



DIGITAL ACCESS TO SCHOLARSHIP AT HARVARD

A Reverse Perspective on Reverse Payment Settlements

The Harvard community has made this article openly available.
[Please share](#) how this access benefits you. Your story matters.

Citation	Paul Bailin, A Reverse Perspective on Reverse Payment Settlements (May 2010).
Accessed	May 23, 2018 4:24:20 PM EDT
Citable Link	http://nrs.harvard.edu/urn-3:HUL.InstRepos:8965635
Terms of Use	This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA

(Article begins on next page)

A Reverse Perspective on Reverse Payment Settlements

Paul Bailin (Class of 2010)
Professor Hutt
Food & Drug Law-Winter 2010
3 Unit Paper in satisfaction of the course requirement
May 3, 2010

Abstract

This essay addresses the ongoing debate, both judicial and political, over whether “pay-for-delay” settlements of patent infringement claims brought by branded pharmaceutical companies against generic competitors under the auspices of a Hatch-Waxman “Paragraph IV” ANDA certification should be deemed *per se* violations of the U.S. antitrust laws. It begins by placing the debate in the context of three overlapping legal regimes: patent, food and drug, and antitrust law. Next, it considers the debate over *per se* liability as a clash between two largely incommensurable legal paradigms. To help resolve the dispute, the author suggests that we consider a nontraditional perspective on intellectual property rights, measuring them not against a but-for world of legally unprotected words and ideas (an approach which tends to emphasize the need to protect and incentivize innovation) but rather against the world of real property. The distinctions between real and intellectual property provide an intellectual framework favoring lower protection for suspect patent claims, and the essay provides both conceptual and empirical arguments for moving in that direction in the Hatch-Waxman context.

I. INTRODUCTION

Among the most hotly debated topics in antitrust law in recent years has been the question whether so-called “pay-for-delay” (PFD) or “reverse payment” settlements of

patent infringement lawsuits brought pursuant to the “Paragraph IV” provisions in the Hatch-Waxman Act should be deemed *per se* violations of the U.S. antitrust laws.

Paragraph IV applies when a pharmaceutical company seeking U.S. Food and Drug Administration (FDA) approval for a generic version of a pioneer drug still under patent certifies its belief that the patent either is invalid or will not be infringed by the generic. Hatch-Waxman authorizes the patent holder to sue in response to this certification, and an increasingly common way of settling the ensuing litigation entails the plaintiff/pioneer drug company paying the defendant/generic to stay off the market for a period of time.

This sort of PFD agreement results in the plaintiff maintaining its monopoly over the sale of that drug, a monopoly which it might have lost had the suit gone to trial and the generic defendant prevailed on the patent claim. As such, the question arises whether this should be considered a naked agreement among horizontal competitors to allocate markets – a quintessential *per se* violation of Section I of the Sherman Act – or whether the fact that the plaintiff holds a patent on the drug provides presumptive immunity from antitrust liability.

The U.S. Federal Trade Commission (FTC) has long considered these sorts of agreements to be illegal, a view embraced by the Sixth Circuit in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (2003), and more recently adopted by the Antitrust Division of the U.S. Department of Justice (DOJ) as well. Nevertheless, despite the FTC’s early successes in prosecuting and restricting PFD agreements, both that agency and private plaintiffs have encountered a series of setbacks since 2004, as most other courts to consider the issue have treated PFDs as presumptively *legal* as long as the agreements do not exceed the facial scope of the patent at issue. Most recently, despite

vocal opposition to PFDs from both of the elected branches, a proposed legislative ban was not included in either of the 2010 health care reform laws.¹

In this paper, I begin by reviewing the three legal regimes – patent, food and drug, and antitrust – that jointly provide the framework for challenges to PFD settlements. I then trace the debate between proponents and opponents of PFDs, focusing on the question of whether such agreements should be treated as presumptively legal or illegal under the antitrust laws. Many of the arguments will be familiar to students of the PFD question. What I offer is what I hope will be a potentially useful framework for assessing those arguments. The conventional perspective is that intellectual property (IP) such as patents should receive legal protection only to the limited extent necessary to encourage innovation. That focus on innovation tends to favor a protective approach to drug patents, which we naturally consider to be among the most socially valuable technological innovations.

I argue that it is equally instructive to think not in terms of why IP does receive some legal protection, but rather in terms of why it gets less protection than does tangible property such as real estate. Focusing on the ways in which IP falls short of physical property, and is less deserving of legal protection, emphasizes the dangers in providing too much legal sanctuary to settlement agreements which sacrifice consumer welfare on the altar of intellectual property rights.

¹ For discussions of recent political activity on PFD restrictions, as well as comparisons of the leading proposals in the House (HR 1706/3962) and Senate (S.369), see generally “Health Bill Drops Ban On Deals Between Brand- Generic-Drug Makers,” Wall Street Journal (17 March 2010); Steven Seidenberg, “The Flip Side of Reverse Payments,” ABA Journal, (10 February 2010); Geoffrey A. Manne and Joshua D. Wright, “New Federal Initiatives Project Reverse Payment Settlements and Upcoming Congressional Action,” The Federalist Society (20 August 2009), available at <http://lawprofessors.typepad.com/files/reversepayments.pdf>.

II. REGULATORY FRAMEWORK

Challenges to PFD reverse payment settlements of generic-branded pharmaceutical patent infringement claims provide fodder for both interesting and complex legal analysis because such agreements take place at the intersection of three distinct legal regimes, raising the question which of these sometimes incommensurable paradigms ought to govern.² The claims settled by PFDs are formally brought as patent infringement actions, and hence implicate the patent laws' concern with balancing the incentivizing of innovation against the desire to bring useful developments into the public domain. In the unique pharmaceutical context, however, such considerations are filtered through the FDA's new drug approval process, and specifically through the Hatch-Waxman regime. The latter represents a Congressional effort to encourage the development of life-saving drugs, while simultaneously assuring that those drugs become available at competitive prices as soon as possible. Finally, the antitrust laws seek to ensure that monopolies are not unreasonably maintained, given their tendency to increase prices, limit output and otherwise compromise consumer welfare. The various proposals which have been developed for applying antitrust standards to PFD agreements must thus be assessed based on their success in reconciling the often conflicting goals of these differing legal regimes.³

² 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, 530 (2010).

³ Of course, at some level of generality the goals of these three legal regimes are the same: the regulation of productive activity so as to maximize social welfare. Nevertheless, the three systems differ, at times substantially, not only in terms of the regulatory levers which they employ and the types of productive activity which they target, but also in terms of their underlying value choices: whether to favor long term innovation over short term consumer welfare, the importance of fairness, how to strike the balance between the interests of society and those of individual economic actors, etc.

A. PATENT LAW

Article I of the U.S. Constitution grants to Congress the authority to pass laws to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁴ The primary goals of the patent system are (1) to promote public disclosure of inventions and (2) to incentivize innovation by rewarding inventors with the exclusive rights, for a period of time, to practice their inventions.⁵ The patent laws generate this incentive by conferring on a patent holder the right “to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.”⁶ In return for the patent right, an inventor is required to disclose how to make and use her invention, enabling the public to recreate and benefit from the invention after the patent term expires.⁷ The length of the term of patent protection, currently set at 20 years for most new inventions, thus represents a Congressional attempt to balance these conflicting goals of encouraging and rewarding innovation with the grant of a temporary monopoly over the fruits of invention while simultaneously ensuring that the invention will eventually redound to the public good as other parties are freed to use and improve upon it.

⁴ U.S. Const. art. I, §8, cl. 8.

⁵ 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, 648 (2008).

⁶ Id. at 648, quoting 35 U.S.C. §154 (a) (1) (2000).

⁷ Kadura at 648.

1. Pharmaceutical patents

The tensions inherent in the patent regime between fostering and disseminating innovation are perhaps most pronounced in the pharmaceutical industry. On the one hand, a sizable share of a drug company's costs lie in the expensive new drug development and approval process.⁸ Because only one in approximately 5,000 novel therapeutic compounds that undergo animal testing will ever successfully pass through the lengthy FDA approval regime, the average cost to develop a new drug is somewhere between \$500 million and \$1 billion.⁹ As a result, it has been estimated that some 60 percent of pharmaceutical products would not have been invented in the absence of potential patent protection.¹⁰ Indeed, one perennial complaint about the legal regime governing nutritional supplements such as herbs is that the inability to obtain patents on naturally occurring substances removes the incentive for vendors to engage in costly research to establish their safety and effectiveness.¹¹

On the other hand, as the ongoing national debate over the 2010 health care reform legislation¹² makes clear, holding down spiraling health care costs is a matter of substantial public concern. In 2006, Americans spent \$217 billion on pharmaceuticals, or more than ten percent of total health expenditures.¹³ As the share of the national health

⁸ See generally Peter Barton Hutt et al, *Food and Drug Law: Cases and Materials* 577, 620 ff. (2007); <http://www.familiesusa.org/assets/pdfs/PPReport89a5.pdf>.

