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**DYNAMIC INNOVATIVE INEFFICIENCY IN PHARMACEUTICAL  
PATENT SETTLEMENTS**

*Ian Hastings*<sup>\*</sup>

*Ineffective policing of bad patents remains a main focus of the academy with respect to Hatch-Waxman challenge settlements, but the potential of the challenge structure for weakening justified, good patents has gone relatively unnoticed. Currently, the most rational target for a generic challenger is a highly profitable patent, whether it is weak or strong. The pioneer patentee will be particularly risk averse with respect to blockbuster drugs and, therefore, willing to concede much in settlement negotiations out of fear of the vagaries of patent trials. Given that blockbuster drugs are used to subsidize the research and marketing of loss-producing drugs, to decrease the expected value of a popular drug is to discourage not only the development of future, likewise profitable drugs, but also a host of other more specialized drugs. This article examines the problem of innovative inefficiency within the Hatch-Waxman regime and proposes an approach for reform.*

**I. INTRODUCTION**

The Hatch-Waxman Act (the “Act”) tries to answer a difficult question—how does one bolster patent protection for pharmaceutical companies that spend hundreds of millions of dollars on researching and developing drugs, while ensuring that the law denies monopoly protection to holders of improvidently granted patents?<sup>1</sup> The Act’s answer, providing off-setting

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<sup>1</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2006)).

incentives for pioneers and generics, has proven moderately successful in spurring greater levels of generic competition without materially suppressing the incentives for pioneer drug manufacturers to invent.<sup>2</sup>

Unfortunately, pharmaceutical companies (pioneers and generics) have manipulated the complex regulatory framework put in place by the Act, and in doing so have stymied the goals of this legislation. The structure that the Act provides for policing “bad patents” forms the arena for these questionable maneuvers.<sup>3</sup> Under the Act, a generic producer is encouraged to challenge the validity of a drug patent on the promise that if it is the first to do so, not only will the Food and Drug Administration (FDA) approval of the patentee’s drug carry over to the generic’s bio-equivalent, but the generic challenger will also gain an extremely valuable 180-day marketing exclusivity period against its competitors; a generic challenger does not need to obtain a court decision in its favor to reap the above benefits; it simply must not lose or withdraw.<sup>4</sup> The generic producer may aim to settle such challenge suits, rather than bring them to judgment.

In settling these challenge proceedings, some brand-name drug manufacturers have been paying potential generic-drug competitors to concede the validity of the relevant patents.<sup>5</sup> Other settlements under the Hatch-Waxman Act do not involve payments from pioneer to generic and will take the form of a “non-

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<sup>2</sup> See Michael A. Carrier, *Unsettling Drug Patents: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 49–51 (2009–10).

<sup>3</sup> See *id.* at 70; C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 78 ANTITRUST L.J. (forthcoming 2011), <http://ssrn.com/abstract=1736822>; C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1568–73 (2006) [hereinafter Hemphill, *Paying for Delay*]; Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1749–56 (2002–03).

<sup>4</sup> See 21 U.S.C. § 355(j)(5)(D)(i) (2006).

<sup>5</sup> See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1327–30 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 899–903 (6th Cir. 2004).

aggression pact” between the two. Here, the status of the patent will remain undetermined, but in return for withdrawing the challenge, the generic will usually be able to enter the market some years earlier than the official end-date of the patent.<sup>6</sup> Both these kinds of settlements, the first commonly referred to as “pay-for-delay” or “reverse-payment” agreements, are a source of considerable academic frustration and debate.<sup>7</sup> Despite receiving the blessing of the Courts of Appeals for the Eleventh and Second Circuits,<sup>8</sup> many argue that these pay-for-delay and non-aggression settlements represent little more than a means for pioneer drug companies to extend the lifespan of ill-gotten patents and harm consumer welfare.<sup>9</sup>

However, others contend that such settlements are not statically inefficient in the allocative sense as they do not unnaturally preserve the deadweight losses associated with patents, but, rather,

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<sup>6</sup> See generally Hemphill & Lemley, *supra* note 3, at \*21.

