (No. 05-2851-cv(L)), *available at* http://www.fdalawblog.net/files/cipro---aarpama.pdf.

17. *Compare Ciprofloxacin III*, 544 F.3d 1323 (conducting antitrust analysis in light of patent scope), Joblove v. Barr Labs., Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187 (2d Cir. 2006) (conducting antitrust analysis in light of patent scope), *and* Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005) (looking to exclusionary scope of patent to examine alleged antitrust violations), *with* La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896 (6th Cir. 2003) (holding reverse-payment settlements per se illegal).

18. *See, e.g.*, Cristofer Leffler & Keith Leffler, *Settling the Controversy over Patent Settlements: Payments by the Patent Holder Should Be Per Se Illegal*, *in* ANTITRUST LAW AND ECONOMICS 475, 479–80 (John B. Kirkwood ed., 2004); Sheila Kadura, Note, *Is an Absolute Ban on Reverse Payments the Appropriate Way to Prevent Anticompetitive Agreements Between Branded- and Generic-Pharmaceutical Companies?*, 86 TEX. L. REV. 647 (2008) (arguing against an absolute ban on reverse-payment settlements but not developing alternative proposals).

19. *See* Hemphill, *supra* note 7, at 1561 (suggesting that courts should accord a presumption of illegality to a settlement "if the settlement both restricts the generic firm's ability to market a competing drug and includes compensation from the innovator the generic firm").

20. *See* Yuki Onoe, Comment, *"Pay for Delay" Settlements in Pharmaceutical Litigation: Drawing a Fine Line Between Patent Zone and Antitrust Zone*, 9 J. MARSHALL REV. INTELL. PROP. L. 528, 549–551 (2010).

21. *See* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 670–83 (2009) (setting forth a novel approach to analyzing settlements that supports a larger role for the FTC).

ranging from a per se rule,[22] to some form of a rule-of-reason analysis,[23] to a simple sham standard that allows all such settlements "unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it."[24]

Yet, virtually none of this commentary steps back and asks which branch is best suited to solve the problem of reverse-payment settlements; it merely addresses what changes a particular branch should make to its own rules.[25] This approach overlooks the teachings of comparative institutional choice analysis.[26] This trend in legal scholarship began with *The Legal Process*, a seminal set of unpublished course notes developed by Professors Henry Hart and Albert Sacks at the Harvard Law School in the 1950s.[27] Professors Hart and Sacks sought to shift the

22. *See* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 67 (2009) (setting out five criteria that, if met, should trigger courts to apply a per se rule of illegality).

23. *See, e.g.*, Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491 (2002) (arguing that courts should favor the rule of reason or quick look analysis for reverse-payment settlement cases instead of per se illegality); Jeff Thomas, Note, Schering-Plough *and* In re Tamoxifen: *Lawful Reverse Payments in the Hatch-Waxman Context*, 22 BERKELEY TECH. L.J. 13, 45–46 (2007) (approving the rule of reason analysis applied by the courts in *In re Tamoxifen* and *Schering-Plough*).

24. *See, e.g.*, Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 FED. CIR. B.J. 617, 632 (2005) (quoting Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003)) (internal quotation marks omitted); *see also* Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 585 (2007) (arguing that courts should make "explicit assessment[s] of third party generic entry" in evaluating reverse-payment settlements).

25. Professor Hemphill's recent article begins to address this question by advocating an expanded role for the FTC vis-à-vis the courts in regulating reverse-payment settlements, primarily due to the FTC's superior ability to gather and synthesize market information. *See* Hemphill, *supra* note 21, at 670–88. He does not, however, address which institutions should set the policies that are enforced. He also explicitly limits his comparative analysis to determining which branch is best suited to implement his suggested regulatory approach. *Id.* at 673 ("There is of course an enormous literature on the choice of courts versus agencies, adjudication versus rulemaking, and rules versus standards, and this Article does not engage the full complexity of those debates. My goal here is simply to suggest how the virtues of an aggregate perspective on settlement practice shift the balance in away that favors agency rulemaking.").

26. For representative applications of comparative institutional choice analysis, see NEIL K. KOMESAR, IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY (1994); Susan Freiwald, *Comparative Institutional Analysis in Cyberspace: The Case of Intermediary Liability for Defamation*, 14 HARV. J.L. & TECH. 569 (2001); Thomas W. Merrill, *The Economic Analysis of Law: Institutional Choice and Political Faith*, 22 LAW & SOC. INQUIRY 959 (1997); and Cassandra Burke Robertson, *Transnational Litigation and Institutional Choice*, 51 B.C. L. REV. 1081 (2010).

27. *See* HENRY M. HART, JR. & ALBERT M. SACKS, THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW (William N. Eskridge, Jr. & Philip P. Frickey

paradigm from analyzing the virtues of individual rules to studying the structure of institutions.[28] They premised their analytical framework on the observation that "[t]he structure of official institutions is immensely significant in shaping the general character and direction of private activity, since it determines both the permissible range of private decision and the conditions under which the decisions are made."[29] At its heart, Professors Hart and Sacks' theory "holds that law should allocate decisionmaking to the institutions best suited to decide particular questions, and that the decisions arrived at by those institutions must then be respected by other actors in the system, even if those actors would have reached a different conclusion."[30] Although Professors Hart and Sachs expounded these ideas over fifty years ago, scholars associated with the law and economics movement have recently picked up the torch of comparative institutional choice.[31]

This Note will contend that comparative institutional choice has particular utility in designing reverse-payment settlement regulation. Part I discusses pharmaceutical patent holders' motives for engaging in reverse-payment settlements. The Part begins with an overview of the Hatch-Waxman regulatory regime, and it proceeds to discuss how this framework affects settlement structures. Part II then explains the many approaches that have been used to regulate settlements so far. It begins by looking at the different analyses used by courts, and it then briefly surveys the positions of the political branches. Finally, Part III uses the tools of comparative institutional analysis to determine the most appropriate forum for each step of the reverse-payment settlement regulatory process. It contends that institutional resources will be maximized if Congress first articulates its policy goals for reverse-payment settlement regulation; the FTC then promulgates rules that further Congress's explicit goals; and the courts use both Congress's pronouncements and the FTC's regulations as a basis to evaluate individual settlements. The Note concludes by providing an example of a reform that follows this institutional structure to efficiently regulate reverse-payment settlements.

Comparative institutional choice cannot, however, tell us which combination of legal rules will most efficiently sort pro-competitive settlement agreements from anticompetitive deals. It is therefore important to highlight what this Note does not seek to accomplish. It does not pur-

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eds., 1994). William Eskridge and Philip Frickey compiled and published the 1958 "preliminary draft" of Hart and Sacks' work in 1994.

28. *See* Ernest A. Young, *Institutional Settlement in a Globalizing Judicial System*, 54 DUKE L.J. 1143, 1149–50 (2005).

29. HART & SACKS, *supra* note 27, at 9.

30. Young, *supra* note 28, at 1149–50.

31. *See supra* note 26.

port to tell Congress, antitrust authorities, or courts which of the competing regulatory approaches to adopt. Rather, it calls attention to governmental institutions' failure to address reverse-payment settlements using the traditional procedures of the administrative state. While such a structure leaves this Note exposed to the charge that it merely seeks to tear down fully formed regulatory structures without offering a solution of its own, this is neither its thesis nor my intent. This Note is instead an exposition on how not to regulate reverse-payment settlements. It contends that the problems that these agreements have caused are no different from many others that have been encountered in the history of the administrative state, and it concludes that they should be solved using the traditional combination of legislation, agency rulemaking, and judicial gap-filling to most effectively utilize each branch's expertise. Put simply, comparative institutional analysis counsels against the current proposals for unilateral action by any one of these actors.

I. THE REVERSE-PAYMENT SETTLEMENT PROBLEM

Legal scholars have consistently touted the patent system as the *sine qua non* of new drug development,[32] and indeed, the economic picture suggests that this may not be an exaggeration. The reason for the patent system's primacy rests in research and development costs: drug development is notoriously expensive.[33] Studies have placed the costs of developing a new chemical entity between $802 million[34] and $3.911 billion.[35] One study concluded that, absent patent protection, sixty-five percent of pharmaceutical inventions would not have been commercially

32. *See, e.g.*, Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 504 (2009) (citing JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 88–89 (2008); ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 39–41 (2004)).

33. *See* Bernard Munos, *Lessons from 60 Years of Pharmaceutical Innovation*, 8 NATURE REVS. DRUG DISCOVERY 959, 959 (2009) (discussing costs associated with drug development).

34. *See* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003). *But see* MERRILL GOOZNER, THE $800 MILLION PILL: THE TRUTH BEHIND THE COST OF NEW DRUGS 239, 245–46 (2005) (citing studies by Ralph Nader's Public Citizen/Congress Watch and the Global Alliance for TB Drug Development that place the cost of drug discovery at $71 million and $115–$240 million respectively, if non-R&D costs are excluded from the calculation).

35. *See* Munos, *supra* note 33, at 962–64.

introduced and sixty percent of pharmaceutical inventions would not have been developed.[36]

The importance of pharmaceutical patents is due to the low costs of appropriation of the knowledge that goes into drug development. While the research and development costs faced by an innovator pharmaceutical company are staggering, it takes little more than an undergraduate chemistry degree and access to basic lab equipment to copy most drugs.[37] Moreover, the cost of manufacturing copies can be quite low; one study found that the average ratio of price to marginal cost for branded pharmaceuticals is over six to one, suggesting that production costs are very low for most drugs.[38] The relatively low costs of both reverse engineering and copying imply that, absent patent protection, pharmaceutical innovators would have no way to recover their research and development costs.

Yet, even the patent system does not always allow an innovator to recover its development costs. Very cheap generic competition and government cost-control measures, such as mandatory-generic-substitution laws,[39] make it nearly impossible for a drug developer to continue recovering its research costs after a drug's patent expires. To alleviate these problems and encourage such uncertain research, Congress passed the Hatch-Waxman Act in 1984.[40]

A. *The Hatch-Waxman Act*

The Hatch-Waxman Act represents "compromises reached in negotiations between the brand name drug industry and the generic drug

36. *See* Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 175 (1986).

37. For information on the syntheses of several drugs, see generally E.J. COREY, BARBARA CZAKÓ & LÁSZLO KÜRTI, MOLECULES AND MEDICINE (2007) (discussing chemical structures of several drugs); K.C. NICOLAOU & SCOTT A. SNYDER, CLASSICS IN TOTAL SYNTHESIS II (2003) (describing, in detail, syntheses of several natural products with therapeutic properties); K.C. NICOLAOU & ERIK J. SORENSEN, CLASSICS IN TOTAL SYNTHESIS: TARGETS, STRATEGIES, METHODS (1996) (same). In fall 2007, the author was an instructor for an undergraduate laboratory course at Harvard University that replicated a synthesis of oseltamivir phosphate (Tamiflu), a therapeutic for Avian influenza (H5N1), among other influenza strains. A junior undergraduate followed a protocol that had recently been published by the course's host laboratory and obtained a very respectable 2.1% yield over a ten-step synthesis. *See* Ying-Yeung Yeung, Sungwoo Hong & E.J. Corey, *A Short Enantioselective Pathway for the Synthesis of the Anti-Influenza Neuramidase Inhibitor Oseltamivir from 1,3-Butadiene and Acrylic Acid*, 128 J. AM. CHEMICAL SOC'Y 6310 (2006) (describing synthetic pathway).

38. James W. Hughes, Michael J. Moore & Edward A. Snyder, *"Napsterizing Pharmaceuticals": Access, Innovation, and Consumer Welfare* 6 (Nat'l Bureau of Econ. Research, Working Paper No. 9229, 2002).

39. *See* BUREAU OF CONSUMER PROT., FED. TRADE COMM'N, DRUG PRODUCT SELECTION 141–55 (1979) (describing state regulation of pharmaceuticals).

40. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, and 35 U.S.C.).

industry"[41] to "assure[] consumers of more low-cost generic drugs when a valid patent expires and the drug industry of sufficient incentive to develop innovative pharmaceutical therapies."[42] A number of problems in the pharmaceutical sector during the 1970s and early 1980s precipitated these compromises. First, after Congress passed the Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetics Act in 1962,[43] the Food and Drug Administration ("FDA") required all new drug applicants—both pioneer and generic—to make a showing of safety and efficacy. In practice, this meant that generic applicants had to "virtually duplicate the same health and safety tests conducted by the original applicant."[44] Rather than incur this expense, generic manufacturers frequently opted to stay out of the market.[45] Second, as FDA review became more rigorous under the Kefauver-Harris Amendments' efficacy requirements, the period of market exclusivity that a pharmaceutical patent holder enjoyed decreased because pre-market clinical trials consumed at least part of the patent period.[46]

The Hatch-Waxman Act sought to alleviate these problems by both encouraging generic entry and restoring the market value of pharmaceutical patents. Congress intended the Act's pro-innovation measures, at their most fundamental level, to enhance market-control periods for truly novel drugs. First, Congress included a pharmaceutical patent term extension to account for the regulatory delay caused by FDA review of a new drug application.[47] The provision allows extensions of market exclusivity of up to five years,[48] calculated as half of the regulatory review period less any time during which the applicant did not act with due diligence in seeking approval.[49] Only one patent may be extended per regulatory review period for a product,[50] and the total term of the extended patent may not exceed fourteen years from the date of regulatory approval.[51] Second, the Act provided for data-exclusivity periods for both new chemical entities[52] and new uses for approved drugs.[53] During such a

41. 130 CONG. REC. H24425 (daily ed. Sept. 6, 1984) (statement of Rep. Henry A. Waxman).
42. *Id.*
43. Pub. L. No. 87-781, 76 Stat. 780 (1962).
44. H.R. REP. NO. 98-857(II), at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688.
45. *Id.*
46. *See, e.g.*, Joseph A. DiMasi, *New Drug Development in the United States from 1963 to 1999*, 69 CLINICAL PHARMACOLOGY & THERAPEUTICS 286, 289 (2001).
47. 35 U.S.C. § 156 (2006).
48. *Id.* § 156(g)(6)(A).
49. *Id.* § 156(c)(1)–(2). The regulatory review period for new drugs is defined at § 156(g)(1)(B).
50. *Id.* § 156(c)(4).
51. *Id.* § 156(c)(3).
52. 21 U.S.C. § 355(j)(5)(F)(ii) (2006).
53. *Id.* § 355(j)(5)(F)(iii).

data exclusivity period, generic manufacturers may not rely on the first applicant's safety and efficacy data. A generic pharmaceutical company is free, however, to submit—and, absent other forms of protection,[54] the FDA may approve—an application for the same chemical entity or new use that relies on clinical trial data that the generic manufacturer generated itself. The need to generate clinical trial data substantially raises the barrier to entry for a generic form of the drug.[55]

On the pro-competition side, the Hatch-Waxman Act created the Abbreviated New Drug Application ("ANDA"), a mechanism that allows generic drug manufacturers to seek FDA approval by showing bioequivalence to an approved drug, thus piggybacking on the first applicant's safety and efficacy data. An ANDA must certify that the generic manufacturer will market the new drug for the same applications as the approved drug and will label it in the same manner as the approved drug. The ANDA must also certify that the new drug is bioequivalent to the approved drug.[56] Generally—and subject to the patent-related provisions discussed below—the Hatch-Waxman Act requires the FDA to approve the generic's ANDA if the applicant can make these showings.[57]

Significantly, when a generic manufacturer files an ANDA, it must submit one of four certifications regarding the patent status of the pioneer drug: the drug is not covered by a patent ("Paragraph I"); the patent has expired ("Paragraph II"); the generic manufacturer will not market its drug until the pioneer drug's patent has expired ("Paragraph III"); or the pioneer drug's "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug" ("Paragraph IV").[58] Because patent protection is not an issue for drugs under the first two certifications, the Hatch-Waxman Act does not provide any sort of patent-linked data exclusivity for them. If an ANDA includes a Paragraph I or Paragraph II certification, the FDA may approve the ANDA at any time.[59] If an ANDA includes a Paragraph III certification, the FDA is prohibited from approving it until the patent expires.[60]

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54. Other forms of exclusivity might include patent protection or market exclusivity.

55. For more on these data exclusivity periods, which are beyond the scope of the reverse-payment settlement problem discussed in this Note, see Valerie Junod, *Drug Marketing Exclusivity Under United States and European Union Law*, 59 FOOD & DRUG L.J. 479, 493–94 (2004).

56. *See* 21 U.S.C. § 355(j)(2)(A)(iv).

57. *See id.* § 355(j)(4).

58. *Id.* § 355(j)(2)(A)(vii).

59. *Id.* § 355(j)(5)(B)(i).

60. *Id.* § 355(j)(5)(B)(ii).

Finally, if a generic manufacturer files a Paragraph IV certification, it has committed an "artificial" act of patent infringement.[61] The patent holder then has forty-five days from the time it receives notice of the Paragraph IV filing to initiate an infringement action.[62] If the patent holder does so, the FDA must stay approval of the ANDA until the earliest of thirty months from the date of notice of the filing, the date on which a district court finds the patent infringed, or the date the district court enters a settlement order or consent decree stating that the patent is invalid or not infringed.[63] If, however, a court finds that the patent is valid and infringed by the generic, the ANDA will be approved no earlier than the expiration date of the patent.[64] Congress intended this automatic thirty-month stay of ANDA approval to give "further assurance to the brand-name drug manufacturers that the generic drug manufacturer would not put his [drug] on [the] market until [the] court decision came through."[65]

To encourage generic manufacturers to use the ANDA system to challenge weak patents, the Hatch-Waxman Act also granted the first generic manufacturer to file a Paragraph IV certification a 180-day market-exclusivity period.[66] During this period, the FDA will not approve a subsequent ANDA application, thus ensuring that the first ANDA filer will be able to capture some supra-competitive rents in a temporary duopoly with the original manufacturer. This exclusivity period is only available once, and the first ANDA applicant may forfeit the exclusivity if it fails to market the drug[67] or, significantly, enters into an agreement with the patent owner that is found to violate the antitrust laws.[68]

The Hatch-Waxman Act thus set up a careful balance of incentives for innovators and generic manufacturers. On the one hand, the Act gives generic manufacturers the ability to file ANDAs, which can rely on the safety and efficacy data submitted by the innovator, and a 180-day market-exclusivity incentive to challenge weak patents. On the other hand, the Act provides innovators with a patent term extension, a non-patent data-exclusivity period for new drugs, and an automatic thirty-month stay of generic approval to settle patent-validity disputes.

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61. *See* 35 U.S.C. § 271(e)(2)(A) (2006); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990).

62. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

63. *Id.*

64. *See id.* § 355(j)(5)(B)(iii)(II)(bb); 35 U.S.C. § 271(e)(4)(A).

65. 131 CONG. REC. H24427 (daily ed. Sept. 6, 1984) (statement of Rep. Henry A. Waxman).

66. 21 U.S.C. § 355(j)(5)(B)(iv)(I).

67. *Id.* § 355(j)(5)(D)(i)(I).

68. *Id.* § 355(j)(5)(D)(i)(V).

These statutory incentives have proven rife for manipulation. The potential generic market-exclusivity period, coupled with the statutory-infringement provision for Paragraph IV filings, has motivated generic manufacturers to challenge many valuable pharmaceutical patents. While the patent holder faces extreme losses if its patent is held invalid, the generic manufacturer does not face a crippling damages judgment because it has not sold any infringing drugs. Thus, while the generic manufacturer is formally the defendant in Hatch-Waxman litigation, it is the patent holder—the plaintiff—that stands to lose the most.[69] Hatch-Waxman plaintiffs have responded to this perverse structure in the way that defendants respond in normal litigation: they pay the generic company to settle. In exchange for the generic manufacturer dropping its challenge to the patent's validity, the patent holder provides some sort of consideration, such as cash, market entry before the expiration of the patent, other licenses, and so on.[70] These are reverse-payment settlements.

B. *Structures of Reverse-Payment Settlements*

Professor Hemphill has divided the types of compensation given to generic firms in reverse-payment settlements into five broad categories.[71] First, and most obvious, is cash. The largest cash settlement to date was the agreement between Bayer and Barr for Cipro.[72] In that single settlement, Bayer agreed to pay Barr roughly $398 million to delay its market entry.[73] Agreements such as this seem most troublesome from an antitrust perspective, and they have attracted a great deal of attention from regulatory authorities.[74]

These simple contracts are therefore giving way to a second type of settlement in which the patent holder pays the generic manufacturer to settle the invalidity claims as well as to acquire something of value from the generic manufacturer.[75] Generic manufacturers have provided licenses to their own intellectual property, promises to develop new products for the patent holder, manufacturing services, inventory of the drug, and promotion services.[76] Some of these agreements are "suspect on their face" because "the brand-name firm does not need a patent li-

69. *See generally* Hemphill, *supra* note 7, at 1555–78 (describing the dynamics of Hatch-Waxman litigation).

70. *See, e.g.*, C. Scott Hemphill, Drug Patent Settlements Between Rivals: A Survey 13 (Mar. 12, 2007) (unpublished manuscript), *available at* http://ssrn.com/abstract=969492.

71. *See generally id.* (listing categories).

72. *See* Hemphill, *supra* note 21, at 663; *supra* pp. 418–19.

73. *Ciprofloxacin III*, 544 F.3d at 1328–29.

74. Hemphill, *supra* note 21, at 663.

75. *Id.*

76. *See* Hemphill, *supra* note 70, at 14–16.

cense that does not clearly cover its product, new drug development that is unrelated to its current core business, a new source of raw material supply, backup manufacturing, or additional promotion."[77] However, some of them seem plausible because real synergies could exist between the patent holder and the generic manufacturer. For example, these synergies may benefit product development, advertising, or patent licenses to research and develop a new product.[78]

A third type of compensation may be present when the generic manufacturer is entitled to, but postpones its use of, a 180-day market-exclusivity period.[79] This allows the generic manufacturer to collect duopoly profits with the patent holder, which can amount to a substantial sum.[80] Furthermore, the very act of acquiring and forfeiting the market-exclusivity period may be profitable for a generic manufacturer. While the Paragraph IV filer must have made enough of an investment in the generic drug to complete its FDA filings, other generic companies likely will not have made such an investment. By removing the possibility of a 180-day market-exclusivity period, the Paragraph IV filing removes the primary incentive for other generics to race to challenge the patent. This may supplement the other forms of compensation by reducing the amount of competition—and thereby the pressure to price the generic at marginal cost—after the generic manufacturer does enter the market.[81]

The fourth major type of settlement agreement is underpayment by the generic firm. In these settlements, the patent holder provides the drug, or a license to produce the drug, to the generic manufacturer.[82] Though the generic manufacturer receives little or no cash payment from the patent holder, it receives duopoly or oligopoly profits for the

77. Hemphill, *supra* note 21, at 664–65.

78. *Id.* at 665.

79. In such a case, the generic simply takes steps to postpone the start date of its exclusivity period, thus providing the original manufacturer with a longer period of market control. This occurs when the generic manufacturer is the first to file a Paragraph IV certification for the drug. While the Medicare Modernization Act of 2003 weakened this form of compensation by providing for forfeiture of the exclusivity period if the generic manufacturer settles with the patent holder, this new provision only applies to ANDAs filed after December 8, 2003. 21 U.S.C. § 355(j)(5)(D)(i)(V) (2006). To be sure, this provision does not require forfeiture upon any settlement agreement—just upon a settlement agreement that is found to violate the antitrust laws. Another provision of the Medicare Modernization Act provides for forfeiture of the exclusivity period if the first applicant fails to market its drug within seventy-five days of the ANDA approval. *Id.* § 355(j)(5)(D)(i)(I). However, most settlement agreements now provide for no judgment on the merits of the patent, thus delaying ANDA approval. *See* Hemphill, *supra* note 7, at 1586.

80. *See* Hemphill, *supra* note 7, at 1588–94.

81. *See id.* at 1583–86 ("Generic firms other than the first filer will lag behind in the approval process, if they have bothered to file at all; they will also be less motivated to initiate or vigorously pursue a challenge.").