⁹ Kadura at 648-49. See also Onoe at 531 (noting that the overall cost of developing a marketable drug is over \$800 million).

¹⁰ See FTC Staff, *Anticipating the 21st Century: Competition in the New High-Tech, Global Marketplace* chs, 6-7 (1996).

¹¹ See, e.g., Jerry I.-H. Hsiao, "Patent Protection for Chinese Herbal Medicine Product Invention in Taiwan," 10 *J. World Intell. Prop.* 1 (2007); Esther Bull et al, "Nutraceuticals," 265 *Pharm. J.* 57 (2000).

¹² Public Law No: 111-148 and Public Law No: 111-152.

¹³ Kaiser Family Foundation, "Prescription Drug Trends," 1-2 (September 2008), available at http://www.kff.org/rxdrugs/upload/3057_07.pdf.

care dollar represented by drugs continues to rise, holding down drug prices will remain a national priority.

2. Patent vulnerability

One feature of the patent laws with significant implications for the generic pharmaceutical industry is that while patents are by law presumed to be valid,¹⁴ in fact many patents are unable to hold up under legal challenge. Indeed, for “those unfamiliar with the nature of prosecution at the [United States] Patent and Trademark Office (PTO) and the reality of patent litigation, the level of uncertainty underlying such intellectual property rights is astonishing.”¹⁵ This uncertainty reflects the inherent nature of intellectual property, as well as various pragmatic factors.

When deciding whether to grant a patent on a (purportedly) new invention, the PTO must determine whether the underlying technologies are sufficiently distinct from closely related ones to count as novel.¹⁶ It must determine whether, in retrospect, one skilled in the art would have seen the innovation as obvious prior to its development.¹⁷ It must determine how narrowly or broadly to construe claim language defining an area of technology about which the examiners may know relatively little and which in fact may describe a process for creating something not yet in existence.¹⁸ Then, courts, upon an infringement challenge, must make all of these determinations anew, viewed through the

¹⁴ Donald S. Chisum, *Chisum on Patents*, § 19.02 (2008).

¹⁵ Alan Devlin, “Indeterminism and the Property-Patent Equation,” 28 *Yale L. & Pol’y Rev.* 61, 75 (2009).

¹⁶ 35 U.S.C. § 102(b) (“A person shall be entitled to a patent unless ... the invention was patented or described in a printed publication in this or a foreign country ... more than one year prior to the date of the application for patent in the United States.”).

¹⁷ *Id.* § 103(a) (“A patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious.”).

¹⁸ Devlin at 75 (noting “the well-documented limitations of language in explaining the nature of a claimed invention concisely”).

filter of a similar, rival invention. Given the ambiguities inherent in this highly subjective process, which tries to cut clear dividing lines into a nearly seamless spectrum of technological research and creative activity, it comes as little surprise that despite the best efforts of the PTO a disturbingly high percent of challenged patents are eventually found to be invalid (or their claims so narrow as to not be infringed by imitative technologies).¹⁹

There are also pragmatic barriers to patent reliability. These encompass “a dearth of pecuniary resources [on the part of the PTO], an increase in the number of [patent] applications, a proliferation of subject matter, examiners’ inability to dispose of an unworthy application once and for all, the nonadversarial nature of the proceeding, information asymmetry, and the fact that an applicant does not bear the burden of patentability[, all of which] combine to limit the PTO’s ability to assess applications accurately.”²⁰ As a result of these factors, it has been estimated that patents litigated to judgment will be invalidated in nearly of half of all infringement suits.²¹

Given these challenges, some commentators have advocated a “probabilistic” view of patent rights under which patents are treated as no more than stochastic “lottery tickets that may or may not yield exclusive power.”²² A corollary of this theory is that rather than being entitled to exclude would-be infringers, patent holders are presumptively entitled only to a “right to try to exclude.”²³ In other words, patentees

¹⁹ Devlin.

²⁰ Id. at 97.

²¹ Id. at 76 and n.73 (collecting studies).

²² Id. at 63. See also Mark A. Lemley and Carl Shapiro, “Probabilistic Patents,” 19 J. Econ. Persp. 75 (2005).

²³ Onoe at 532.

have the right to assert their patents, but their exclusionary power is not fully vested until validated by judicial decisions upholding the patent validity.²⁴

B. THE FOOD, DRUG & COSMETIC ACT

Along with obtaining a patent, or patents, on its formulation, the major procedural hurdle that a pharmaceutical company must surmount in bringing a pioneer drug to market is to obtain FDA approval of a New Drug Application (“NDA”).²⁵ The Federal Food, Drug, and Cosmetic Act (FDCA) empowers FDA to monitor and review the safety of any new drug prior to sale and marketing. As part of this process, drug manufacturers must file an NDA providing detailed information about the safety and effectiveness of each new drug intended for sale.

1. Pre-Hatch-Waxman generic drug regime

Prior to the passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman”), manufacturers of generic pharmaceuticals faced significant obstacles in bringing generic versions of pioneer drugs to market.²⁶ Under the pre-1984 FDCA regime, a company seeking to develop and introduce a generic version of a licensed drug had to go through the same rigorous NDA process as a pioneer drug manufacturer.²⁷ However, the research supporting the pioneer NDA was protected as trade secrets, meaning that unless the generic company was able to enter into a licensing agreement with the pioneer company, the former was forced to conduct its own studies

²⁴ Id.

²⁵ 21 U.S.C. § 355.

²⁶ See generally Raymond Fersko et al., “Hatch Waxman: A Work in Progress - Responding to the Conundrum: How to Encourage Innovative New Drugs While Reducing the Cost of Access,” 8 J. Biolaw Bus. 20 (2005).

²⁷ Id.

and develop its own safety and effectiveness data.²⁸ Further, the patent laws precluded other parties from studying the pioneer drug while it was under patent protection, nor could they conduct experimentation in order to replicate a generic version.²⁹ The result was that generic manufacturers could not even begin the lengthy and expensive drug development and testing process until the pioneer patent expired. Moreover, unlike the pioneer company, the generic would never be able to charge monopoly prices to help recoup its research and development costs.³⁰ The result of this regime was that pioneer drug companies were often able to charge monopoly prices on their branded drugs long past the point of patent expiration, and many successful drugs never faced generic competition.³¹ Of the approximately 150 drugs that went off patent between 1962 and 1984, none faced competition from generic follow-ons.³² Nor were generics in a position to challenge the validity of the pioneer patents prior to the date of expiration.

2. Hatch-Waxman

In passing the Hatch-Waxman amendments to the FDCA, Congress sought to reduce the barriers to entry for generic drugs, both during and after the expiration of patent protection for pioneer drugs.³³ At the same time, legislators strove to maintain a new drug approval regime which would continue to incentivize the development of novel drugs.³⁴ These at times conflicting goals are reflected in several provisions of the Act.

²⁸ Id.

²⁹ Id.

³⁰ Id.

³¹ Id.

³² Id.

³³ Jon Leibowitz, “‘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),” FTC speech (23 June 2009) available at <http://www.ftc.gov/speeches/leibowitz.shtm>.

³⁴ Id.

To encourage the development and commercialization of generic pharmaceuticals, Hatch-Waxman opened a new path to drug approval for generic drugs. When filing an Abbreviated New Drug Application (ANDA), a manufacturer no longer need conduct and submit to FDA its own safety and effectiveness research. Rather, after demonstrating that its generic version is bioequivalent to the pioneer drug, the generic firm can incorporate the safety and effectiveness data developed and submitted by the original pioneer drug manufacturer in its NDA application.³⁵ Further, to ensure that a generic version can be ready to enter the market upon expiration of the pioneer patent, Hatch-Waxman amended the patent laws so that a generic manufacturer does not infringe by studying a pioneer drug, and developing and testing a generic version, during the period of patent protection.³⁶

However, Hatch-Waxman goes beyond merely facilitating the post-patent entry of low-cost generic drugs. Rather, it actively incentivizes generic manufacturers to challenge what may be weak or invalid branded drug patents *prior* to expiration.³⁷ To issue such a challenge, a generic firm submitting an ANDA seeking market entry prior to the expiration of the pioneer patent files a so-called “Paragraph IV certification.”³⁸ The certification states the applicant’s belief that the patent on the pioneer version of the drug either is invalid or would not be infringed by the generic version.³⁹ This Paragraph IV filing sets in motion a series of procedures designed to protect and balance the interests of

³⁵ Lisa M. Ferri and Monique A. Morneault, “Reverse Payment Patent Settlements: The Interplay of Antitrust and Patent Policies,” 20 *Intell. Prop. & Tech. L.J.* 14, 14 (2008).