<sup>7</sup> See, e.g., Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, in 4 INNOVATION POLICY AND THE ECONOMY 145 (Adam B. Jaffe et al. eds., 2004); ROBIN FELDMAN, *THE ROLE OF SCIENCE IN LAW* 167 (2009); HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 15.3A1 (2d ed. 2010); Carrier, *supra* note 2; Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 779–96 (2002); Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents?*, 98 AM. ECON. REV. 1347 (2008); Hemphill, *Paying for Delay*, *supra* note 3; Hovenkamp et al., *supra* note 3; Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSPECTIVES 75 (2005); Catherine J.K. Sandoval, *Pharmaceutical Reverse Payment Settlements: Presumptions, Procedural Burdens, and Covenants Not to Sue Generic Drug Manufacturers*, 26 SANTA CLARA COMPUTER & HIGH TECH. L.J. 141 (2010); Marc G. Schildkraut, *Patent Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033 (2004); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003); Robert D. Willig & John P. Bigelow, *Antitrust Policy Towards Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655 (2004).

<sup>8</sup> See, e.g., *In re Ciprofloxacin*, 544 F.3d at 1333–37; *In re Tamoxifen*, 466 F.3d at 193; *Schering-Plough Corp.* 402 F.3d at 1058.

<sup>9</sup> See generally Bulow, *supra* note 7, at 145; FELDMAN, *supra* note 7, at 167; HOVENKAMP ET AL., *supra* note 7, § 15.3A1; Carrier, *supra* note 2, at 37.

stand to reduce them.<sup>10</sup> Patent litigation is an extremely costly and uncertain endeavor for pioneer drug manufacturers.<sup>11</sup> In exchange for a certain cheaper outcome through settlement with a generic challenger, a pioneer may be willing to negotiate outside the range of its expected value from trial. If we translate this value into units of years of a patent term, this means that under certain (arguably quite common conditions) a settlement will result in earlier generic entry than would occur through litigation.<sup>12</sup>

Beyond issues of static allocative efficiency and systemic under-enforcement, there is the question of dynamic *innovative* efficiency, which is the focus of this paper. Dynamic innovative efficiency in the context of pharmaceutical patent litigation relates to how effectively the Hatch-Waxman Act provides incentives to pioneer drug manufacturers to develop and market drugs. While it is certainly true that settlements reduce the uncertainty of litigation generally, the character they adopt under the Hatch-Waxman Act renders them a considerable threat to the innovation landscape of the pharmaceutical industry. The first generic challenger of a drug patent is not cowed by litigation costs, as it stands to receive a valuable bounty simply by being first in line. Knowing that the uncertainty of patent litigation and the high stakes involved will make the patentee particularly amenable to settlement along a broad negotiation spectrum, the generic producer has no need to root out only the weakest patents, and can chose instead to target the most valuable.<sup>13</sup>

This Article shall analyze the problem of dynamic innovative inefficiency against the background of the main arguments that have been put forward by proponents and opponents of the Hatch-Waxman settlement regime. This article shall examine what

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<sup>10</sup> See generally Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 367 (Winter 2010); Schildkraut, *supra* note 7, at 1057–67; Gerald Sobel, *Consideration of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Act Settlements*, 20 FED. CIR. B.J. 47, 69–76 (2010).

<sup>11</sup> See ANTHONY L. MIELE, *PATENT STRATEGY: THE MANAGER'S GUIDE TO PROFITING FROM PATENT PORTFOLIOS* (2000); Crane, *supra* note 7, at 757.

<sup>12</sup> See Schildkraut, *supra* note 7, at 1057–67.