82. *See* Hemphill, *supra* note 21, at 665–66.

remainder of the patent term. This is, in effect, a privately negotiated market-exclusivity period, which is shared with the patent holder in the same way that the 180-day period awarded for a Paragraph IV filing is shared. Finally, along these same lines, a settlement may provide for other indirect compensation, such as settlement of unrelated disputes between the firms.[83]

II. Regulatory Approaches to Limit Reverse-Payment Settlements

Faced with these diverse settlement structures, courts, government agencies, and Congress have all sought to regulate reverse-payment settlements. As discussed below, they have not done so in a coherent way. This Part surveys judicial, administrative, and legislative challenges to reverse-payment settlements. It highlights the difficulty that courts have faced in discerning the motivations for these agreements, as well as the mixed messages sent by the FTC, the DOJ, and Congress. The Part analyzes the positions of these bodies, focusing on their solutions for sorting legitimate, non-anticompetitive reverse-payment settlements from agreements that should result in antitrust liability.

A. *Courts*

To date, all challenges to reverse-payment settlements have been brought under Section 1 of the Sherman Act.[84] The first such case was *In re Cardizem CD Antitrust Litigation*,[85] which held that an agreement between Hoescht Marion Roussel ("HMR") and Andrx Pharmaceuticals ("Andrx") violated the Sherman Act.[86] HMR held a patent on Cardizem CD, the active ingredient of which is diltiazem hydrochloride.[87] While HMR's patent on diltiazem hydrochloride expired before the settlement, HMR held a patent on a controlled-release system that permitted once-daily dosing of Cardizem CD.[88] Andrx was the first to file a Paragraph IV certification challenging the scope of HMR's patent, thus making Andrx eligible for the 180-day market-exclusivity period and triggering the

83. *See* Hemphill, *supra* note 70, at 19–20.

84. 15 U.S.C. § 1 (2006).

85. La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896 (6th Cir. 2003).

86. *Id.* at 900.

87. Diltiazem HCl is a calcium channel blocker that is used in the treatment of hypertension and some arrhythmias. *Cardizem CD Label, Reference ID 2867302*, U.S. Food & Drug Admin., 2–3 (2010), http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020062s040lbl.pdf.

88. U.S. Patent No. 5,470,584 (filed Feb. 27, 1995).

automatic thirty-month stay.[89] Just prior to the expiration of the stay, Andrx and HMR entered into an agreement providing that Andrx would not market a bioequivalent form of Cardizem CD—including any forms that were off-patent—until Andrx either obtained a favorable, unappealable decision that HMR's patent was invalid or until HMR licensed Cardizem CD to a third party. Andrx also agreed not to take any action to terminate its rights to the 180-day market-exclusivity period, thus eliminating the incentive for other generic manufacturers to challenge HMR's patent. In exchange for these concessions, HMR agreed to make quarterly payments of $10 million to Andrx, beginning when Andrx received FDA approval to market Cardizem CD. HMR also agreed to pay Andrx $100 million annually to stay off the market once there was a final, unappealable determination that Andrx's product did not infringe the patent or once HMR dropped its patent-infringement suit.[90]

After the district court granted partial summary judgment for the plaintiffs, the Sixth Circuit took up the question of "whether the Agreement was a *per se* illegal restraint of trade."[91] It agreed with the district court that, "at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States [was] a classic example of a *per se* illegal restraint."[92] The court focused on the effect of the settlement agreement on challenges by other market competitors. It reasoned that, "[b]y delaying Andrx's entry into the market, the Agreement also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx's 180-day period of market exclusivity, which Andrx had agreed not to relinquish or transfer."[93] Thus, the court concluded that the Agreement divided up the entire market for Cardizem CD between HMR and Andrx by blocking other Paragraph IV challengers. Put simply, there was no incentive for other generic manufacturers to develop Cardizem CD because they would have to wait for Andrx to market its product before they could market theirs. By erecting an insurmountable barrier to market entry, the settlement could not "be fairly characterized as merely an attempt to enforce patent rights."[94] The Sixth Circuit based its analysis entirely on the antitrust aspect of the settlement; it found that, regardless of the scope of the patent, the agreement contravened the Sherman Act. When applied to a simple settlement like the one in *In re Cardizem CD*, the Sixth Circuit's approach makes sense. It is an uncomplicated formula that courts can

89. *In re Cardizem CD*, 332 F.3d at 902.
90. *Id.* at 901–04 (describing the facts of settlement agreement).
91. *Id.* at 900.
92. *Id.* at 908.
93. *Id.* at 907.
94. *Id.* at 908.

apply, and it does not require them to swim in the murky waters of patent law and business judgment.

The pharmaceutical industry did not stand still. Later settlements introduced more complications, forcing courts to consider how to evaluate agreements that were not plainly unreasonable on their face. The next major case was *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*,[95] in which the Eleventh Circuit upheld two settlement agreements for patent litigation regarding certain crystalline forms of terazosin hydrochloride.[96] The first agreement resulted from a Paragraph IV filing by Zenith Goldline Pharmaceuticals ("Zenith"), in which Zenith challenged the validity and scope of two of Abbott Laboratories' patents.[97] Abbott and Zenith entered into an agreement whereby Zenith would acknowledge the validity of Abbott's patents and refrain from entering the terazosin hydrochloride market until either the patents expired or other generics entered the market. In exchange, Abbott agreed to pay Zenith $3 million up front, $3 million after three months, and $6 million every three months thereafter.[98] The second agreement arose from a patent-infringement suit that Abbott filed against Geneva Pharmaceuticals ("Geneva"). Geneva had filed a Paragraph IV certification for a terazosin hydrochloride product that Geneva admitted infringed one of Abbott's patents.[99] In exchange for an agreement from Geneva not to enter the terazosin hydrochloride market until the patent's expiration, other generic entry, or an unappealable judgment of invalidity or noninfringement, Abbott agreed to pay Geneva $4.5 million per month.[100]

When a group of private plaintiffs challenged these agreements, the U.S. District Court for the Southern District of Florida held that "the Agreements were *per se* violations of § 1 of the Sherman Act" because they "essentially allocat[ed] the entire United States market for terazosin drugs to Abbott, who shared its monopoly profits with other cartel members during the life of the Agreements."[101] The district court relied on four aspects of the Geneva agreement to conclude that it was anticompetitive:

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

96. *Id.* at 1298. Terazosin hydrochloride is used to treat hypertension and benign prostatic hyperplasia. *Application Number 75-140, Final Printed Labeling*, U.S. FOOD & DRUG ADMIN., 2 (2000), http://www.accessdata.fda.gov/drugsatfda_docs/nda/98/75140_Terazosin%20Hydrochloride_prntlbl.pdf.

97. U.S. Patent No. 5,412,095 (filed May 20, 1994); U.S. Patent No. 5,504,207 (filed Oct. 18, 1994).

98. *Valley Drug*, 344 F.3d at 1298–301 (describing facts of settlement agreement).

99. Geneva allegedly infringed the '207 patent. *Id.* at 1299.

100. *Id.* at 1300–01.

101. *Id.* at 1301.

> (1) Geneva's promise not to market its terazosin capsule until the Agreement terminated; (2) Geneva's promise not to market its terazosin tablet until the Agreement terminated; (3) Geneva's promise not to sell its rights in its capsule and tablet ANDAs until the Agreement terminated; and (4) Geneva's promise to aid Abbott in opposing any attempt by other ANDA applicants to enter the market before the Agreement terminated.[102]

The district court reached the same conclusion regarding the Zenith agreement for similar reasons.[103]

On appeal, the Eleventh Circuit began by highlighting the inherent tension involved in these settlements: "If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's order. This is not such a case, however, because one of the parties owned a patent."[104] It explained that the scope of the patent was particularly important for evaluating the antitrust elements of the settlement, "as market allocation agreements . . . are at the heart of the patent right and cannot trigger the *per se* label."[105] In undertaking its patent-scope analysis, the Eleventh Circuit suggested that sham or frivolous lawsuits can give rise to antitrust liability if the settlement affected rights that were included in the patent, but subsequent invalidity alone cannot lead to such liability.[106] Furthermore, because patent holders have a right to settle costly litigation and to divide markets territorially,[107] the court found that the settlement could very well be within the scope of the patent.[108] Finally, the court opined that, because the Sixth Circuit "did not purport to measure the several provisions [of the *In re Cardizem CD* settlement agreement] against the exclusionary power of the patent[] or differentiate between provisions that fell within the scope of the patent's protection and those that did not," the Sixth Circuit's opinion in *In re Cardizem CD* was fundamentally flawed.[109]

The Eleventh Circuit reiterated this view two years later in *Schering-Plough Corp. v. FTC*,[110] which centered around a patent for Schering-Plough's extended-release coating on potassium chloride supplements.[111]

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102. *Id.* at 1301–02.
103. *See id.* at 1302.
104. *Id.* at 1304.
105. *Id.* at 1306.
106. *Id.* at 1309.
107. *See* 35 U.S.C. § 261 (2006).
108. *Valley Drug*, 344 F.3d at 1310–11.
109. *Id.* at 1311.
110. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1056–76 (11th Cir. 2005).
111. *See id.* at 1058.

In agreements with two separate generic manufacturers, Schering-Plough agreed to make up-front payments in exchange for the generic manufacturers' promise not to enter the market before an agreed-upon date and for licenses to some of the generic manufacturers' patented products.[112] The FTC challenged both of these settlements pursuant to Section 1 of the Sherman Act and section 5 of the Federal Trade Commission Act.[113] An administrative law judge ("ALJ") ruled that neither settlement was per se invalid and that each should be evaluated relative to the exclusionary potential of the patent.[114] On appeal, the full Commission reversed the ALJ.[115] The unanimous Commission explained that, while it was "not . . . prepared to say that all such payments should be viewed as *per se* illegal or 'inherently suspect,'"[116] "it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."[117] Finally, the Commission concluded that, with respect to the parties in the case, "settlements under which the generic 'receives anything of value' and agrees to defer its own research and development, production or sales activities" are prohibited.[118]

The Commission's decision then went before the Eleventh Circuit, which reversed and reiterated its test from *Valley Drug*: "[T]he proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."[119] The court explained that this analysis ensured "a delicate balance . . . between the [patent and antitrust] regulatory schemes."[120] As to the Commission's argument that Congress, in passing the Hatch-Waxman Act, did not intend to immunize reverse-payment settlements from antitrust scrutiny and "specifically decided that it wanted to encourage patent challenges for pharmaceutical products,"[121] the court held that "[r]everse payments are a natural by-product of the Hatch-Waxman process."[122] Thus, the Eleventh Circuit's position is clear: if the terms of a

112. This is an overpayment-type settlement, as described *supra* in notes 75–78 and the accompanying text. Significantly, the ESI settlement was negotiated under the supervision of a U.S. Magistrate Judge. *Schering-Plough*, 402 F.3d at 1060–61.

113. 15 U.S.C. § 45 (2006).

114. *Schering-Plough*, 402 F.3d at 1061.

115. *Id.* at 1062.

116. *In re* Schering-Plough Corp., 136 F.T.C. 956, 991 (2003).

117. *Id.* at 988.

118. *Id.* at 1062.

119. *Schering-Plough*, 402 F.3d at 1066.

120. *Id.* at 1067 (citing Simpson v. Union Oil Co. of Cal., 377 U.S. 13 (1964)).

121. *In re Schering-Plough*, 136 F.T.C. at 990.

122. *Schering-Plough*, 402 F.3d at 1074 (quoting *In re* Ciprofloxacin Hydrocloride Antritust Litig., 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003)).

reverse-payment settlement fall within the scope of a party's patent rights, which rights were obtained in good faith and were valid at the time of the agreement, the agreement will not result in liability under the antitrust laws.