³⁶ 35 U.S.C. § 271(e) (1). See also Ferri and Morneault at 14.

³⁷ In this paper, I use the term patent “weakness” broadly, to include not only invalid drug patents but also those for which, because of the limited scope of their patent claims when properly construed, a generic version could be produced without infringement.

³⁸ 21 USCS § 355 (j) (2) (A) (vii) (IV).

³⁹ Ferri and Morneault at 14-15. It might not be infringed, for example, if the generic company succeeded in designing around the patent so that the generic version was bioequivalent to the patented drug but not all of the patent claims read onto the generic.

the generic filer and the pioneer drug manufacturer. First, Paragraph IV certification creates an immediate cause of action for patent infringement by the pioneer drug manufacturer.⁴⁰ That is, unlike in normal patent infringement suits, the pharmaceutical patent holder need not wait until another party actually enters the market with an allegedly infringing product to have standing to sue. Second, the ANDA filer must notify the patent holder of its intent to challenge the patent, upon such notice of which Hatch-Waxman grants the patentee 45 days within which to sue for infringement.⁴¹ If the patent holder does opt to file suit, the Act imposes an automatic stay of 30 months, during which FDA cannot approve the ANDA.⁴² In theory, the 30-month stay provides sufficient time for the parties to litigate the generic challenge and avoids the disruption to both drug manufacturers and consumers which would obtain if the generic were to enter and then subsequently leave the market.⁴³ The court can prolong this stay by granting the patent holder a preliminary injunction, which “extends the FDA approval process pretty much indefinitely until the court rules that the patent is either invalid or not infringed.”⁴⁴

Third, Hatch-Waxman grants the first generic challenger to submit a “substantially complete” ANDA with a Paragraph IV certification a 180-day exclusivity period during which no other generic version of the drug may be approved.⁴⁵ The 180-day period does not begin to run until after the first generic filer commences marketing of

⁴⁰ Id.

⁴¹ Id.

⁴² Id.

⁴³ *Ben Venue Laboratories, Inc. v. Novartis Pharmaceutical Corp.*, 146 F.Supp.2d 572, 579 (D.N.J.2001) (citing to 130 Cong. Rec. H9118 (daily ed. Sept. 6, 1984) (statement of Rep. Waxman); 130 Cong. Rec. S10504 (daily ed. Aug. 10, 1984) (statement of Sen. Hatch) (“[T]he purpose of the 30-month stay is . . . to create an adequate window of time during which to litigate the question of whether a generic will infringe the patented product, without actually having to introduce the generic product to the market.”).

⁴⁴ A. Paul Heeringa, “Dodging Antitrust Bullets in Patent Settlement Agreements: Lessons Learned from the ‘Reverse Payment’ Dilemma,” 5 *DePaul Bus. & Com. L.J.* 266, 274 (2007).

⁴⁵ Ferri and Morneault at 14-15.

the generic drug.⁴⁶ However, under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress amended Hatch-Waxman so that the first ANDA filer may forfeit its exclusivity period.⁴⁷ Exclusivity can be forfeited if, *inter alia*, the first ANDA filer fails to launch its product promptly after the 30-month stay expires or a court enters a final decision that the patent is invalid or not infringed, or if it loses a complaint charging that an agreement governing the drug violates the antitrust laws.⁴⁸

During the duopolistic 180-day exclusivity period, the generic version will typically be priced lower than the branded drug (which has been commanding a monopoly price), but well above the competitive market price which will obtain once other generics enter the market.⁴⁹ This valuable six months of generic exclusivity is intended to overcome the collective action problems that would otherwise discourage the challenging of pioneer drug patents.⁵⁰ That is, without the reward of temporary generic market exclusivity, a would-be generic entrant would be deterred from investing the funds necessary to mount a legal battle against the pioneer drug manufacturer, knowing that if it succeeded other generic firms could free ride on its success, enter the market, and quickly drive the price down to a competitive level.⁵¹

At the same time, Hatch-Waxman was not without benefit for the pioneer drug companies. The Act provided brand-name drug companies with patent term extensions

⁴⁶ 21 USCS § 355(j) (5) (B) (iv) (I). The Hatch-Waxman provisions regarding Paragraph IV certification were amended as part of the Medicare Modernization Act of 2003, with the impact of those amendments clarified by FDA guidance issued in October 2004. See Clifford M. Davidson, “More than One Year Later – MMA’s Effect on Hatch-Waxman,” (2005), available at <http://www.ddkpatent.com/pubs/MoreThan.pdf>.

⁴⁷ 21 USCS § 355 (j) (5) (D).

⁴⁸ *Id.*

⁴⁹ See Anne Layne-Farrar, “Reversing the Trend? The Possibility that Rule Changes may Lead to Fewer Reverse Payments in Pharma Settlements,” 5 *Competition Pol’y Int’l* 165, 169-70 (2009).

⁵⁰ John R. Thomas, “Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties,” 2001 *U. Ill. L. Rev.* 305, 337 (2001).

⁵¹ *Id.*

to compensate for delays in commercialization resulting from the lengthy NDA approval process, in addition to nonpatent market exclusivity in certain cases.⁵² Further, the automatic 30-month stay imposed for Paragraph IV challenges amounts to the patent holder obtaining the equivalent of a 2.5 year preliminary injunction without needing to make any showing on the merits.⁵³

Hatch-Waxman has been largely successful at accomplishing its stated purposes.⁵⁴ Generic drugs accounted for 65 percent of all prescriptions issued in 2008, up from fewer than 20 percent at the time Congress passed the Act in 1984.⁵⁵ Although most have entered the market after the expiration of the corresponding pioneer patent, a number of generics have entered by successfully challenging pioneer patents through the Paragraph IV process.⁵⁶ Average drug prices have declined significantly as a result of these trends,⁵⁷ both because manufacturers of generics have lower cost structures⁵⁸ and because the advent of competition drives down prices.⁵⁹ At the same time, pioneer drug development proceeds apace, with the FDA approving 100 NDAs in 2009, up from 76 in 1983, the year before Hatch-Waxman went into effect.⁶⁰

In summary, then, the Hatch-Waxman regime, when properly functioning, (1) rewards the first generic firm to challenge potentially weak patents which are improperly

⁵² 35 USCS § 156. See Reid F. Herlihy, Note: “The Federal Circuit’s Interpretation of the Hatch-Waxman Act: Allowing Generics to Induce Infringement,” 15 Fed. Cir. B.J. 119, 121 (2005).

⁵³ Michael Kades, “Whistling Past the Graveyard: The Problem with the Per Se Legality Treatment of Pay-for-Delay Settlements,” 5 Competition Pol’y Int’l 143, 146 (2009).

⁵⁴ See Leibowitz.

⁵⁵ Michael A. Carrier, “Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality,” 108 Mich. L. Rev. 37, 49 (2009) (hereinafter “Carrier 2009”).

⁵⁶ See Leibowitz (citing a 2002 FTC study finding that when Paragraph IV patent challenges were litigated to trial, the generics won over two-thirds of the time).

⁵⁷ Id.

⁵⁸ Onoe at 532-33 (explaining that they need “not incur the research, development, and promotional costs normally associated with the creation and marketing of an original product”).

⁵⁹ Onoe at 533.

⁶⁰ Drugs@FDA database, searched 25 April 2010, available at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu>.

imposing monopoly drug pricing on consumers; (2) allows drug patent validity challenges to be resolved prior to costly commercialization of a potentially infringing product; (3) preserves and prolongs the patent monopoly of truly innovative drugs; and (4) ensures that competitive pricing is achieved within several years of the filing of a legitimate pharmaceutical patent challenge.

3. Pharmaceutical patent dispute settlements under Hatch-Waxman

Despite its successes, Hatch-Waxman did have one “unintended consequence,”⁶¹ which was the emergence of the reverse payment, or “pay-for-delay,” settlement agreement. Outside the pharmaceutical industry, the normal way to challenge a disputed patent would be for an alleged infringer to place his or her product on the market, and for the patent holder to sue for infringement damages and an injunction against future sales. If, as often happens,⁶² the parties decide to settle their lawsuit, the infringer will frequently pay the patent holder a share of the alleged damages arising from the infringer’s time on the market.⁶³ Because settlements take place “in the shadow of the law,” the share of the claimed damages which the defendant infringer agrees to pay typically rises the more likely the infringer is to get an adverse verdict, based on the probability that a court will find that the disputed patent was both valid and infringed.⁶⁴ So for example, if a patent holder (PH) loses \$10 million in profits during the time that an infringing manufacturer (IM) is on the market, but the parties agree that there is a 70

⁶¹ Ferri and Morneault at 15.