<sup>13</sup> See Crane, *supra* note 7, at 759–62.

proposals for regulatory reform might best reduce dynamic innovative inefficiency while countering other negative consequences of the Act that have been identified. Part II lays out the regulatory framework of the Hatch-Waxman Act. Part III considers the arguments that have been proffered in support of the Act's current settlements regime. Part IV looks to the grievances of those who stand in opposition to the Act's present format. This part also outlines the issue of dynamic innovative inefficiency. Part V examines the approach that has been taken by the courts with respect to settlements under the Hatch-Waxman Act, and how this approach should be changed in order to reduce the inefficiencies born of the current regime. This part also outlines a proposal for regulatory reform that could work in concert with a change in tack by the courts. Part IV concludes the Article.

## II. THE HATCH-WAXMAN ACT REGULATORY STRUCTURE

### A. *Fostering Innovation in the Pharmaceutical Industry*

In 1984, Congress enacted the Hatch-Waxman Act to promote innovation and promote generic competition within the pharmaceutical industry.<sup>14</sup> Producing and commercializing a new drug is extremely difficult; a company must spend anywhere between \$150 million and two billion dollars in conducting the research to develop a new drug and bring it to market.<sup>15</sup> The great majority of New Drug Applications (NDAs) do not receive FDA endorsement, and for those that do, the process of approval takes twelve years on average to complete.<sup>16</sup> The clock of the patent term is ticking all the way through the struggle to get to market,

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<sup>14</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2006)).

<sup>15</sup> See Alan Devlin, *Systemic Bias in Patent Law*, 61 DEPAUL L. REV. at \*14–19 (forthcoming 2011), <http://ssrn.com/abstract=1808912>. Some of this high cost comes from the fact that even if a company manages to synthesize a drug that is actually effective, the drug must undergo extensive clinical trials in order meet the approval of the FDA before it can be put to market. *Id.*; see also H.R. REP. NO. 98-857, pt. 2, at 14–19 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688.

<sup>16</sup> See PHARM. RESEARCH & MFR. OF AM., 2006–2007 ANNUAL REPORT 12 (2007).

meaning that, without some sort of intervention, the effective patent length would be reduced severely, and the incentive to innovate along with it.

The Hatch-Waxman Act compensates for the delays and difficulties of the FDA approval process by providing certain extensions to pharmaceutical patents, thus increasing their expected value and so encouraging more innovation within that field.<sup>17</sup> Prior to its enactment, the estimated effective patent length of a drug was seven years.<sup>18</sup> The extension contained within the Act allows the addition of half the time a patented drug is in the FDA trials plus the period the patentee is left waiting for approval upon completion of the process. This extension can last up to five years and, with the remaining patent length, give a drug-patentee an effective patent life of up to fourteen years.<sup>19</sup>

Congress also provided for other periods of market exclusivity not based on patents. A company that offers a drug with a new active ingredient, as opposed to a delivery mechanism, is entitled to an extension of up to five years, during which generic applications are not entertained.<sup>20</sup> In addition, new clinical investigations essential for approval of new dosage forms, new uses, and adoption of over-the-counter status would be granted three years of exclusivity.<sup>21</sup>

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<sup>17</sup> Carrier, *supra* note 2, at 43–45.

<sup>18</sup> JOHN W. EGAN ET AL., *ECONOMICS OF PHARMACEUTICAL INDUSTRY* 105–06 (Praeger 1982); see James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 451–52 (1986).

<sup>19</sup> 35 U.S.C. § 156(c), (g)(6) (2006). See generally Elizabeth S. Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTRITRUST L.J. 585, 591 (2003).

<sup>20</sup> 21 U.S.C. § 355(j)(5)(F)(ii) (2006). The exclusivity period is four years for generic filers certifying patent invalidity or noninfringement and five years for other generic filers. *Id.*

<sup>21</sup> 35 U.S.C. § 156(c), (g)(6). See generally Weiswasser & Danzis, *supra* note 19, at 593.