In a 2006 case, the Second Circuit built upon the Eleventh Circuit's approach.[123] The Second Circuit was confronted with a settlement agreement between AstraZeneca Pharmaceuticals ("AstraZeneca"), the holder of a patent on tamoxifen citrate, a popular breast cancer drug, and Barr Laboratories ("Barr"), which had filed a Paragraph IV certification challenging the patent's validity. Astrazeneca agreed to pay Barr $21 million and grant it a non-exclusive license to sell—but not manufacture—tamoxifen in the United States.[124] In exchange, Barr agreed to change its Paragraph IV certification to a Paragraph III certification and delay manufacture of its own tamoxifen until the patent's expiration.[125]

The Second Circuit began from the *Schering-Plough* court's premise that "reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them."[126] It then announced its analysis: "[S]o long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."[127] The Second Circuit went on to explain that this particular settlement agreement "did not extend the patent monopoly by restraining the introduction or marketing of unrelated or non-infringing products";[128] "ended all litigation between Zeneca and Barr and thereby opened the tamoxifen patent to immediate challenge by other potential generic manufacturers";[129] and "did not entirely foreclose

123. *See* Joblove v. Barr Labs., Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 193 (2d. Cir. 2006).

124. *Id.* at 193. This is an example of using authorized generics as part of a reverse-payment settlement's compensation. *See supra* note 83 and accompanying text.

125. *In re Tamoxifen*, 466 F.3d at 193–94.

126. *Id.* at 206.

127. *Id.* at 208–09.

128. *Id.* at 213. The court added that, "[i]t is thus unlike the agreement the Sixth Circuit held *per se* illegal in [*In re Cardizem CD*], . . . which included not only a substantial reverse payment but also an agreement that the generic manufacturer would not market non-infringing products." *Id.* at 213–14.

129. *Id.* at 214. The court went on to conclude that "[t]he Agreement thus avoided a 'bottleneck' of the type created by the agreements in *Valley Drug* and [*In re Cardizem CD*], which prevented other generic manufacturers from obtaining approval for their own generic versions from the FDA." *Id.* at 215. The court also concluded that later challengers were "spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit." *Id.* at 214. As Professor Hemphill points out, this conclusion is incorrect. Hemphill, *supra* note 7, at 1583–86. Only the first ANDA application with a Paragraph IV certification is eligible for an

competition in the market for tamoxifen" because the license from AstraZeneca to Barr resulted in a net reduction in cost to consumers of approximately five percent.[130]

It remains unclear whether the Second Circuit's analysis is the same as the Eleventh Circuit's or more restrictive. While the Second Circuit distinguished the *Tamoxifen* settlement from the *Valley Drug* settlement, it did not say if that distinction mattered. In other words, it did not say that it would have ruled differently from the Eleventh Circuit on the facts of *Valley Drug*.

Furthermore, uncertainty now surrounds the Second Circuit's commitment to stand by its *Tamoxifen* ruling. In *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*,[131] decided in April 2010, the Second Circuit affirmed a district court holding that relied on *Tamoxifen* as precedent.[132] The panel, however, noted "several reasons why [*Arkansas Carpenters*] might be appropriate for reexamination" en banc,[133] including a DOJ brief that urged the court to reconsider the *Tamoxifen* precedent, the increased rate of reverse-payment settlements since *Tamoxifen*, statements condemning reverse-payment settlements made by Representative Waxman after *Tamoxifen*, and an error in the *Tamoxifen* court's understanding of the Hatch-Waxman regulatory framework.[134] While the full court denied that motion for rehearing,[135] it did so over the strong objection of Judge Pooler, who concluded that, "[i]t will be up to the Supreme Court or Congress to resolve the conflict among the Courts of Appeals."[136] Despite that invitation, the Supreme Court recently declined to grant certiorari.[137]

Thus, courts have struggled with how to find both the appropriate antitrust standard of review and how to apply it. While the Sixth Circuit focused on the antitrust aspect of the settlement agreement, the Eleventh and Second Circuits placed more emphasis on the exclusionary rights of

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exclusivity period. 21 C.F.R. § 314.107 (2010). In this particular case, the incentive did not seem to matter: three other generic manufacturers quickly followed Barr in filing Paragraph IV certifications after the settlement. *In re Tamoxifen*, 466 F.3d at 212 n.25.

130. *In re Tamoxifen*, 466 F.3d at 215.

131. *Ark. Carpenters I*, 604 F.3d 98 (2d Cir.), *reh'g en banc denied*, 625 F.3d 779 (2d Cir. 2010).

132. *Id.* at 110.

133. *Id.* at 108.

134. *Id.* at 108–10.

135. *Ark. Carpenters II*, 625 F.3d 779.

136. *Id.* at 782 (Pooler, J., dissenting).

137. *La. Wholesale Drug Co. v. Bayer AG*, 131 S. Ct. 1606 (2011), *denying cert. to Ark. Carpenters I*, 604 F.3d 98 (2d Cir. 2010). Note that neither Justice Sotomayor nor Justice Kagan participated in this decision, presumably because of their involvement with this case in their prior positions at the Second Circuit and Department of Justice, respectively.

the patent holder. The legality of reverse-payment settlements currently seems to turn on where a case is brought.

B. *Federal Trade Commission*

Administrative agencies have also been unable to clear up the legal uncertainty surrounding these agreements. Since the emergence of reverse-payment settlements, the FTC has closely monitored their legality.[138] In the early days of these agreements, the FTC sought to monitor them through consent decrees.[139] In 2000, the first such dispute began with the FTC's challenge to the settlement agreement between Abbott and Geneva that would later give rise to *Valley Drug*.[140] In seeking to ensure compliance with federal trade and antitrust laws, the FTC order imposed restrictions on further agreements both between the parties and with third parties; required the parties to keep the FTC informed of their future settlements; and required that Geneva waive its exclusivity period to prevent the "bottleneck" problem that so troubled the Sixth Circuit in *In re Cardizem CD*.[141] Thus, while not finding the terazosin reverse-payment settlement per se unlawful, the FTC's efforts to restrict and monitor future agreements clearly demonstrated its concern about the settlement. At this point, the FTC's position was essentially that reverse-payment settlement agreements did not violate competition laws but that they had the potential to become illegal when used either to block other generic challenges or to exceed the scope of the relevant patents. The FTC vigilantly monitored these agreements, but it did not have a set of rules, or safe harbors, describing when agreements would be acceptable.

The FTC clarified its position with *In re Schering-Plough Corp.*[142] In *In re Schering-Plough*, the unanimous Commission announced a simple rule declaring the circumstances under which reverse-payment settlements are illegal: if the terms of the settlement require the generic to

138. *See, e.g.*, *Examining Issues Related to Competition in the Pharmaceutical Marketplace: A Review of the FTC Report, Generic Drug Entry Prior to Patent Expiration, Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 107th Cong. 6 (2002) (statement of Timothy J. Muris, Chairman, Fed. Trade Comm'n) ("Such agreements may be pro-competitive, they may be competitive-neutral, and, of course, they may be anti-competitive. . . . [T]hey have the potential to raise antitrust issues . . . .").

139. Jon Leibowitz, Comm'r, Fed. Trade Comm'n, Health Care and the FTC: The Agency as Prosecutor and Policy Wonk, Remarks at the Antitrust in HealthCare Conference 5–6 (May 12, 2005), *available at* http://ftc.gov/speeches/leibowitz/050512healthcare.pdf.

140. Complaint, *In re* Abbott Labs., No. C-3945, 2000 WL 681848 (FTC May 22, 2000). For the terms of the settlement, see *supra* notes 98–102 and accompanying text.

141. *See* La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (*In re* Cardizem CD Antitrust Litig.), 332 F.3d 896, 908 (6th Cir. 2003).

142. *In re* Schering-Plough Corp., 136 F.T.C. 956 (2003); *see also supra* notes 110–122 and accompanying text (discussing *Schering-Plough*).

delay entry and the patent holder to provide monetary compensation to the generic in exchange for that delay, the agreement is illegal.[143] The Commission simply reasoned that "the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."[144]

The Commission's rationale centers on a theory that entry dates should be determined only by the parties' views of the strength of the patent.[145] By giving the pioneer patent holder a patent term that is equal to its expectations of the validity of the patent, the innovator receives a just prize, and the public gets access to the generic at the earliest possible date.[146] In contrast, if reverse payments are permitted, the innovator may seek monopoly profits in excess of the patent's strength and may share these high profits with a generic manufacturer to avoid challenges.[147]

Recent enforcement actions have reiterated this interpretation of the FTC's position,[148] and the Commission has made no secret of its desire to produce a circuit split to improve its chances of Supreme Court review.[149] The FTC has recently filed court challenges to agreements between Cephalon, Inc. and Solvay Pharmaceuticals, Inc.,[150] and it has shown no signs of backing down. In a recent address, Chairman Leibowitz proclaimed that "the Commission has made stopping these deals a top priority."[151]

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143. *In re Schering-Plough*, 136 F.T.C. at 988.

144. *Id.*

145. *See* Thomas B. Leary, Chairman, Fed. Trade Comm'n, Antitrust Issue in the Settlement of Pharmaceutical Patent Disputes, Part II, Address Before the American Bar Association's Antitrust Healthcare Program (May 17, 2001), *available at* http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.shtm.

146. *Id.*

147. *See, e.g.*, *In re Schering-Plough*, 136 F.T.C. at 989.

148. *See* FTC v. Watson Pharm., Inc., 611 F. Supp. 2d 1081 (C.D. Cal. 2009); FTC v. Cephalon, Inc., 551 F. Supp. 2d 21 (D.D.C. 2008).

149. *Protecting Consumer Access to Generic Drugs: Hearing on H.R. 1902 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce*, 110th Cong. 3 (2007) (statement of Jon Leibowitz, Comm'r, Fed. Trade Comm'n), *available at* http://www.ftc.gov/speeches/leibowitz/070502reversepayments.pdf ("It's public knowledge that we're looking to bring a case that will create a clearer split in the circuits, and we're hopeful that the Supreme Court will review the Tamoxifen decision.").

150. *Watson Pharm.*, 611 F. Supp. 2d 1081; *Cephalon*, 551 F. Supp. 2d 21. Following transfer of *Watson Pharmaceuticals* to the U.S. District Court for the Northern District of Georgia, the court, relying on *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), granted the Watson defendants' motion to dismiss the FTC's claim on February 22, 2010. *In re* Androgel Antitrust Litig. (No. II), 687 F. Supp. 2d 1371 (N.D. Ga. 2010).

151. Leibowitz, *supra* note 10, at 4.

C. *U.S. Department of Justice*

The DOJ has also provided its views on reverse-payment settlements, notably in amicus briefs before the U.S. Circuit Courts of Appeals and the Supreme Court of the United States.[152] Its views have not been consistent, however, leading some to refer to it as a "switch hitter" that "has had little trouble changing its stance on reverse payments."[153]

In its first foray into the world of reverse-payment settlements, the DOJ opposed the FTC's petition for certiorari by the Supreme Court in *Schering-Plough*.[154] The DOJ acknowledged that "[reverse] payments can be a device for the sharing of monopoly rents made possible by the alleged infringer's exclusion from the market, and may result in less competition than would likely have prevailed in the absence of the payment."[155] It concluded, though, that "the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful."[156] Rather, because "the Hatch-Waxman context creates a litigation dynamic that makes some settlements reasonable," the DOJ suggested that "an appropriate legal standard should take into account the relative likelihood of success of the parties' claims, viewed ex ante."[157] This likelihood-of-success analysis should involve an "assess[ment of] the strength of the patent in the context of the infringement settlement itself."[158] The DOJ specifically rejected the FTC's approach of measuring the "'expected value' of the patent holder's lawsuit against the generic,"[159] which it characterized as "reflect[ing] a high degree of suspicion of any reverse payment settlement."[160] Finally, the DOJ recommended that the Supreme Court deny certiorari because determining the amount of the payment given to the generic would necessarily require valuing licenses that were part of the settlement[161] and because the case suffered from procedural

152. *See* Brief for the United States as Amicus Curiae, FTC v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273); Brief for the United States in Response to the Court's Invitation, *Ark. Carpenters II*, 625 F.3d 779 (No. 05-2851-cv(L)).

153. *See, e.g.*, Seidenberg, *supra* note 6, at 18.

154. Brief for the United States as Amicus Curiae, *Schering-Plough*, 548 U.S. 919 (No. 05-273).

155. *Id.* at 9.