⁶² Heeringa at 274.

⁶³ Such damages include both the loss of volume sales resulting from loss of market share to the infringer, as well as reduced profitability on the remaining sales stemming from the advent of price competition in those cases where the patent had previously conferred market power on the plaintiff.

⁶⁴ Robert J. Rhee, “Toward Procedural Optionality: Private Ordering of Public Adjudication,” 84 N.Y.U. L. Rev. 514, 516 (2009).

percent likelihood that a court would not uphold the patent, the parties might agree to a settlement under which IM agrees to pay PH \$3 million – PH’s expected value at litigation (ignoring transaction costs). Beyond assessing these “damages,” the settlement may require IM to pull the infringing product from the market, or there may be some sort of licensing or contract manufacturing agreement.

Under Hatch-Waxman, by contrast, the legal challenge typically comes *before* the allegedly infringing product is ever commercialized, because the Act makes the filing of a Paragraph IV ANDA itself an infringement. Because the actual infringement imposes no monetary damage on the patent holder, in this case splitting the difference will mean that proper settlement damages will in theory be “reversed.” That is, if there is a 70 percent chance that the pioneer drug patent is invalid, and if the generic firm lost \$10 million in potential profits during the time when it was excluded from marketing its generic drug, then a settlement might entail the *patent holder paying the infringer* \$7 million to compensate for what the latter could have earned by marketing its drug during that period. In reality, a reasonable payment might be somewhat higher, reflecting PH’s desire to avoid the costs and uncertainty inherent in the litigation process. And again, such a payment might be paired with an agreement for IM to stay off the market, licensing or contract manufacturing, etc.⁶⁵

Another alternative is that rather than PH paying IM to settle the infringement claim, the parties might agree to delay the point at which IM could enter the market with its generic drug. So, for example, if PH’s pioneer drug had 10 years of patent life remaining at the time IM filed its ANDA, and assuming again that the parties agreed that the pioneer patent was only 30 percent likely to withstand legal challenge, the parties

⁶⁵ See Carrier 2009.

might agree that IM would wait three years and then market its generic drug during the remaining seven years of the patent.⁶⁶

Finally, these two approaches can be combined in a pay-for-delay settlement agreement. Under a PFD, the generic agrees to refrain from entering the market longer than it would have if the duration of delay correlated solely with its chance of prevailing at trial -- so for more than three years in the previous hypothetical. The additional delay is compensated by a monetary reverse payment from the pioneer drug company.⁶⁷ The prevalence of such agreements has increased significantly in recent years. According to a U.S. Federal Trade Commission (FTC) report, in 2007 branded and generic drug companies reached more than 30 agreements to settle patent litigation, with 14 of those agreements including compensation to the generic challenger and an agreement to delay marketing of a generic version of a drug.⁶⁸ That compares with zero such agreements in 2004, and only three in 2005.⁶⁹

⁶⁶ See Michael Carrier, 2 April 2009 blog post, available at <http://www.truthonthemarket.com/2009/04/01/professor-carriers-response> (hereinafter “Carrier blogpost”).

⁶⁷ As PFDs have come under increasing antitrust scrutiny, a rising number of Hatch-Waxman settlements have incorporated nonmonetary components in lieu of or in addition to financial reverse payments. See American Antitrust Institute, *Transition Report on Competition Policy*, 336 (2008) available at http://www.antitrustinstitute.org/archives/files/Health%20Chapter%20from%20%20AAI%20Transition%20Report_100520082050.pdf (“More recent agreements have become increasingly nuanced and difficult to trace. No longer are brand name companies making simple cash payments for generics not to enter the market. Instead, they are paying generics for intellectual property licenses, for the supply of raw materials or finished products, and for helping to promote products. They are paying milestones, up-front payments, and development fees for unrelated products. They are also agreeing not to launch authorized, brand-sponsored generics.”).

⁶⁸ Ferri and Morenault at 17 (citing “Agreements Filed with the FTC under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003”).

⁶⁹ *Id.*

III. THE ANTITRUST CHALLENGE

As early as the late 1990s, the FTC took the position that pay-for-delay settlements of patent infringement claims arising out of Paragraph IV Hatch-Waxman ANDA filings are presumptively anticompetitive and violate the antitrust laws.⁷⁰ The Commission's opposition stems from the belief that if a patent is sufficiently likely to be found invalid to warrant an ANDA challenge, then for the patent holder (i.e., the manufacturer of the branded pioneer drug) and the generic challenger to agree to maintain the patent monopoly, and to divide the resulting monopoly profits, amounts to a conspiracy to deprive consumers of the benefits of a competitive market.⁷¹ According to a recent FTC study, such agreements cost consumers and the federal government (the largest purchaser of pharmaceutical products in the U.S.) an estimated \$3.5 billion per year in higher drug prices.⁷² As a result of these concerns, both the FTC and private parties have challenged a number of PFD agreements in the courts. Their general lack of success on that front has put growing pressure on Congress to forge a legislative solution.

A. THE SHERMAN ACT

The primary antitrust law in the U.S. is the Sherman Act, codified at 15 U.S.C. § 1-7. Section 1 of the Sherman Act prohibits “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States.”⁷³ The standard courts use to decide whether a particular multi-party agreement unreasonably restrains trade under the Sherman Act depends on what general type of

⁷⁰ Geraldine M. Alexis and Zorah Braithwaite, “FTC Improperly Injects Itself into Drug Patent Settlements,” 16:47 Washington Legal Foundation Legal Backgrounder 2-3 (2001).

⁷¹ *Id.*

⁷² See generally Leibowitz.

⁷³ 15 U.S.C. § 1.

agreement it is.⁷⁴ The “accepted” or default standard is the rule of reason, under which “the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition. Appropriate factors to take into account include specific information about the relevant business and the restraint’s history, nature, and effect. . . . In its design and function the rule distinguishes between restraints with anticompetitive effect that are harmful to the consumer and restraints stimulating competition that are in the consumer’s best interest.”⁷⁵ This typically occurs through balancing the pro-competitive and anti-competitive aspects of an agreement, and then considering whether the purported benefits might be achieved by less restrictive or problematic means.⁷⁶

In other cases, where courts have sufficient experience with a category of agreements to conclude that they “would always or almost always tend to restrict competition and decrease output,” the Supreme Court has deemed them to be *per se* illegal.⁷⁷ Imposing a *per se* standard “eliminates the need to study the reasonableness of an individual restraint in light of the real market forces at work [and gives courts] clear guidance for certain conduct. Restraints that are *per se* unlawful include horizontal agreements among competitors to fix prices . . . or to divide markets. . . . To justify a *per se* prohibition a restraint must have manifestly anticompetitive effects . . . and lack any redeeming virtue.”⁷⁸

Lastly, in certain cases courts will employ a hybrid “quick look” or “truncated rule of reason” standard. This more flexible standard of review, which allows a court to

⁷⁴ *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877, 885-87 (2007).

⁷⁵ *Leegin* at 885-86; internal citations and quotation marks omitted.

⁷⁶ *Onoe* at 536.

⁷⁷ *Leegin* at 886.

⁷⁸ *Id.*; internal citations and quotation marks omitted.

conduct less than the full rule of reason analysis, makes sense when challenged agreements “are not *per se* unlawful but are sufficiently anticompetitive on their face that they do not require a full-blown rule of reason inquiry.”⁷⁹

The Sherman Act is administered both by the Antitrust Division of the U.S. Department of Justice (DOJ) and by the FTC.⁸⁰ In addition, both the Sherman Act and the Clayton Act give private parties a right of action for treble damages if they can establish that they have antitrust standing.⁸¹

B. ANTITRUST CHALLENGES TO PAY-FOR-DELAY AGREEMENTS

As they have become more prominent in recent years, PFD settlements have come under increasing scrutiny, and antitrust challenges have been brought both by the elected branches and private parties. Concerns regarding the potential anticompetitive impact of PFDs arise from the fact that, at least superficially, they appear to be horizontal market divisions, a type of agreement which the Supreme Court has deemed to be *per se* illegal.⁸² That is, in a PFD a monopolist (the branded drug manufacturer) is paying a potential competitor (the generic firm) to stay off the market, at least for a period of time, which allows the former to continue to charge monopoly prices.

Of course, the same sort of concern arises any time two firms settle a patent infringement dispute so that the infringer agrees to leave, or stay off, the market.⁸³

⁷⁹ Onoe at 537 (citing *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 763 (1999), and arguing for applying the quick look standard to PFDs).

⁸⁰ Areeda, Kaplow and Edlin, *Antitrust Analysis: Problems, Text, and Cases* 43-45 (2004).

⁸¹ *Id.* at 58-67.