### B. *Encouraging Greater Generic Entry in the Pharmaceutical Industry*

Prior to the passing of the Act, generic entry was rare.<sup>22</sup> If a generic manufacturer wanted to market the bio-equivalent of a particular brand-name drug, it needed to submit a New Drug Application (“NDA”) for the generic. In other words, the clinical trials and FDA approval process had to be performed twice over with respect to the same drug. In the case of the generic, the FDA approval process could only begin after the relevant drug patent had expired.<sup>23</sup> The costs associated with FDA approval discouraged many generics from attempting to enter the market, and as such, monopoly prices for brand name drugs persisted, often well after the allotted patent term.<sup>24</sup> The Hatch-Waxman Act tackled this problem by permitting generics to submit an Abbreviated New Drug Application (“ANDA”). Under the Act, one wishing to market a generic drug can rely on the efficacy and safety data associated with an FDA-approved, patented drug by showing that the generic is the bio-equivalent of the approved drug and that patent concerns have been resolved in one of the forms discussed below.<sup>25</sup>

A pioneer drug company whose NDA is approved must identify the patents that it believes would be infringed by the marketing of generic drugs by listing such patents in a publication known as the Orange Book.<sup>26</sup> When submitting an ANDA covering a patented drug, a generic must file one of the following four certifications in respect of each patent covering the drug:

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<sup>22</sup> At the time Congress enacted the Hatch-Waxman Act, there was no generic equivalent for 150 drugs whose patent terms had lapsed. *See* H.R. REP. NO. 98-857, pt.1, at 17 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650.

<sup>23</sup> *See* ANNA COOK, CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 38 (1998), *available at* <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf>.

<sup>24</sup> H.R. REP. NO. 98-857, pt. 2, at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688.

<sup>25</sup> FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 43 (2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

<sup>26</sup> *See* JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 15 (2005).



- (I) no patent information appears in the Orange Book,
- (II) the patent has expired,
- (III) it will not seek approval until the patent has expired,  
or
- (IV) the patent is invalid or will not be infringed by the  
generic drug.<sup>27</sup>

The FDA can approve the first two certifications immediately and the third when the relevant patent has expired.<sup>28</sup> Settlement agreements come into play with the fourth certification, making it the focus of academic and judicial commentary on the Hatch-Waxman Act.

When a generic drug manufacturer files a Paragraph IV challenge, it must notify the NDA and patent holders within twenty days, detailing support for its claim of non-infringement and/or invalidity of the patent.<sup>29</sup> The patent holder has forty-five days to initiate suit for this artificial form of infringement, otherwise the FDA may approve the ANDA, putting an end to the challenged patent.<sup>30</sup>

However, if the patent holder does initiate suit, it receives an automatic thirty-month stay on FDA approval of the ANDA.<sup>31</sup> This thirty-month stay acts as another form of extension to safeguard the expected value of the patent, as well as an encouragement to the patentee to bring suit in the first place.<sup>32</sup> If the generic drug manufacturer successfully defends its filing by showing that it either did not infringe the brand name patent, or that the patent was invalid, the ANDA may be approved, and the generic may enter the market.

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<sup>27</sup> See 21 U.S.C. § 355(j)(2)(A)(vii) (2006). See generally THOMAS, *supra* note 26, at 313.

<sup>28</sup> § 355(j)(5)(B)(i).

<sup>29</sup> § 355(j)(2)(B)(ii)–(iii). The twenty-day limit was added in the 2003 amendments to the Act. *Id.*

<sup>30</sup> § 355(j)(5)(B)(iii).

<sup>31</sup> *Id.*

<sup>32</sup> *Id.* The period could extend an additional twelve months depending on when the generic filed its Paragraph IV certification. § 355(j)(5)(F)(ii); see Hemphill, *Paying for Delay*, *supra* note 3, at 8–9, n.17.