156. *Id.* at 11.

157. *Id.*

158. *Id.* (quoting Brief of States as Amici Curiae in Support of Federal Trade Commission at 18, *Schering-Plough*, 548 U.S. 919 (No. 05-273)).

159. *Id.*

160. *Id.* at 12.

161. *Id.* at 12–13. Recall that *Schering-Plough* involved an overpayment-type settlement in which Schering-Plough licensed several drugs from the generic challengers.

infirmities at the ALJ stage.[162] The Supreme Court followed the DOJ's recommendation and denied the petition on June 26, 2006.

The DOJ again opposed a per se rule of illegality in its amicus brief accompanying the certiorari petition in *Tamoxifen*.[163] It contended that "the public policy favoring settlements, and the right of a patent holder to exclude competition within the scope of its valid patent, would be frustrated by adoption of a legal standard that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation."[164] Instead, the DOJ reiterated its relative-likelihood-of-success test from the *Schering-Plough* amicus brief.[165] While the DOJ disagreed with the *Tamoxifen* standard—which did not require inquiry into the strength of the patent—it nonetheless counseled against granting certiorari because of the unusual facts of the case.[166] The Supreme Court agreed again and denied certiorari.

Thus, the DOJ's first two statements on reverse-payment settlements—both made under the Bush Administration—seemed to follow the Eleventh Circuit. The DOJ emphatically rejected the per se or presumptively invalid approaches as too harsh, and it similarly rejected the "objective baselessness" standard articulated by the Second Circuit as too lenient.

This position, as well as the DOJ's antitrust enforcement priorities, has changed markedly during the Obama Administration. With his appointment of Christine Varney as the Assistant Attorney General in charge of the DOJ's Antitrust Division, President Obama signaled a shift to a more robust antitrust enforcement regime.[167] In her first major speech in office, Assistant Attorney General Varney announced that "vigorous antitrust enforcement must play a significant role in the Government's response to economic crises to ensure that markets remain competitive."[168] This enhanced scrutiny has been applied to reverse-payment settlements, as the DOJ now believes that "a rule of antitrust

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162. *Id.* at 13–14.

163. Brief for the United States as Amicus Curiae, Joblove v. Barr Labs., Inc., 551 U.S. 1144 (2007) (No. 06-830).

164. *Id.* at 11.

165. *Id.* at 12.

166. *Id.* at 19. Recall that the case involved a settlement following a district court judgment of patent invalidity, followed by vacatur of that judgment while the appeal was pending. *Id.* at 19. Such vacatur is no longer permitted under the Supreme Court's holding in *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994).

167. Stephen Labaton, *Administration Plans to Strengthen Antitrust Rules*, N.Y. TIMES, May 11, 2009, at A1.

168. Christine A. Varney, Assistant Attorney Gen., Antitrust Div., U.S. Dep't of Justice, Vigorous Antitrust Enforcement in This Challenging Era, Address Before the Center for American Progress 4 (May 11, 2009), *available at* http://www.justice.gov/atr/public/speeches/245711.pdf.

immunity [is] particularly inappropriate in this context."[169] Indeed, even the Obama White House has spoken out against reverse-payment settlements.[170]

It is thus unsurprising that the DOJ took a new position in its brief to the Second Circuit in *Arkansas Carpenters Health & Welfare Fund v. Bayer AG* in July 2009:

> The anticompetitive potential of reverse payments in the Hatch-Waxman context in exchange for the alleged infringer's agreement not to compete and to eschew any challenge to the patent is sufficiently clear that *such agreements should be treated as presumptively unlawful under Section 1 of the Sherman Act*. Defendants may rebut that presumption by providing a reasonable explanation of the payment, so that there is no reason to find that the settlement does not provide a degree of competition reasonably consistent with the parties' contemporaneous evaluations of their prospects of litigation success.[171]

The DOJ now appears to reject its previous position that these settlements should be judged by a rule of reason after an inquiry into the strength of the patent.[172] Rather, it now contends that "[i]t is neither necessary nor appropriate to determine whether the patent holder would likely have prevailed in the patent-infringement litigation in determining liability for a . . . reverse payment settlement."[173]

D. *Congress*

Finally, there has been much talk of banning reverse-payment settlements through legislation. Senator Kohl introduced the first such attempt on January 17, 2007.[174] That bill, titled the Preserve Access to Affordable Generics Act, stated that "settlements which include a payment from a brand name manufacturer to a generic manufacturer to delay entry by generic drugs are anti-competitive and contrary to the

169. Phil Weiser, Deputy Assistant Attorney Gen., Antitrust Div., U.S. Dep't of Justice, Antitrust Doctrine, Competition Policy, and International Dialogue, Address Before the Antitrust Section of the American Bar Association 4 (Nov. 12, 2009), *available at* http://www.justice.gov/atr/public/speeches/251859.pdf.

170. Office of Mgmt. & Budget, Exec. Office of the President, A New Era of Responsibility: Renewing America's Promise 28 (2009), http://www.gpoaccess.gov/usbudget/fy10/pdf/fy10-newera.pdf.

171. Brief for the United States in Response to the Court's Invitation, *supra* note 14, at 10 (emphasis added).

172. The DOJ explicitly commented on its policy reversal: "We acknowledge some tension between statements in our *Joblove* brief and our current views." *Id.* at 26.

173. *Id.* at 24.

174. Preserve Access to Affordable Generics Act, S. 316, 110th Cong. (2007).

interests of consumers."[175] It proposed to ban agreements in which "an ANDA filer receives anything of value [or] agrees not to research, develop, market, or sell the ANDA product for any period of time."[176]

While this bill never received a vote by the full Senate, Senator Kohl reintroduced the bill in substantially the same form on February 3, 2009.[177] This bill is still pending and was amended to declare reverse-payment settlements presumptively unlawful instead of per se invalid.[178] The bill allows the presumption to be overcome with "clear and convincing evidence that the pro-competitive benefits of agreement outweigh the anticompetitive effects of the agreement."[179] This change brings the pending bill in line with the DOJ's position in its *Arkansas Carpenters* brief.[180]

Representative Bobby Rush introduced a close analog in the House on March 25, 2009.[181] The inclusion of a per se prohibition on reverse-payment settlements in the House health-care reform bill drew praise from FTC Chairman Leibowitz. Leibowitz commended the House for adopting a "measure [that] will put an end to the sweetheart deals between brand and generic pharmaceutical companies that force consumers to wait—sometimes years—for more affordable generic drugs."[182] The House bill was later added to the House health-care reform bill,[183] though it was not included in the Senate health-care or reconciliation bills that were ultimately enacted.[184]

Thus, Congress has made several attempts to regulate reverse-payment settlements, but none have yet succeeded. Furthermore, these attempts have painted with very broad strokes; the bills have proposed either bans on reverse-payment settlements or a presumption-of-illegality approach, leaving little room for a case-by-case analysis of the economic reality of the transaction. While the amended Senate bill

175. *Id.* S. 316 § 2(a)(11).

176. *Id.* S. 316 § 3(2).

177. Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009).

178. *Id.* S. 369 § 3(a)(2)(B) (as reported by S. Comm. on the Judiciary Oct. 15, 2009).

179. *Id.* S. 369 § 28(a)(2)(B).

180. *See, e.g.*, Dennis Crouch, *Patent Reform: Reverse Payments*, PATENTLY-O (Oct. 16, 2009, 4:29 PM), http://www.patentlyo.com/patent/2009/10/patent-reform-reverse-payments.html.

181. Protecting Consumer Access to Generic Drugs Act, H.R. 1706, 111th Cong. (2009).

182. Press Release, Fed. Trade Comm'n, Statement by FTC Chairman Jon Leibowitz on Adoption of the Pay for Delay Amendment to the America's Affordable Health Choices Act of 2009 by the House Energy and Commerce Comm. (July 31, 2009), *available at* http://www.ftc.gov/opa/2009/07/pay4delay.shtm.

183. America's Affordable Health Choices Act of 2009, H.R. 3200, 111th Cong. § 2563 (as reported by H. Comm. on Energy & Commerce, Oct. 14, 2009).

184. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010); Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

leaves open the possibility of an exception to the presumption, this sort of ex post review will, in practice, likely have a chilling effect on patent settlements of both a pro-competitive and anticompetitive nature.[185]

This Part has shown that the various branches of the U.S. government have all considered the reverse-payment settlements problem, yet none has been able to agree on a regulatory solution. The courts have divided between a per se rule of illegality and rule-of-reason approaches. The FTC has advocated a ban on payments, but it has not been able to effectuate this standard in litigation. The Department of Justice has shifted between a rule-of-reason and a presumption of illegality. Finally, Congress has failed to agree on the substance of proposed bills. The current regulatory landscape is, at best, confused.

III. Failings of the Unilateral Approaches

The preceding survey of regulatory approaches highlights a central theme in reverse-payment settlement regulation to date: while all relevant governmental actors have expressed *some* preference about these settlements, there is little agreement on the details, and no governmental actor has suggested a cooperative solution. Comparative institutional analysis counsels against this fragmented, unilateral approach. Different governmental actors have different competencies, and to achieve the most efficient outcome, any regulatory proposal should seek to capitalize on these institutional strengths. The following section applies the teachings of comparative institutional choice to the reverse-payment settlement problem. It proposes a common-sense regulatory scheme in which Congress outlines broad policy goals, the FTC crafts safe-harbor rules based on its knowledge of the pharmaceutical industry, and courts fill in the blanks by drawing on these explicit policy statements. The resulting scheme would be superior to any of the current unilateral proposals. This Part concludes by examining how the regulatory details of such a system might look.

A. *Regulatory Goals & Constraints*

To resolve the question of what role different institutions should play in regulating reverse-payment settlements, we must first determine the

185. The FTC itself has highlighted this chilling effect. *See* Supplemental Brief for the Petitioner at 4, FTC v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273) ("A key drawback to [ex post review of the legality of reverse-payment settlements]—discussed in the Commission's opinion, but not addressed in the United States' brief—is that it places parties contemplating settlement in the predicament of not knowing, at the time of settlement, whether particular settlement terms will appear unreasonable to a future antitrust tribunal.").

desired goals of such regulation.[186] Fortunately, in the context of reverse-payment settlements, the controversial points that have defined the contours of the disagreements have clearly defined the relevant policy goals. The FTC's position, as well as the DOJ's, is that the regulatory structure must be pro-competitive and ensure the earliest possible entry of generic drugs to the marketplace.[187] Such a goal is consistent with the general policies of antitrust law: absent a compelling reason, the public policy of the United States favors a free-market system.[188]

Second, nearly all of the players in the current debate agree that any regulatory system should respect the exclusionary rights accorded to holders of valid patents.[189] This is consistent with our tradition of using patent rights as an incentive for innovation.[190] Our economy is built on a foundation of strong intellectual property rights, and since the Founding, Congress has exercised its power to grant patents "[t]o promote the . . . useful Arts."[191] Further, our legal traditions clearly recognize that these rights cast a penumbra within which the patent holder may license and enforce the patent as he wishes.[192]

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186. *See, e.g.*, Robertson, *supra* note 26, at 1115 ("Institutional choice theory suggests that the goals should be articulated first, and then institutions' competence at meeting those goals can be compared.").

187. *See, e.g.*, Leibowitz, *supra* note 10.

188. *See* Standard Oil Co. v. FTC, 340 U.S. 231, 248 (1951) ("The heart of our national economic policy long has been faith in the value of competition.").

189. *See, e.g.*, Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1304 (11th Cir. 2003); *Confirmation Hearings on Federal Appointments: Hearings Before the S. Comm. on the Judiciary*, 111th Cong. 958 (2009) (statement of Christine Varney, Nominee for Asst. Att'y Gen. for Antitrust) ("Lawful patents should be enforced and upheld until their expiration. A patent holder who enters into a commercial arrangement to allow a competitor to enter the market prior to the patent's expiration would most likely be procompetitive."); Petition for a Writ of Certiorari at 16, FTC v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273) (accepting that patent rights should not necessarily be curtained, but contending that, "[u]nlike forms of property that are defined in terms of title to tangible items with clearly defined boundaries, the exercise of rights conferred even by a valid patent requires that the boundaries of the patent's coverage be delimited in relation to an accused infringing product"). While the political branches have not explicitly acknowledged this goal, none of their proposed regulatory efforts have sought to curtail valid patent rights. *See supra* notes 174–185 (discussing Congress's proposed bills, which are silent on curtailing patent rights).