⁸² Leegin at 904.

⁸³ Compare the Supreme Court’s treatment of such agreements in *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931) (“Where there are legitimately conflicting claims or threatened interferences, a

However, the potential antitrust threat is greater in the unique context of the Hatch-Waxman regime.⁸⁴ To see why this is so, consider a traditional patent infringement settlement, one where the patent holder (PH) has lost, say, \$10 million in profits during a year (Y1) in which the infringing manufacturer (IM) was on the market. When negotiating a settlement under which IM will agree to leave the market and pay damages to compensate PH for part of its loss, the interests of the two parties are fully opposed. IM has no future market prospects (at least until PH's patent expires), and so it can "win" only by having to pay less of the \$10 million in compensation to PH. Importantly, in this scenario, consumers have already derived some benefit from the year's worth of competition during Y1. The parties are now left to divvy up what was left of the Y1 market after purchasers took the consumer surplus in the form of reduced prices. That is, the potential settlement pie to be divided by the parties, based on their expected outcomes at litigation, is what is left *after* consumers have gained some economic benefit from competition. Consumers are not players in this zero-sum game.

In the Hatch-Waxman context, by contrast, where *de jure* infringement occurs prior to the imposition of any damage on PH, there is no upper limit on the possible size of PH's reverse payment to IM.⁸⁵ Indeed, in some cases the would-be infringer actually receives more in settlement payments than it would have earned by infringing and marketing its generic.⁸⁶

settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act.") with *United States v. Singer*, 374 U.S. 174 (1963) (finding antitrust liability where the parties intended to conspire to violate the Sherman Act).

⁸⁴ See generally Carrier blogpost.

⁸⁵ See Seidenberg (noting that PFD settlements "can run into hundreds of millions of dollars"). Of course, in most cases it would be economically irrational for PH to pay IM more than PH's total expected profits from selling under the patent.

⁸⁶ Carrier 2009 at 73 ("Red flags of potential invalidity are raised when brands pay generics more

Consider a scenario, then, in which PH has been charging a monopoly price of \$100 for a pill which costs \$10 to produce, based on a patent set to expire in five years. If IM were to put a generic version on the market, and other generics were to follow, assume the price would drop to \$12 per pill. Here, a PFD agreement might entail IM agreeing to stay off the market for three years, in exchange for PH paying it \$15 per pill for 70 percent of PH's sales volume (assume that this would be IM's expected market share in a competitive market). PH continues to receive a monopoly price of \$85 on those sales during the three year period of market exclusivity, earning a per-pill profit of \$75, and PH receives \$15 per pill for doing absolutely nothing, versus a \$2 profit if it were to actually commercialize its drug.

The problem here is that in a PFD agreement the consumer surplus is on the table, with the interests of the parties aligned against consumer welfare. The longer IM stays off the market, the longer the parties have the \$88 per pill of monopoly rents to play with. The concern thus arises that the reverse payments in PFD agreements “make possible agreements that do not reflect the parties’ reasonable assessment of success in patent litigation.”⁸⁷ Indeed, such an agreement may presumptively indicate that the PH does not actually believe that it would win in litigation.⁸⁸

C. THE DEBATE

The crux of the antitrust complaint against pay-for-delay pharmaceutical settlement agreements, then, is that they essentially amount to branded pharmaceutical

than they ever could have gained by entering the market. . . . The generic, in fact, often gains more through settlement than through successful litigation.”); Seidenberg (“The supposed infringer is not merely getting off scot-free but is also getting extremely well-compensated by the supposedly injured party.”).

⁸⁷ Carrier blogpost.

⁸⁸ Id.

manufacturers conspiring with would-be generic challengers to maintain monopolies based on potentially invalid patents. Plaintiffs and defendants then divide the resulting profits, which stem from overcharging consumers and the government for lifesaving medicines.

Whether this is in fact the proper way to characterize these agreements, and how the courts should handle such antitrust claims, is disputed along several parameters. Ultimately, however, the core of the argument is over which of two incommensurable paradigms should trump: the antitrust rule that horizontal market divisions are *per se* illegal, regardless of the unique conditions under which they occur, or the IP principles that patents are presumed valid, and that a patent holder is free to maintain, share or devise his legal monopoly over his invention in any way he sees fit.

1. Judicial statements

Courts and commentators on both sides of the debate have a tendency to beg the question. In one camp are those who begin, and end, with the proposition that any agreement between competitors to restrict output, divide markets or set prices is *per se* illegal. Once that conclusion is reached, the essence of the *per se standard* is that courts need not – and ought not – consider other extenuating factors, such as the special characteristics of the particular industry, or any potential pro-competitive justifications. Indeed, the principle value of the *per se* standard is that it spares courts and litigants from having to delve into the quiddities of each individual deal – and there will always be claims that a particular situation is different or unique – when experience teaches that this

type of agreement is for the most part without redeeming virtues. PFDs are that sort of agreement, so the argument goes, and *ergo* illegal.

That is the position the U.S. District Court for the Southern District of Florida reached, both initially and (having taken a closer look) on remand, in the Terazosin case.⁸⁹ Citing the Supreme Court’s Topco decision⁹⁰ and the Hovencamp treatise⁹¹ for the proposition that horizontal market allocations are *per se* illegal,⁹² the court dismissed the patent issue with the blanket assertion that when a pioneer firm pays a generic challenger a sum that does “not have a demonstrable link to the amount of damages that [the generic] would incur if [the pioneer] obtained an injunction but was ultimately unsuccessful in the infringement action,” the agreement exceeds the scope of the patent.⁹³ The Sixth Circuit concurred in Cardizem,⁹⁴ indicating that the “anticompetitive potential inherent in all price-fixing agreements justifies their facial invalidation even if procompetitive justifications are offered. . . . Thus, the law is clear that once it is decided that a restraint is subject to *per se* analysis, the claimed lack of any actual anticompetitive effects or presence of procompetitive effects is irrelevant.”⁹⁵ The FTC and many commentators have reached similar conclusions.⁹⁶

⁸⁹ In re Terazosin Hydrochloride Antitrust Litigation (Terazosin I), 164 F.Supp.2d 1340 (S.D.Fla. 2000); In re Terazosin Hydrochloride Antitrust Litigation (Terazosin II), 352 F.Supp.2d 1279 (S.D.Fla. 2005).

⁹⁰ Topco Associates, 405 U.S. 596, 608 (1972), (noting that horizontal market allocations are “one of the classic examples of a *per se* violation”).

⁹¹ Hovencamp, *Antitrust Law: An Analysis of Antitrust Principles and their Application*, ¶ 1902a, at 190 (1999) (“Horizontal agreements are antitrust’s most ‘suspect’ classification.”).

⁹² Terazosin I at 1349.

⁹³ Terazosin II at 1317.

⁹⁴ In re Cardizem CD Antitrust Litigation, 332 F.3d 896, 908 (6th Cir. 2003).

⁹⁵ Id. at 909.

⁹⁶ See, e.g., Manne and Wright (noting that “the FTC, many state attorneys general, and numerous consumer protection groups suggest a *per se* approach is appropriate.”).

Since 2003, however, the majority of courts to consider the question have come to the opposite conclusion, that such agreements are presumptively *legal*.⁹⁷ These courts begin from the premise that a patent is by its very nature the grant of a monopoly, so that an agreement which merely preserves the period of market exclusivity conveyed by a patent can be anticompetitive only where it exceeds the exclusionary scope of the patent. This might occur, for example, if the parties agreed not to compete in the provision of other products not claimed by the patent, if they maintained market exclusivity past the patent's expiration date, or if they entered into sham infringement litigation and a subsequent settlement merely as a pretext for colluding to fix prices and divide markets.⁹⁸

Ultimately, the problem may be inherent in the somewhat circular nature of the *per se* standard itself. An instance of concerted action is treated as illegal, without reference to the unique characteristics of the agreement or the industry in which it transpires, if it is sufficiently akin to other types of agreements that have been found in the past to be clearly anticompetitive. But it is arguably precisely those unique traits and features that make a particular agreement a different sort of creature from those that have been analyzed in the past, and so not amenable to *per se* treatment. That is to say, one can only determine if an agreement is sufficiently like those deemed *per se* illegal by

⁹⁷ See, e.g., Schering-Plough Corp. v. Federal Trade Commission, 402 F.3d 1056, 1065-66 (11th Cir. 2005) (considering only whether the agreement exceeds the scope of the patent, which by nature confer the right to exclude and “cripple competition”); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 208-09 and n.22 (2d Cir. 2006) (applying a presumption of legality even where a patent holder pays a generic “manufacturer more than either party anticipates the [generic] manufacturer would earn by winning the lawsuit and entering the newly competitive market”); In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1333 (Fed Cir. 2008) (purporting to apply a rule of reason analysis but in fact affirming trial court conclusion that “any adverse anti-competitive effects within the scope of the . . . patent could not be redressed by antitrust law”).