Knowing that patent litigation is extremely expensive, the framers of the Act provided a bounty to generics to file a Paragraph IV certification and defend themselves in the litigation that would most likely follow.<sup>33</sup> The bounty takes the form of a 180-day exclusivity period to the first filer of a “substantially complete” ANDA with a Paragraph IV certification; the first filer has exclusive marketing rights of the generic drug for six months following initial commercialization.<sup>34</sup> This period is extremely valuable, accounting for most of the profits a generic can make off of a particular drug.<sup>35</sup> During the 180-day exclusivity period, the FDA cannot approve ANDAs from other generic filers.<sup>36</sup> Prior to 1998, a generic only secured this bounty when it successfully defended a Paragraph IV suit against a brand-name manufacturer, but the courts found such a requirement to be outside the terms of the Act.<sup>37</sup> Now, regardless of whether or not it actually shows non-

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<sup>33</sup> See Carrier, *supra* note 2, at 41–45.

<sup>34</sup> § 355(j)(5)(B)(iv). Multiple applicants that file paragraph IV ANDAs on the same day share exclusivity. OFFICE OF GENERIC DRUGS, FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAS ARE SUBMITTED ON THE SAME DAY 4–6 (2003), available at [http://www.fda.gov/downloads/](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072851.pdf)

Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072851.pdf.  
<sup>35</sup> Daniel F. Coughlin & Rochelle A. Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective: From Ticlid® to Pravachol®, Apotex Has Difficulty Telling Who's on First*, 25 BIOTECH. L. REP. 525, 525–26 (2006) (“In general, most generic drug companies estimate that sixty to eighty percent of their potential profit for any one product is made during this exclusivity period.”); see also MARTIN A. VOET, *THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA AND PHARMACEUTICAL LIFE-CYCLE MANAGEMENT* 61 (Brown Walker Press 2005) (arguing that the 180 days often provides the majority of total profits).

<sup>36</sup> H.R. REP. NO. 98-857, pt. 2, at 7 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2688; Carrier, *supra* note 2, at 80 n.62 (2009) (“Until amended in 2003, the Hatch-Waxman Act included as a second trigger for the 180-day period a court decision finding invalidity or lack of infringement.”).

<sup>37</sup> *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998) (“The language of the statute . . . is plain and unambiguous. It does not include a ‘successful defense’ requirement, and indeed it does not even require the institution of patent litigation.”); see also *Granutec, Inc. v. Shalala*, No. 97-1873, 1998 U.S. App. LEXIS 6685, at \*17–18 (4th Cir. Apr. 3, 1998).

infringement or invalidity, the first generic filer may maintain the exclusivity period by reaching a settlement agreement with the pioneer manufacturer.<sup>38</sup> The certainty of the bounty has been identified by Hemphill and Lemley as the primary facilitator of the anti-competitive behavior that this Article shall explore.<sup>39</sup>

### *C. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003*

Congress crafted the amendments contained within the Medicare Prescription Drug, Improvement, and Modernization Act of 2003<sup>40</sup> (“MMA”) to prevent both brand-name drug makers and generic producers from manipulating certain elements of the Hatch-Waxman Act to bring about anti-competitive results. This article explores further the manner in which the Hatch-Waxman Act facilitates gaming below, but a brief introduction of such practices is required now so as to properly frame the amendments to the 1984 Act that the MMA affected.

First, the Act prevented pioneer drug manufacturers from “evergreening.”<sup>41</sup> This practice involved brand-name manufacturers listing additional patents in the Orange Book after an ANDA had been filed by a generic so as to secure multiple stays in respect of a single drug. For example, the manufacturer of the drug Paxil, pending litigation over a Paragraph IV challenge by a generic, listed additional patents over Paxil, forcing a total of five additional overlapping stays, which amounted to a stay of sixty-five months.<sup>42</sup> The MMA permits only one thirty-month stay with

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<sup>38</sup> § 355(j)(5)(D)(iv).