190. *See, e.g.*, Letter from Thomas Jefferson to Isaac M'Pherson (Aug. 13, 1813), *in* 6 THE WRITINGS OF THOMAS JEFFERSON 175, 181 (H.A. Washington ed., 1854) ("Society may give an exclusive right to the profits arising from [inventions], as an encouragement to men to pursue ideas which may produce utility . . . ."); *see also* STAFF OF SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE S. COMM. ON THE JUDICIARY, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM 23–25 (Comm. Print 1958) (prepared by Fritz Machlup).

191. U.S. CONST. art. I, § 8, cl. 8.

192. *See, e.g.*, 35 U.S.C. § 261 (2006) (authorizing territorial licensing); Standard Oil Co. v. United States, 283 U.S. 163, 171 (1931) ("An interchange of patent rights and a division of royalties according to the value attributed by the parties to their respective patent claims is frequently necessary if technical advancement is not to be blocked by threatened litigation.").

Given the paramount importance of patents in the pharmaceutical industry, a third policy goal must be to maximize predictability and uniformity. The teachings of the law and economics movement have made clear that predictable background rules are crucial to facilitate private ordering.[193] If each transaction—in this case, each settlement—is a potential source of legal liability for the parties, fewer legitimate transactions will take place. This concern has dominated commercial law in the United States, and it has prompted a number of procedural devices to maximize predictability outside of the settlement context, notably the many safe-harbor provisions built into the Securities and Exchange Act regulations.[194] Furthermore, uniformity is important to ensure the appearance of a fair and impartial regulatory system. The appearance of regulatory impropriety in these already opaque settlement agreements may lead to public distrust of the regulatory regime and prompt unnecessary and radical changes, like the per se bans on reverse-payment settlements seen in some recent bills.

Finally, any regulatory system should seek to minimize the costs that it creates. For example, the adjudicative process—with its formalities and generalist judges and juries—is a notoriously expensive way to resolve disputes.[195] Agencies, however, offer cheaper alternatives because of their relaxed evidentiary standards and relatively expedited litigation schedules. In seeking to reform the regulatory system governing reverse-payment settlements, we should be mindful of institutional efficiencies both to reduce cost to the parties and to reduce the overall cost to society.

B. *Institutional Competencies*

1. Courts

In the battle over reverse-payment settlement regulation, courts have, so far, played the most prominent role. Although the FTC and DOJ can

193. A fundamental insight of Professor Ronald Coase's work is that low transaction costs favor the most efficient allocation of resources. Ronald H. Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1, 15 (1960); *see also* Francesco Parisi, *Coase Theorem*, *in* 1 THE NEW PALGRAVE DICTIONARY OF ECONOMICS 855, 858 (Steven N. Durlauf & Lawrence E. Blume. eds., 2d ed. 2008).

194. *See, e.g.*, 17 C.F.R. §§ 230.147, 230.175, 230.501–508, 230.901–905 (2010). The SEC's safe harbors are particularly relevant in the antitrust context, because the securities statutes, like the antitrust statutes, are quite short relative to the regulations that have been built up around them. In other words, the SEC's regulations provide an example of how clear rules develop from ambiguous statutes to promote private ordering.

195. *See* KOMESAR, *supra* note 26, at 149 ("Judicial independence, which characterizes the beginning and end of many institutional analyses of the courts, comes at a high price."). The average cost of patent litigation if a case proceeds to trial was estimated to exceed $1.5 million in 2001. Kimberly A. Moore, *Xenophobia in American Courts*, 97 NW. U. L. REV. 1447, 1546 n.167 (2003).

bring enforcement actions to express their views, those actions are ultimately adjudicated in a federal courtroom. Furthermore, while Congress has expressed its disapproval of reverse-payment settlements, it has failed to take any action to curb them. As to the legality of reverse-payment settlements, the agencies and Congress have spoken in a whisper beneath the bench's bullhorn.

To a large degree, this system seems to be working. Courts are well equipped and flexible enough to handle factually complex cases, particularly because of their ability to order formal discovery.[196] They are also well suited to inquire into the merits of a settlement, as settlements are essentially instruments of judicial creation. To the extent that reverse-payment settlements involve compensation in connection with a patent, courts are arguably the best institutions to apply the complex doctrines of patent law and determine a patent's scope.[197]

So, with all of these advantages for the courts, what has gone wrong? The first problem arises from a fundamental feature of the judiciary: federal courts are very good at applying broad policies to discrete cases. Unfortunately, the relevant policy under which to judge reverse-payment settlements is not clearly articulated.[198] While courts may seek guidance from the antitrust principles espoused by the Sherman Act, they may also look to the pro-innovation policies of the Patent Act and Article I of the Constitution.[199] Some have argued that the Hatch-Waxman Act clearly weighs against a pro-patent approach, primarily because of its incentives for patent validity challenges.[200] This assertion, however, ignores the reality that most courts have found that reverse-

196. *See* KOMESAR, *supra* note 26, at 126.

197. This premise, however, has not been unquestioned. Some scholars have accepted that courts are superior institutions for adjudicating patent disputes, yet they have questioned whether the current court structure for patent cases is efficient. *See, e.g.*, Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 15 HARV. J.L. & TECH. 1, 1, 39 (2001) (concluding "that district court judges improperly construe patent claim terms in 33% of the cases appealed to the Federal Circuit" and contending that "[e]xpedited appeals of a limited number of claim construction issues would strike the appropriate balance" between accuracy and certainty); Arti K. Rai, *Specialized Trial Courts: Concentrating Expertise on Fact*, 17 BERKELEY TECH. L.J. 877, 881 (2002) (proposing "a [trial] court composed of individuals who would have some exposure to scientific methodology but who would rely heavily on court-appointed experts"); Gregory J. Wallace, Note, *Toward Certainty and Uniformity in Patent Infringement Cases After* Festo *and* Markman*: A Proposal for a Specialized Patent Trial Court with a Rule of Greater Deference*, 77 S. CAL. L. REV. 1383, 1410 (2004) (proposing the creation of a U.S. patent trial court, which the Federal Circuit would give greater deference for rulings on claim construction and prosecution history estoppel).

198. *Cf.* Robertson, *supra* note 26, at 1119 (contending that the policy rationale underlying the forum non conveniens doctrine is "extremely imprecise").

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

200. *See, e.g.*, Carrier, *supra* note 22, at 64; Hemphill, *supra* note 7, at 1614.

payment settlements are a natural outgrowth from the Act—that "patents, payments, and settlement are, in a sense, all symbiotic components that must work together in order for the larger abstract to succeed."[201] While Congress may have intended to put a thumb on the scale to disfavor patent protection,[202] it by no means clearly articulated that policy. As a result, some courts, like the Sixth Circuit, favor a robust antitrust policy, while others, like the Eleventh Circuit and Second Circuit, give more weight to patent protection. This split stems not from an institutional failure of the courts but rather from the lack of clear guidance from lawmakers.

Furthermore, the political process has also failed to instruct the courts as to the relevant factors to consider in evaluating these settlements. While the pending Senate bill does include a list of relevant concerns—such as the length of time remaining until the expiration of the patent, the value to consumers if the ANDA is approved, and the form and amount of consideration received by the generic in resolving the infringement claim[203]—there is nothing currently on the books. The Hatch-Waxman Act arguably hints at a policy that favors the litigation of patent-infringement claims by, for instance, providing an exclusivity period to Paragraph IV challengers; this implies that patent validity is relevant, as the Eleventh Circuit held in *Schering-Plough*.[204] However, even that factor was not clearly articulated, forcing courts to grapple with the problem of identifying other relevant factors.

This lack of guidance has led to irregularity. The district courts that have considered the reverse-payment settlement problem have reached a wide range of results.[205] While this uniformity problem may be fixed on appeal, at least within circuits, such a situation raises two problems. First, appeals take several years, during which the parties to the settlement may suffer the negative financial consequences of an unfavorable district court decision.[206] While a ruling against a reverse-payment

201. *See, e.g.*, Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1074 (11th Cir. 2005).

202. For example, Congress has proposed bills that suggested either per se rules against reverse-payment settlements or a presumption-of-illegality standard. *See supra* Part II.B.

203. Preserve Access to Affordable Generics Act, S. 369, 111th Cong. § 3 (2009) (as reported by S. Comm. on the Judiciary Oct. 15, 2009).

204. *Schering-Plough*, 402 F.3d at 1066.

205. *Compare Ciprofloxacin II*, 363 F. Supp. 2d 514 (rejecting antitrust challenge), *with In re* Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340, 1348–49 (S.D. Fla. 2000) (adopting per se standard and finding antitrust violations), *order rev'd sub nom.* Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294 (11th Cir. 2003).

206. As one study noted, "[a] decision by the U.S. Court of Appeals for the Federal Circuit to invalidate an Eli Lilly patent on Prozac in 2000, less than two years before the patent was set to expire, caused Lilly's stock price to drop 31 percent in a day." Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSP. 75, 76 (2005). Of course, the effect of a negative district court ruling should not be so significant because of the possibility for

settlement would be unlikely to have such disastrous consequences for a company, it is reasonable to assume that opening a patent up to invalidity challenges by voiding a settlement would not be met with investor optimism. Second, building a coherent body of law through appellate decision-making is a very slow process.[207] While this uncertainty at the district-court level will be alleviated after the appellate courts have had more time to develop an evaluative framework, potentially pro-competitive agreements will be chilled in the meantime. Furthermore, as is apparent in the different tests adopted by the Sixth, Eleventh, and Second Circuits, even appellate review does not guarantee nationwide uniformity. Until there is a uniform body of law governing reverse-payment settlements, this uncertainty will prevent parties from entering into these agreements—whether pro-competitive or anticompetitive.

Finally, while the rules of discovery allow courts to gather the relevant facts to evaluate a settlement agreement, these rules may not allow courts to inquire into the entire business plan of a pharmaceutical company.[208] This is most evident in the case of overpayment settlement agreements in which the patent holder pays a generic challenger in exchange for both dropping an invalidity claim and licensing agreements for some of the generic's products.[209] While a court may decide that a patent holder is paying a generic challenger far more than market price for one of its patents as part of a settlement agreement, the court might not be able to evaluate that payment in light of the value of the patent to the company's other drug development efforts. Evaluating the payment in these cases will require the court to inquire into the business judgment of the parties and determine, inter alia, if the licenses were potentially profitable for the patent holder, if the patent holder had the production capacity to use the licenses, and if the licenses were reasonably valued given the entire state of the market. While an agency like the FTC, which monitors the market and employs economic analysts, may be able to answer these questions, it will be very difficult for a generalist judge to answer them in accordance with the formal discovery procedures that are used by the courts.[210]

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reversal at the Federal Circuit. Yet, this observation illustrates that adverse court rulings can have at least some affect on stock prices.

207. *See* Robertson, *supra* note 26, at 1120–21.

208. *See* Christopher R. Leslie, *Rationality Analysis in Antitrust*, 158 U. PA. L. REV. 261, 264 (2010) ("[F]ederal courts are generally not effective arbiters of whether alleged business conduct is implausible.").

209. *See Schering-Plough*, 402 F.3d 1056; *supra* notes 75–78 and accompanying text (describing overpayment-type settlements).