⁹⁸For an approach more closely akin to the rule of reason, see *Asahi Glass v. Pentech Pharmaceuticals*, 289 F. Supp. 2d 986, 993-994 (N.D. Ill. 2003) (Posner, J. sitting by designation) (indicating that the level of deference to be afforded the challenged patent – and hence the corresponding PFD agreement’s presumptive immunity to antitrust scrutiny – varies with the *prima facie* plausibility of the Paragraph IV claim that the patent is invalid or not infringed).

considering its distinctive traits, but that consideration is precisely what the *per se* standard forbids. The arguments often made with regard to PFD settlements bring this problem into especially stark relief.

2. The innovation approach

One possible way out of this dilemma, a way favored by many proponents of PFD agreements, is to consider the reasons why society provides intellectual property rights in the first place. In the Terazosin case, for example, the Eleventh Circuit began from the conventional assumption that ideas, inventions and other forms of intellectual property should be freely available to all, absent a compelling societal interest to the contrary. The main justification for granting a patent or copyright on IP is that the reward of a temporary monopoly is necessary to incentivize innovation, where the fruits of research and creation will otherwise be wholly externalized. The court explained that the “exclusionary right is granted to allow the patentee to exploit whatever degree of market power it might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions.”⁹⁹

On this view, the degree of legal protection granted to a patent holder should be only that necessary to encourage and reward socially useful innovation. Mark Lemley sums up this perspective nicely:

Intellectual property protection in the United States has always been about generating incentives to create. Thomas Jefferson was of the view that “inventions cannot, in nature, be a subject of property;” for him, the question was whether the benefit of encouraging innovation was “worth to the public the embarrassment of an exclusive patent.” On this long-standing view, free competition is the norm. Intellectual property rights are an exception to that norm, and they are granted only when-and only to

⁹⁹ Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294, 1304 (11th Cir. 2003).

the extent that they are necessary to encourage invention. . . . On this view, the proper goal of intellectual property law is to give as little protection as possible consistent with encouraging innovation.¹⁰⁰

One might think that evaluating PFD settlements against the backdrop of a world in which innovations such as new drug formulations are freely sharable would argue in *favor* of strict scrutiny of agreements which prolong the monopoly granted by dubious patents. In fact, however, this emphasis on innovation tends to work in the opposite direction. If we focus on the fact that IP rights are warranted as needed to encourage creation, and then consider the prohibitive costs involved in developing and testing a new, potentially lifesaving medicine, then the logical conclusion may be that pioneer drug companies should be given broad leeway over the exercise of their patent rights. Further, the fact that patent protection is of limited duration makes one less wary of permitting restrictions on consumer access to the benefits of price competition, knowing that any such burden on the free market system has been narrowly tailored and will be relatively short lived.

¹⁰⁰ Mark A. Lemley, "Property, Intellectual Property, and Free Riding," 83 Tex. L. Rev. 1031 (2005) (some internal punctuation omitted) (hereinafter "Lemley").

IV. A REVERSE PERSPECTIVE

A. THE OWNERSHIP CONTINUUM

I am not convinced that a but-for world of fully unprotected IP rights presents the proper lens through which to view PFD settlements. That approach emphasizes the *intellectual* component of “intellectual property.” It appeals to the notion that IP is not all that different from a passing thought, an off-the-cuff comment, or other products of the human psyche. But there is, in a very real sense, also a *property* component to “intellectual property.” Companies acquire, value and protect their intellectual property in a manner akin to other, physical assets. IP such as a new pharmaceutical formulation or a Hollywood movie can be the result of years of toil and hundreds of millions of dollars of financial investment. And the creator of IP may have just as strong a desire to exclude others from its use as an owner of land or chattels.

Turning for a moment to actual, tangible physical property, on the ownership spectrum, physical property falls at the opposite extreme from those passing remarks and stray thoughts. Making but a few exceptions (e.g., takings, adverse possession), the law grants us a full monopoly over our tangible property, one of potentially infinite duration. This is a monopoly in two senses of the term. First, the law grants us the sole right to control our own physical assets, defined in terms of the power to exclude others from their use. This is the sense in which Adam Smith spoke of land as a monopoly,¹⁰¹ a characterization that David Hume extended to all private property.¹⁰² Second, one’s ownership over a physical asset carries with it the innate the potential to become an actual market monopoly in the antitrust sense. This is of course true of unique physical

¹⁰¹ Adam Smith, *Wealth of Nations*, I Chap. xi.

¹⁰² See Stephen Holmes and Cass Sunstein, *The Cost of Rights: Why Liberty Depends on Taxes*, 61 (2000).

assets; if I own an original Picasso painting, I may charge others quite a bit for the pleasure of viewing it.¹⁰³ But even more-or-less fungible property has the potential to transform an ownership monopoly into economic monopoly, given the right external circumstances. For example, my backyard might be home to 20 scrub pine trees, each virtually indistinguishable from the millions of other scrub pines across Massachusetts. But if the last known pair of a highly endangered bird species were to select one of my trees for nesting, I would instantly gain the ability to charge for access the various ornithologists, photographers, birders and collectors who might take an interest in that tree.

I will assume for the sake of argument that where a reverse payment takes place within the context of a real property dispute, there is no question of antitrust liability. For example, when an owner (A) sues to quiet title to a piece of real property in which a second party (B) claims an interest, one possible resolution of such a suit is that A will pay B to drop B's claim to the property.¹⁰⁴ A's payment to B will presumably represent some portion of the value of B's claim to the asset, with the size of the share reflecting both anticipated litigation costs and the parties' expectations of success were they to litigate to a final decision. Now further assume that the disputed asset is one which by happenstance gives rise to an economic monopoly. Say, for example, that A owns land containing the only salt mine for 200 miles, so that, given the high cost of transporting salt relative to its price, A can charge monopoly rents in the local salt market. Now B comes along and claims title to ten percent of A's land. If valid, B's claim would allow

¹⁰³ http://jockcoats.me/land_and_libertarians blog.

¹⁰⁴ See, e.g., *Bailey v. Bailey*, 2007 WL 2175197 (Cal. Superior 2007). In that case, a father brought suit to quiet title to a modular home he had constructed in which his son, a renter, claimed an ownership interest. Under the settlement, the father agreed to buy out the son and retained the entire property.

him to compete with A in the local salt business, driving down prices. If the parties settle the dispute with A paying B to drop his claim, leaving A in sole control of that market, I will assume that absent any other evidence of anticompetitive conduct, the agreement would survive antitrust scrutiny since it merely preserves the potential to monopolize inherent in all physical property.

B. REAL v. INTELLECTUAL PROPERTY

So a different way to select the paradigm by which we should assess the reasonableness and anti-competitiveness of a PFD agreement is to ask not how pharmaceutical development differs from other types of legally unprotected intellectual activity, but rather to query how IP such as a drug formulation differs from physical property, which receives more robust legal protection. IP and physical property differ in at least two important ways. Both tend to suggest that we should afford less, rather than more, legal protection to PFD agreements; both point in the direction of antitrust law trumping patent law in close cases regarding intellectual property.

1. Intellectual property is infinitely replicable

First, IP, unlike physical property, is infinitely replicable. Only one person at a time may sit in a particular chair, in front of a particular desk, and type on a particular computer. We permit monopolization (in the ownership, not economic, sense) of physical assets in part because in most cases their use is necessarily exclusive. Of course, we might have a property regime favoring public ownership of assets, so that when I was not using my computer anyone else might enter and do so. One reason we do not is the

so-called “tragedy of the commons.” If my computer were publicly available, each user would be inclined to take more than his share (in terms of disk storage space and the like) and to give less (in terms of chipping in for memory upgrades, taking the time to defragment the drives, etc.).

The story is very different in the case of IP, which generally does not feature a tragedy of the commons.¹⁰⁵ The same software running on my computer can be copied and run simultaneously on thousands of others. Moreover, the marginal cost of doing so is almost negligible, especially if the copying and distribution are accomplished electronically. Nor am I likely to suffer overmuch from others’ simultaneous use. If anything, I may benefit if many other clever minds have the opportunity to improve the software in an “open source” environment. So one reason we give less protection to inventions under the patent laws than we give to ownership of physical property is that protecting IP (1) affords little if any benefit to each user and (2) comes at the tremendous cost of restricting the economic benefits associated with being able to leverage an economically productive innovation almost infinitely.¹⁰⁶

These considerations are directly relevant to the PFD question. To restrict unnecessarily the development of a competitive market in pharmaceuticals is to maintain exorbitant prices for life saving medications, placing pressures on public and household budgets, and in some cases precluding access for the poor both in the U.S. and abroad.¹⁰⁷ Everything else being equal, then, we should favor an outcome which would result in greater consumer access to affordable medications.