210. *See* HERBERT HOVENKAMP, THE ANTITRUST ENTERPRISE 47 (2005) ("[T]here is relatively little disagreement about the basic proposition that often our general judicial system is not competent to apply the economic theory necessary for identifying strategic behavior as

Thus, the formal adjudicative procedures in courts suffer from a number of challenges in the reverse-payment settlement context. While courts can effectively apply broad policies to concrete cases and use their formal discovery powers to compel disclosure of relevant information in a settlement, they lack the power to declare policies and to conduct broad, inexpensive investigations. As one scholar noted, the "limited resources of the adjudicative process" should be substituted for the political process only if "the balance of bias, competence, and scale favors that substitution."[211]

2. Agencies

Agencies can overcome many of the problems that trouble courts. First, agencies have ready access to information about reverse-payment settlements. In the Medicare Modernization Act of 2003, Congress required patent holders and generics who enter into a settlement agreement to "file[] [the agreement] with the Assistant Attorney General [for Antitrust] and the [Federal Trade] Commission not later than 10 business days after the date the agreements are executed."[212] Furthermore, as discussed above, the FTC has knowledge of the entire pharmaceutical market. As Professor Hemphill notes, the notification filings can be used as a "key input in a comprehensive study of side deals" to identify anticompetitive agreements.[213]

The FTC is also an expert agency, and "by definition, is less likely to make mistakes" in evaluating strategic behavior in the context of the complex Hatch-Waxman statute.[214] Notably, the complex regulatory framework has presented a problem for some courts in reviewing settlements under the Hatch-Waxman Act. In *Tamoxifen*, the Second Circuit explained that, by ending litigation between Zeneca and Barr, the settlement agreement "spurred [additional challenges] by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit."[215] As Professor Hemphill has pointed out, the exclusivity period is only available to the *first* generic challenger.[216] The FTC, as an expert agency

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anticompetitive."); Hemphill, *supra* note 21, at 674 ("[C]ourts have trouble correctly identifying anticompetitive strategic behavior.").

211. KOMESAR, *supra* note 26, at 150.

212. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 177 Stat. 2066, 2461–63 (codified as amended in scattered sections of 21 and 42 U.S.C.).

213. Hemphill, *supra* note 21, at 672.

214. *Id.* at 674.

215. Joblove v. Barr Labs., Inc. (*In re* Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 214 (2d Cir. 2006).

216. Hemphill, *supra* note 7, at 1583.

that deals exclusively with complex market-regulating statutes, would be less likely than generalist judges to make such mistakes in interpreting the Hatch-Waxman provisions.[217]

Agencies are not, however, the saviors of antitrust regulation. Modern public-choice theory suggests that agency rulemaking provides an opportunity for self-interested lobbying that ultimately leads to inefficient regulations.[218] Public-choice theory rests on the assumption that all actors—legislators, industry leaders, and voters—are rational actors who seek to maximize their personal utility by responding to the most powerful political players.[219] Such players are traditionally smaller groups that stand to receive a large fraction of the total legislative or administrative benefit.[220] In the context of reverse-payment settlements, two groups play such a role: consumer groups and unions, which wield considerable political power, and the pharmaceutical industry, which has the largest war chest in Washington.[221] While we cannot be certain which of these groups will dominate, it is clear that both of them will advocate regulations that are in their own interests. Because of this inherent politicization in the rulemaking process, we must be cautious about granting the FTC too much discretion.[222]

In addition to the capture problem, agencies also suffer from overspecialization. Just as the Court of Appeals for the Federal Circuit has been accused of being too pro-patent because of its specialization,[223]

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217. *See* Hemphill, *supra* note 21, at 674. Indeed, the *Arkansas Carpenters* panel cited Professor Hemphill's work approvingly, acknowledging that the *Tamoxifen* court misconstrued the Hatch-Waxman incentive scheme. *Ark. Carpenters I*, 604 F.3d at 110 (citing Hemphill, *supra* note 7, at 1583–86) ("[T]he *Tamoxifen* panel appears to have relied on an erroneous characterization of the Hatch-Waxman Act.").

218. *See, e.g.*, DANIEL A. FARBER & PHILIP P. FRICKEY, LAW AND PUBLIC CHOICE: A CRITICAL INTRODUCTION 1–37 (1991); DENNIS C. MUELLER, PUBLIC CHOICE 1 (1979). *See generally* PUBLIC CHOICE AND PUBLIC LAW (Daniel A. Farber ed., 2007) (describing various perspectives on the public choice problem).

219. FARBER & FRICKEY, *supra* note 218, at 1–2.

220. *See* MANCUR OLSON, THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS 127 (1965).

221. *See Lobbying Spending Database—Top Industries*, OPENSECRETS, http://www.opensecrets.org/lobby/top.php?indexType=i (last visited Apr. 29, 2011).

222. While some may contend that the Administrative Procedures Act offers sufficient opportunity for all sides to express their views to the decision makers, this does not change the political nature of the agency. Even if all views are adequately expressed, the resulting regulations may still be inefficient because of political pressures. To be clear, I am not arguing that agency rulemaking will always be inefficient; I am simply contending that placing a check on the agency's discretion minimizes the probability of inefficient regulation.

223. *See* KOMESAR, *supra* note 26, at 145 ("[S]pecialized courts substituted for general courts are more likely to be subject to long-term influence by information provision and even by replacement than general courts. Courts become more attractive targets for special interest groups as their jurisdiction is narrowed."); Rochelle Cooper Dreyfuss, *In Search of Institutional Identify: The Federal Circuit Comes of Age*, 23 BERKELEY TECH. L.J. 787, 818–19 (2008).

there is reason to believe that agencies—particularly the FTC and the Antitrust Division of the DOJ—will favor antitrust interests.[224] These agencies, while very capable of providing information about market structure and business motives in particular situations, are far less capable of striking a desirable balance between antitrust law and patent law because of their place within the antitrust—and not patent—regulatory system.

3. Congress

Finally, congressional action remains an attractive alternative to both agency and court decisions. Chief among the advantages of legislation is the very nature of the reverse-payment settlements problem: it requires a simple policy choice between antitrust law and patent law. As the policymaking branch of government, it is only natural to leave that balancing to Congress. Indeed, it is a fundamental principle of our government that "the very function of the legislative branch is to debate and determine policy."[225] Furthermore, if the policy balancing is left to the DOJ, FTC, or courts, it may suffer from serious legitimacy challenges.[226] As Hart and Sacks explain, law itself is premised on a principle of institutional settlement that "expresses the judgment that decisions which are the duly arrived-at result of duly established procedures of this kind ought to be accepted as binding upon the whole society unless and until they are duly changed."[227]

Furthermore, Congress is better equipped than the judiciary to resolve policy disputes prospectively.[228] While one possibility for striking a balance between antitrust and patent law is for the Supreme Court to rule on the issue, such a ruling must necessarily be retrospective with respect to the parties before the court.[229] Because of the immense value at stake in reverse-payment settlements and their increasing ubiquity in ANDA litigation, the reliance interests of the parties are particularly important. A prospective decision by Congress on the appropriate balance between

224. This conclusion flows from the theories of interest-group capture discussed above. Just as the Federal Circuit is likely to suffer from capture by the patent bar, the players who regularly come before it, the antitrust regulatory authorities are likely to suffer from capture by consumer lobby groups.

225. Robertson, *supra* note 26, at 1122.

226. *See id.*

227. HART & SACKS, *supra* note 27, at 4.

228. *See generally id.* at 599–615 (describing the case for prospective overruling).

229. *See* James B. Beam Distilling Co. v. Georgia, 501 U.S. 529, 549 (1991) (Scalia, J., concurring) ("I am not so naive (nor do I think our forebears were) as to be unaware that judges in a real sense 'make' law. But they make it *as judges make it*, which is to say *as though* they were 'finding' it—discerning what the law *is*, rather than decreeing what it is today *changed to*, or what it will *tomorrow* be.") (emphasis in original). Such a ruling would not, of course, be retrospective with respect to settlements occurring after the ruling.

antitrust law and patent law would allow a transition to an improved regulatory regime without upsetting the expectations of parties to completed settlement agreements.

As with agencies, the legislature is a political creature and is subject to capture.[230] The same factors that make agencies particularly vulnerable to capture also suggest that the legislature will over-represent majority interests, and any proposed legislative action will need to be mindful of that concern.[231] The self-interested behavior that public-choice theory predicts is also particularly dangerous in the context of statutory revision.[232] Unlike agency rules that can be changed without congressional involvement,[233] inefficiencies that make their way into statutes are much harder to eliminate. Furthermore, as expected, Congress has favored bright-line rules—the per se invalidity of reverse-payment settlements and the presumption of illegality—in its reform efforts thus far.[234] Any reform effort originating in Congress must be careful not to paint in such broad strokes as to ban pro-competitive, lawful payments.

C. *Optimizing Reform*

Against this backdrop of pros and cons for each player in the regulatory system, we can formulate a prescription for reform. First, Congress should take the lead in setting forth policy objectives to strike the balance between antitrust law and patent law. Courts are neither capable of making nor empowered to make such decisions, and policy choices by agencies suffer from similar legitimacy and overspecialization problems. While Congress may be subject to capture and disproportionate political influence, we should be less concerned about capture in Congress than in any other institution. Simply put, Congress is "vested" with the "legislative Powers" of our government,[235] and even its biased judgments are procedurally legitimate. Congress, however, should do no more than strike this policy balance. Rather than risk making specific rules that are overbroad, Congress should simply state a general principle. Unlike Senate Bill 369,[236] Congress, however, should not attempt to set forth factors for courts and agencies to consider in evaluating agreements. Be-

230. *Cf.* Margo Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 533 (2003) (discussing public-choice hazards in congressional responses to the transgenic mouse patent).

231. Indeed, Professor Komesar "lump[s]" agencies and the legislature under the same heading—"the political process"—in his treatise. KOMESAR, *supra* note 26, at 9.

232. *See* DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 99–100 (2009).

233. *See, e.g.*, 5 U.S.C. § 551(5) (2006).

234. *See supra* Part II.D.

235. U.S. CONST. art I, § 1.

236. *Supra* note 174 and accompanying text.

cause reverse-payment settlements seem to evolve with regulatory interpretations,[237] Congress should allow the institution that is most in touch with the market to lay down specific rules.

Thus, Congress should delegate rulemaking power to the FTC to (1) promulgate safe-harbor regulations under which reverse-payment settlements will neither be presumed unlawful nor be challenged and (2) draft rules governing which factors will be relevant in determining if an agreement is pro-competitive—and thus valid—in enforcement actions. These rules will provide additional guidance for courts when they are called upon to evaluate agreements that fall outside of the regulatory safe harbors. Furthermore, Congress should grant the FTC exclusive enforcement power over the antitrust and trade laws involved in reverse-payment settlement regulation. Such a change would involve carving out an exception to the general private right of action provided in 15 U.S.C. § 15 and expanding the FTC's enforcement authority under the Federal Trade Commission Act. Finally, Congress should provide for review of the FTC's decisions in a single appellate court: the U.S. Court of Appeals for the District of Columbia Circuit.[238] To date, Congress has only granted exclusive appellate jurisdiction to the D.C. Circuit and the Federal Circuit. In this context, granting exclusive appellate jurisdiction to the Federal Circuit may place a thumb on the scale in favor of patents because of the Federal Circuit's central role in patent law, so the D.C. Circuit may be a more neutral arbiter.[239]

This proposal capitalizes on two key features of the FTC. First, as an expert agency that already receives data on every settlement agreement that arises from the Hatch-Waxman Act, the FTC is structured such that

237. *See* Hemphill, *supra* note 21, at 682–88.

238. Several statutory review provisions instruct challengers to appeal directly to a specific circuit court of appeals. *See, e.g.*, U.S. DEP'T OF JUSTICE, ATT'Y GEN.'S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT §10(b) (1947), *available at* http://www.oalj.dol.gov/PUBLIC/APA/REFERENCES/REFERENCE_WORKS/AG09.HTM; 10 U.S.C. § 950g(a) (2006 & Supp. I) (granting the D.C. Circuit exclusive appellate jurisdiction over military commissions); 28 U.S.C. § 1295 (2006) (granting the Federal Circuit exclusive appellate jurisdiction over most patent disputes).