¹⁰⁵ Lemley at 1050.

¹⁰⁶ See generally Lemley.

¹⁰⁷ See, e.g., Peter B. Bach, “Limits on Medicare's Ability to Control Rising Spending on Cancer Drugs,” 360 *New Eng. J. Med.* 626 (2009).

2. Intellectual property lacks precise boundaries

The second relevant distinction between real and intellectual property is that the boundaries defining the former, as well as the means of identifying those boundaries, are much clearer. Chattels are, for the most part, discrete objects. There is no doubt where my computer ends and yours begins. Land boundaries, while less distinct, can be surveyed and defined according to agreed upon methods. The disputes are, quite literally, at the margins. Even where clear boundaries lack, as with aqueous property, the law has succeeded in defining use rights in such a way as to provide a fairly high degree of predictability to those who must rely on their rights and obligations with regard to the property.

Not so with intellectual property. As discussed previously,¹⁰⁸ both the indeterminate nature of language (which defines patent claims) and the unlimited potential to combine and vary ideas and innovations mean that whether or not we treat them so for legal purposes, as a practical matter, patents are essentially probabilistic.

Part of why we can grant an enduring monopoly over tangible property, then, is the relative ease of determining where one piece stops and the next begins. Indeed, over time the boundaries between pieces of real property may, if anything, become clearer, as fences and walls are erected, improvements made, and usage patterns established. And predictable geographic boundaries are not only achievable but necessary, in order to promote long-term investment in the land, reduce conflict between neighbors, facilitate the alienability of real property, and so forth.

¹⁰⁸ See IIA2 *supra*.

By contrast, as new ideas and technologies arise, evolve, and combine in myriad ways with other ideas and technologies, over time it becomes increasingly difficult – and unnecessary – to trace the origins of a particular “piece” of IP and to determine whether it infringes, or merely stands upon, prior art. Again, these considerations speak directly to the PFD issue, and argue for a less deferential construction of IP rights where there is a real question as to whether a drug patent is even valid. On the probabilistic view of patents, a PFD which gives rise to a reasonable suspicion that the parties are skeptical of the strength of the underlying patent, and which precludes a judicial determination of validity (or, especially, infringement), ought not be treated as presumptively free from antitrust liability. We may defer to parties’ settlement of a land dispute where monopoly is at stake, such as the salt mine hypothetical, based on (1) our faith that there is in fact a determinable right answer to the conflict; and (2) our preference for not unearthing settled expectations about the legitimacy of present land ownership. Neither consideration applies in the case of IP.

C. THE PROPERTY BALANCE

To summarize, then, intellectual property such as a pharmaceutical formulation falls somewhere on a continuum between spontaneous ideas and expressions, to which society affords no ownership rights at all, and real estate, to which we attach an enduring right of exclusion. In the case of a PFD agreement, the strength of a particular patent has come into question, and the costs to society of nevertheless preserving the patent monopoly, without the opportunity for judicial determination of its validity, may run into the hundreds of millions of dollars. Lives may even be lost. So the question is whether

the need to provide sufficient rewards to incentivize the ongoing development of pharmaceuticals, and to relieve the burdens on the judicial system by encouraging the settlement of lawsuits, outweighs the disadvantages of treating patents in the same way we treat real property. Only if it does ought we exempt PFDs from our usual judgment that horizontal market allocations are *per se* illegal. There are two main reasons to think that we should not afford PFDs that sort of presumed immunity.

1. The legislative intent of Hatch-Waxman

First, although the Constitution makes clear that the patent laws in general are geared towards inciting innovation, Congress's primary intent in passing the Hatch-Waxman amendments appears to have been to encourage generic companies to challenge pioneer patents. It is widely agreed that through the Act Congress sought to balance the interests of pioneer drug manufacturers and their generic challengers.¹⁰⁹ This conflict is often expressed as a tradeoff between encouraging innovation (by protecting and rewarding pioneer patents) and expediting the advent of price competition (by facilitating the entry of generic versions).¹¹⁰

Less obvious is how exactly Congress sought to strike that balance, and particularly how (if at all) the Act sought to protect consumer welfare as a consideration independent from, and potentially opposed to, the interests of the various segments of the pharmaceutical industry. Still, there appears to be rather broad agreement among

¹⁰⁹ See, e.g., http://www.fenwick.com/docstore/publications/IP/Authorized_Generics.pdf (“The legislative intent of Hatch-Waxman was to balance the competing policy interests of manufacturers of brand-name drugs and those of the generic trade group.”).

¹¹⁰ Id; Martha M. Rumore, “The Hatch-Waxman Act— 25 Years Later: Keeping the Pharmaceutical Scale Balanced,” *Pharmacy Times* (15 August 2009) (suggesting that “the legislative intent of Hatch-Waxman was to achieve a delicate balance of innovation and competition”).

antitrust scholars that reverse payment agreements were not an intended result of the Act.¹¹¹ Rather, the consensus is that the main purpose of Hatch-Waxman was to encourage both the development of the generic drug market and the pre-expiration challenging of vulnerable drug patents.¹¹² Supporting this position is Congress's 2003 addition of forfeiture provisions to the Act, evincing a desire that patent holders and first entry generics not be able to conspire to keep other would-be generics off the market.¹¹³

Indeed, the Paragraph IV challenges made possible by Hatch-Waxman can occur only if a generic firm, acting on behalf of the public (which itself lacks standing to challenge the validity of a drug patent), actively prosecutes the claim. In that sense, PFDs fundamentally alter the nature of the regime created by Hatch-Waxman, aligning the interests of the generic applicant with those of the branded drug maker (in preserving and exploiting monopoly pricing) and against those of the public (whose potential consumer surplus is siphoned into the reverse payment). Particularly in a case where the pioneer company pays the generic more to stay off the market than the latter could have earned by actually entering and competing (an outcome which one assumes is

¹¹¹ Ferri and Morneault at 15.

¹¹² See, e.g., Carrier 2009 ("Settlements by which generics agree not to challenge patents threaten the drafters' intentions."); Wayne H. Matelski, Letter to FDA, "Comments regarding 180 day generic drug exclusivity for Ramipril Capsules," (19 October 2007) available at <http://www.fda.gov/ohrms/dockets/dockets/07n0382/07n-0382-c000001-vol1.pdf> ("[T]o permit a company . . . to indefinitely 'park' its exclusivity without actually marketing a product, and then, through its [agreement with the patent holder] to block other generics from coming to market, stands in direct contradiction to Congress' intent."); Layne-Farrar at 176 ("Because Hatch-Waxman enables generic drug firms to challenge a brand name drug without actually entering the market and without making any allegations of patent invalidity, the Act lowers the risk of and thus encourages patent challenges."); Thomas Chen, "Authorized Generics: A Prescription for Hatch-Waxman Reform," 93 Va. L. Rev. 459, 502 (2007) ("Authorized generics manufacturers, with their divide and conquer strategy to deter Paragraph IV entry, clearly undermine the original intent of Title I, which was designed to accelerate generic market entry.").

¹¹³ See, e.g., Matelski (arguing that recent Hatch-Waxman amendments are a clear Congressional statement that "expanded access to generic drugs is of paramount importance to the public interest"); Rumore ("Hatch-Waxman was amended several times to close [loopholes which delay competition] and increase generic drug approval times. . . . Unfortunately, anticompetitive strategies and loopholes continue today and fuel the momentum for further legislative Hatch-Waxman reform.").

increasingly likely the more vulnerable the challenged patent), one is hard pressed to see why a generic would ever aggressively prosecute a meritorious claim in the way that the Hatch-Waxman drafters intended. In that regard, PFDs run directly counter to the legislative intent animating Hatch-Waxman, even accounting for the Act's continued interest in promoting innovation.