239. Some have concluded that this sort of bias at the Federal Circuit is illusory. *See* Peter M. Boyle, Penelope M. Lister & J. Clayton Everett, Jr., *Antitrust Law at the Federal Circuit: Red Light or Green Light at the IP-Antitrust Intersection?*, 69 ANTITRUST L.J. 739, 773 (2001) ("The majority's decision in *Nobelpharma I* may lend some credence to the notion that the Federal Circuit, or at least certain Federal Circuit judges, harbor a bias against imposing antitrust liability on IP owners. The court's ultimate ruling, however, upholding the antitrust verdict against a patentee—one of the very few cases in the *Walker Process* line ever to impose antitrust liability on a patentee—tends to show that this bias is more a matter of perception than reality."). My proposal to consolidate these cases in the D.C. Circuit is simply crafted out of an abundance of caution.

it may easily make these rules without substantially greater resources.[240] Second, because the safe harbors would be entitled to *Chevron* deference in federal courts,[241] they would provide a stable and predictable backdrop against which parties could negotiate Hatch-Waxman settlement agreements. Indeed, parties would be assured that any agreements falling within these safe harbors would be presumed valid by reviewing courts pursuant to the *Chevron* doctrine. This change would facilitate private ordering and the execution of pro-competitive settlement agreements. Moreover, granting the FTC exclusive enforcement authority would promote uniformity by concentrating enforcement power in one agency.

This change would keep courts from having to fill in the blanks in a regulatory framework before the agency that is charged with that task has an opportunity to confront the problem. Courts would still be called upon to resolve disputes that arise outside of the FTC's safe harbors, but many of the challenges that have faced courts to date would no longer be present.[242] Courts would not be without congressional guidance on how to strike the appropriate balance between antitrust and patent law, and the FTC's enforcement guidelines would indicate to courts which factors the FTC believes are most relevant for identifying an anticompetitive agreement. Similarly, this policy guidance would improve the predictability and uniformity of court decisions, and the FTC's regulatory safe harbors would reduce the social cost of reverse-payment settlement litigation by keeping more disputes out of court. Thus, courts will be freed from the Morton's Fork of favoring either patent law or antitrust law, and making a policy choice regardless. They will be free to do what courts do best: apply the existing law to the facts of a particular case.

Furthermore, concentrating review in a single appellate court avoids the uniformity problems that have plagued this area of law to date. Pharmaceutical companies and generic manufacturers operate on a global scale, and, for most of their operations in the United States, they are regulated on the federal level. Given the nature of this industry, allowing different—and conflicting—law to govern different regional circuits is not practical. By providing a single forum for appellate review of the FTC's decisions, Congress will both foster predictability and facilitate the development of a body of law.[243]

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240. It has also been suggested that the FTC could use the notification requirement to better understand reverse-payment settlement agreements. *See* Hemphill, *supra* note 21, at 671–73.

241. *See* Chevron, U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 840–45 (1984).

242. *See supra* Part III.B.1.

243. Prior to the creation of the Federal Circuit, a common criticism of the role of the regional circuits in the development of patent law was that each circuit applied divergent doctrines to similar disputes. This led to costly and inefficient forum shopping among patent

D. *An Efficient Solution*

To better understand how this reform proposal might work, it is useful to examine precisely what decisions each institution might make. While this Note does not advocate any of the following policy positions—its focus is strictly on *how the process should work*, not what the outcome should be—the following proposal would allow each branch to capitalize on its institutional strengths to achieve a more efficient regulatory outcome than the scattered court decisions and divergent policy statements that define the legal and political landscape today.

To date, bills introduced in both houses of Congress have come down in favor of more competition and against strong patent rights. Assuming that Congress wishes to strike that policy balance, it should do so in a way that actually ensures a more competitive market rather than simply paying lip service to economic efficiency. Beyond taking current market conditions into account, this means that Congress should also attempt to further the predictability and cost-reducing goals discussed earlier in this Part.

First and foremost, such a statute should simply articulate a broad principle—an end, not the legal means for achieving it. This approach is not new to Congress, particularly in highly technical and rapidly evolving areas of the law. The heart of the Sherman Act, 15 U.S.C. § 1, contains just ninety-six words, and the statutory backbone of securities fraud actions, section 10(b) of the Securities Exchange Act of 1934,[244] is only slightly longer at 107 words. Yet, despite their lack of detail, these two statutes account for a substantial portion of commercial litigation in federal courts. Rather than embedding a particular period's prevailing notions of "competition" and "the protection of investors" in the *United States Code*, these statutes announce broad principles and direct agencies that are more in touch with market standards and realities to effectuate their goals. Some have even gone so far as to call the Sherman Act "the Magna Carta of free enterprise,"[245] emphasizing its status as an ideal rather than a centralized, step-by-step plan for a capitalist economy.

Reverse-payment settlements constitute a legal problem that is similarly complex and dynamic. Given the large sums that are at stake in

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plaintiffs, and it frustrated plaintiffs' goals of finality. *See* Pauline Newman, *The Federal Circuit—A Reminiscence*, 14 GEO. MASON U. L. REV. 513, 516 (1992). Similar trends are emerging for reverse-payment settlement litigation. For instance, the defendants in *FTC v. Watson Pharmaceuticals, Inc.*, 611 F. Supp. 2d 1081 (C.D. Cal. 2009), sought a change of venue to Georgia to benefit from the 11th Circuit's *Schering-Plough* standard. This emerging inconsistency supports centralization.

244. 15 U.S.C. § 78j(b) (2006).

245. Hemphill, *supra* note 7, at 1555 (citing United States v. Topco Assocs., 405 U.S. 596, 610 (1972)).

ANDA litigation, pharmaceutical companies will certainly find ways around any specific statutory provisions enacted to limit reverse-payment settlements. Additionally, as in securities and antitrust litigation, today's understanding of the public good may not match tomorrow's. While a detailed statute, such as one creating a presumption of illegality, may effectuate our current understanding of how to create more efficient pharmaceutical markets, it may not correspond with that understanding when research and development costs change or when we have a more complete data set that describes settlements that have been signed to date. Because Congress cannot open statutes to revision as quickly as market conditions or understandings change, it would be wise to avoid legislating the regulatory details.

Thus, the substance of this proposed statute should include, at most, Congress's desired ends and the framework upon which to build the means. First, Congress might provide that a patent is not a defense to an otherwise illegal market-sharing agreement. This provision would strike a policy balance between patent and antitrust law, thus eliminating the conflicting goals that have plagued courts so far. Furthermore, the statute should create administrative safe harbors to further predictability. It might provide that any settlement that complies with the rules and regulations that the FTC promulgates is presumptively legal,[246] and it may similarly provide the converse, establishing that any agreements that fall outside of those safe harbors are presumptively illegal, subject to a rule-of-reason analysis by a court. Such a provision would allow pharmaceutical companies to structure their settlements against a clear legal backdrop, thus avoiding the chilling effects created by today's chaotic standards of review. Yet, to allow both legal and market innovation, Congress should ensure that the risk of litigation for agreements falling outside of the FTC's safe harbors is not prohibitively high. It could accomplish this by eliminating any private rights of action to challenge reverse-payment settlements, vesting enforcement power only in the FTC. Under such a system, pro-competitive agreements that fall outside of the safe harbors would be unlikely to result in substantial litigation costs. This change would allow the FTC to be the sole judge of whether reverse-payment settlements are contrary to the public interest, and it would foster a dialogue between the FTC and industry to encourage effective regulation.[247] Similarly, Congress should consolidate review of

246. The FTC's regulations would, of course, be subject to judicial review under the Administrative Procedures Act, and regulations that are inconsistent with the statute may be invalidated.

247. Some may object to this provision, however, because a perceived goal of a safe harbor may be to provide penalties for stepping outside of the FTC's preapproved settlement terms. Proponents of this view may counter that the FTC already engages in a dialogue with

the FTC's decisions in the U.S. Court of Appeals for the District of Columbia Circuit, as discussed in the previous Section, to ensure uniformity of review for agreements outside of the safe harbors.

Upon receiving this statutory authority, the FTC should use its industry knowledge to distinguish pro-competitive from anticompetitive settlements, and it should implement its conclusions by crafting safe harbors, just as the SEC currently does to implement the broad language of the securities laws.[248] Without delving too deeply into the economics of reverse-payment settlements, it is possible to imagine several simple types of safe harbors. The FTC may establish a settlement value cap, allowing cash payments that are equal or less than the expected cost of patent litigation, as determined by market data such as the American Intellectual Property Law Association's biennial *Report of the Economic Survey*.[249] Furthermore, it may allow in-kind payments, such as the overpayment and underpayment settlements described above,[250] provided that the sum of the cash plus the fair market value of any licenses or rights transferred in the settlement are less than the settlement value cap. It may further establish safe harbors for determining the fair market value of such licenses and rights, such as requiring proof of an auction or affirmative management efforts to ensure a fair market price before allowing the in-kind payment to fall within the safe harbor.[251] Finally, if the FTC were to take a broader view of the patent holder's incentives to

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industry through its rulemaking process, and that a private right of action is necessary to encourage industry to participate in the rulemaking process. Yet, this view rests on the assumption that the optimal level of antitrust enforcement is the maximum possible level. This may not be the case. First, agency enforcement is centralized and strategic, while litigation is pluralistic and uncoordinated. The FTC may bring a case to emphasize a particular point, while it may choose to ignore agreements that are outside a safe harbor yet arguably not anticompetitive. To allow such agreements to be challenged would chill legal and business innovation. Second, vesting enforcement authority in the FTC ensures that specialists, instead of generalist judges, evaluate all agreements. This avoids the difficulties associated with courts evaluating a pharmaceutical company's business plan, as discussed above. Finally, agency enforcement has a bias toward negotiation—that is, a dialogue between the agency and all industry participants—because an agency's enforcement priorities will affect decisions for all market players. This supplements and guides the rulemaking process, and may provide a way around impasses. Judicial enforcement, on the other hand, has a bias toward litigation and settlement, as deals struck in one case do not bind other parties. A private right of action may actually provide a way for industry participants to avoid the rulemaking process.

248. *See supra* note 194.

249. *See, e.g.*, AM. INTELL. PROP. L. ASS'N, REPORT OF THE ECONOMIC SURVEY (2009).

250. *See supra* notes 75–78, 82 and accompanying text.

251. Such a requirement to invoke the safe harbor may be analogous to the duty of a corporation's directors under Delaware law to ensure maximum value for a company when a sale or takeover is imminent. *See* Revlon, Inc. v. MacAndrews & Forbes Holdings, Inc., 506 A.2d 173 (Del. 1986). These auctions would be exclusively to value non-monetary components of a reverse-payment settlement. These valuations could then be used to determine if the total compensation provided to the generic manufacturer constitutes fair market value.

settle ANDA litigation, it may create a multiplier for the settlement value cap to account for the reduced market risk—and the accompanying increase in stock price—which the settlement of ANDA litigation might bring. While calculation of such a multiplier is beyond the scope of this Note and likely beyond the capabilities of Congress, it is well within the competence of an expert agency. Thus, the FTC may use its rulemaking power to further promote predictability and reduce costs to the parties of a settlement agreement, all the while ensuring that Congress's policy goals are translated to real economic efficiency gains.

Conclusion

As the above survey of reverse-payment settlement cases demonstrates, the current law governing these agreements is, at best, confused. With the FTC and DOJ advocating different positions, various circuit courts applying related-yet-different tests, and Congress's failure to pass a bill that regulates these agreements, patent holders and generic manufacturers simply must roll the dice in negotiating these deals. As pressure for reform mounts—particularly from the Obama Administration's firm stance on antitrust and the discussion of reverse-payment settlements during the debates on the 2010 healthcare reform law—policymakers will face a question of institutional choice. Who should determine the legality of these agreements, and who should tell them how to do it?

This Note has undertaken a comparative analysis of all of the key players. The various branches of our government are endowed with different powers, and, as scholars in the Hart-and-Sacks vein have so passionately preached, allocating decision making to the appropriate institution is crucial to an efficient and legitimate system of government. In the context of reverse-payment settlements, reform should begin with Congress laying down broad policy goals and then delegating further rulemaking authority to the FTC. The FTC may then use its unique resources to study the market and promulgate safe harbors for procompetitive settlement agreements, and courts may fill in the blanks by looking to the policies and regulations of these two bodies. By establishing a clear, predictable framework—and returning to common-sense regulatory strategies that respect institutional competencies—this reform will eliminate the chilling effects of uncertainty that now plague this area of law.