2. Empirical considerations

A second set of considerations when evaluating whether we ought to favor the traditional view of intellectual property (which tends to favor immunity from antitrust liability for PFDs) or the “reverse view” which I have outlined (which tends in the other direction) are the likely empirical consequences of either choice. As conceptually attractive as a reverse approach might be, it will hold little appeal if the proponents of PFDs are correct that banning such agreements will hamper either the development of new pioneer drugs or the commercialization of the generic versions that Hatch-Waxman sought to promote.

a. Settlements

There is little disagreement that, as a general matter, settlements are a necessary and desirable element of our legal system. Settlements are “efficient and socially beneficial. They avoid unnecessary litigation costs and, more important, create certainty

that allows parties to plan and invest for the future.”¹¹⁴ This is especially true in the case of patent litigation, which tends to be complicated and resource-intensive.¹¹⁵

Those opposed to imposing restrictions on the ability of branded and generic drug manufacturers to enter into PFD settlements of litigation resulting from Paragraph IV claims argue that restrictions would make it more difficult to settle such disputes. This, in turn, would both deter generic firms from bringing ANDA challenges and result in prolonged litigation where such claims were brought. Both results would be undesirable. Fewer challenges would mean that some pioneer drugs that would lose at least part of their patent monopoly period under the current regime would instead continue to control the market, resulting in higher prices to consumers and frustrating the goals of Hatch-Waxman.¹¹⁶ At the same time, unnecessarily lengthy litigation would clog the courts, result in greater uncertainty and possibly delay the entry of generics.¹¹⁷

This argument rests on several questionable assumptions. First, there is the assumption that reverse payments are an important, even necessary, tool in the settlement toolbox. If such payments were treated as presumptively illegal, the argument goes, fewer settlements could be accomplished.¹¹⁸ Marc Schildkraut, for example, speculates

¹¹⁴ Sean-Paul Brankin, “An EU Competition Law Perspective on Reverse Payments,” (February 2010) available at http://www.wipo.int/wipo_magazine/en/2010/01/article_0004.html.

¹¹⁵ Valley Drug, 344 F.3d at 1308 (“Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.”).

¹¹⁶ See, e.g., Ken Letzler and Sonia Pfaffenroth, “Patent Settlement Legislation: Good Medicine or Wrong Prescription?,” 23 Antitrust 81, 83 (2009) (discussing cases in which PFD “settlements produced earlier entry than the patents—which were subsequently upheld as valid—would have allowed”).

¹¹⁷ See, e.g., Michael K. Friedland, “Antitrust Implications of Patent Settlements: Balancing Patent Policy, Antitrust Law, and the Practical Limits of Litigation,” Findlaw (2008) available at <http://library.findlaw.com/2008/Jun/1/247217.html> (noting the “critical and practical consideration [that] the judiciary cannot afford to discourage settlements”).

¹¹⁸ See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litigation, 363 F.Supp.2d 514, 532 (E.D.N.Y. 2005) (“Requiring parties to a lawsuit either to litigate or negotiate a settlement in the public interest, at the risk of treble damages is, as a practical matter, tantamount to establishing a rule requiring litigants to

that reverse payments can provide essential support to a “cash-strapped alleged infringer [who] needs to receive cash earlier rather than later,” and hence who will be more amenable to settlement when some cash is on the table.¹¹⁹ I am skeptical that a firm on the verge of gaining approval for a generic version of a blockbuster drug would have no access to venture or other sources of capital, even in the current economic climate. Indeed, one wonders how the hypothetical cash-starved generic firm intended to bring its product to market in the case that the brand owner simply declined to challenge its ANDA, or in the event that settlement was not reached and the generic won at trial. Surely a business plan that depended for its funding on the possibility that the firms would enter into a PFD would be a highly risky proposition.

Indeed, critics of PFDs properly question why parties to Paragraph IV patent litigation cannot simply settle their disputes based on earlier generic entry *without* reverse payments, rather than later entry *with* payments.¹²⁰ This would maintain the desirable alignment of consumer and generic interests (both will want generic entry at the earliest possible date), while still encouraging parties to settle their disputes and recognizing the patent holder’s ultimate control over its patent. As the FTC argued in Schering-Plough:

If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer

continue to litigate when they would prefer to settle and to act as unwilling private attorneys general and to bear the various costs and risks of litigation”) (internal quotation marks omitted).

¹¹⁹ Marc Schildkraut, “Patent-splitting Settlements and the Reverse Payment Fallacy,” 71 *Antitrust L.J.* 1033, 1063 (2004).

¹²⁰ See Carrier blogpost. See also Letzler and Pfaffenroth at 82 (discussing the FTC’s belief that if a Paragraph IV “case would settle by the Brand granting the Generic early entry and cash, then it would settle for earlier entry and no cash”).

entry beyond the date that represents an otherwise reasonable litigation compromise.¹²¹

Thus, critics conclude, if, in a given case, a reverse payment is truly necessary to achieve settlement, then it is only because the settlement is one which prolongs a dubious patent at consumers' expense. We ought not mourn the loss of such agreements.

b. Paragraph IV challenges

A second empirical claim made by supporters of PFDs is that the possibility of achieving settlement is a major factor motivating generic drug companies to bring Paragraph IV challenges. Thus, assuming that imposing *per se* liability on PFDs would chill settlements, it would also thwart the purposes of Hatch-Waxman by slowing the penetration of generic drugs. The Generic Pharmaceutical Association, for example, has warned that that “an across-the-board ban [on pay-for-delay pacts] would reduce the number of patent challenges brought by generics, creating an unnecessary hurdle to bringing lower cost generic drugs to the market.”¹²² Judge Posner embraced this position in *Asahi Glass v. Pentech Pharmaceuticals*, reasoning that a “ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger’s settlement options should he be sued for infringement, and so might well be thought anticompetitive.”¹²³

¹²¹ FTC, Pet. App. at 76a-77a, petition for certiorari to the Supreme Court in *FTC v. Schering-Plough Corp.*, No. 05-273 (2005). Compare *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 n.15 (11th Cir. 2005) (dismissing the FTC’s position as “untenable”).

¹²² Generic Pharmaceutical Association press release, (17 March 2010) available at <http://www.gphaonline.org/media/press-releases/2010/gpha-statement-patent-settlements>.

¹²³ *Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc.*, 289 F.Supp.2d 986, 994 (N.D.Ill. 2003) (Posner, J. sitting by designation).

Again, critics of PFDs respond here – rightfully so, I think – that if generic ANDAs are enticed primarily by the possibility of entering into settlements in which they will earn more by staying off the market than by actually competing, then we ought not celebrate such challenges.¹²⁴ Beyond that, there is serious doubt as to whether generic firms would really stop filing ANDAs if PFD settlements were taken off the table. FTC Chairman Jon Leibowitz points out that companies actively brought, and settled, Paragraph IV challenges prior to the early 2000s, when reverse payments first became commonplace. They “simply picked a date based on the strength of their case without any exclusion payments.”¹²⁵ Thus, there is strong reason to believe that (1) PFDs, if made illegal, would most likely be replaced by more pro-competitive types of settlement agreements; and (2) where the availability of PFDs does skew parties’ incentives, it is precisely because such agreements improperly allow them to appropriate the consumer surplus which would result from a competitive drug market. Claims to the contrary are belied by the Act’s successful two-decade record of cultivating a flourishing generic drug industry before PFDs ever entered the picture.¹²⁶

¹²⁴ See, e.g., Leibowitz (“In any event, if generics are filing patent challenges only to get a payoff, then those patent challenges are no longer serving consumers.”).

¹²⁵ Leibowitz.

¹²⁶ A third point of empirical dispute, the resolution of which lies beyond the ambit of this paper, concerns the extent to which a PFD agreement is able to create a “cork-in-the-bottle” effect by “parking” the first ANDA filer’s 180-day exclusivity period so that other generics are excluded indefinitely from the market (or at least until patent expiration). Compare Layne-Farrar at 176 (suggesting that the forfeiture provisions implemented by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 have eliminated the risk of bottlenecking) with Brankin; Rumore (concluding that “most often the forfeiture is avoided by legal maneuvers and ‘bottlenecks’ continue”). See also the FTC’s testimony before the House Commerce Subcommittee, 24-27 (2 May 2007), available at http://www.ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf (detailing various scenarios under which a patent holder could maintain the bottleneck notwithstanding the 2003 forfeiture rules).

V. CONCLUSION

In this paper, I have argued that pay-for-delay settlements, or at least the most facially anticompetitive types, should be subject to *per se* antitrust liability. My reasons for thinking such agreements anticompetitive are familiar ones. PFDs improperly align the interests of branded and generic competitors against those of consumers, in a way that runs counter to the apparent intent of the Hatch-Waxman amendments. They maintain elevated drug prices when more consumer-friendly early entry agreements could achieve the same benefits (aside from elevated drug company profits). They do not appear to be necessary to either the settling of lawsuits or the incentivizing of generic challenges. And they bear strong indicia of a belief by the parties that the contested patents are likely not valid.

But the question remains whether any of these considerations should count. After all, we are talking about a patent, a form of intellectual property that is presumptively valid and, when valid, confers a legal monopoly. What I have tried to offer here is a different paradigm by which to evaluate that claim, one which places less weight on the importance of incentivizing innovation and more on the ways in which the notion of intellectual “property” is just a metaphor. To the extent that IP rights confer few of the traditional benefits of property ownership, and bear their own unique costs, in close cases such as this we should be especially wary of allowing IP to don the mantle of monopoly at the expense of public health and welfare.