<sup>39</sup> Hemphill & Lemley, *supra* note 3, at \*17–18.

<sup>40</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 21, 26, and 42 U.S.C.).

<sup>41</sup> For a discussion of evergreening, see Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 233–35 (2001) and Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 81–83 (2004).

<sup>42</sup> H.R. REP. NO. 98-857, pt. 2, at 43, 51 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688.

respect to a single drug and has thus halted the practice of evergreening.<sup>43</sup>

The second problem tackled by the MMA was manipulation of the 180-day exclusivity period by pioneers and generics to stymie competition. In addition to unilateral action such as evergreening and “product hopping,”<sup>44</sup> the Hatch-Waxman Act also invited opportunities for collusion between the brand-name manufacturer and the first ANDA filer, both of whom would be eager to ward off further generic entry. Later ANDA filers for a particular drug could not market their generic versions until after the exclusivity period of the initial filer had elapsed, but the 180 days only started to run after the ‘first commercial marketing’ by the first filer.<sup>45</sup> The first filer was therefore able to effectively bottleneck later generic ANDA applicants by waiting to enter the market and frustrate competition beyond the pioneer drug manufacturer.

The ability of first-in-line generics to block subsequent ANDA filers invited collusion between the generic and the brand-name drug manufacturers. Patentees were eager to ward off any further assault on their patents and happy to pay the first filers through a settlement to refrain from commercialization and stand guard against subsequent ANDA filers. Such a situation was more beneficial to the generic first filer than a successful Paragraph IV defense.<sup>46</sup> In addition to possessing a secure and extremely valuable exclusivity period, it would now also receive additional revenue from the patentee. If the settlement took the form of a non-aggression pact without payment, both patentee and generic still stood to benefit from a prolonged period in which the first generic filer remained outside of the market. The patentee could rest safely in the knowledge that no further disputes lurked over the horizon, while the first filer could generate greater exclusivity

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<sup>43</sup> § 355(j)(5)(B)(iii).

<sup>44</sup> See generally Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1472 (2008) (“Product hopping brand name manufacturers (‘product hoppers’) make a slight alteration to their prescription drug and engage in marketing efforts to shift consumers from the old version to the new.”).

<sup>45</sup> Hemphill & Lemley, *supra* note 3, at \*25–27.

<sup>46</sup> *Id.* at \*27–29.

by driving away generic companies too cash-strapped to stay off the market for the remaining patent length plus the exclusivity period.<sup>47</sup>

The MMA sets out a number of forfeiture scenarios whereby a first filer may lose its exclusivity period, but the manner in which Congress devised these provisions robbed them of much of their efficacy. Forfeiture may be triggered by two events. The first is an event known as the “(aa) clause date,” either seventy-five days after FDA makes effective approval of the first applicant or thirty months after the date of submission of the first ANDA application.<sup>48</sup> The second event is the “(bb) clause date,” seventy-five days after the date on which at least one of the following has occurred regarding the patents in the Paragraph IV certification:

- (1) in an infringement action or declaratory judgment regarding the patent in the Paragraph IV certification “a court enters a final decision from which no appeal (other than petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed,” or
- (2) in an infringement action or a declaratory judgment a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed, or
- (3) the patent information submitted in the ANDA application is withdrawn by the applicant.<sup>49</sup>

The forfeiture event is triggered upon the occurrence of the later of the (aa) date or the (bb) date.<sup>50</sup> Even if more than thirty months pass after the ANDA is submitted, satisfying the (aa) clause, the (bb) clause does not come into effect where a settlement between the pioneer manufacturer and the first ANDA filer ends the litigation over the patent’s validity or the generic’s non-infringement.<sup>51</sup> A settlement ensures that no judicial determination initiates forfeiture of the 180-day period under the Hatch-Waxman Act.<sup>52</sup>

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<sup>47</sup> *Id.* at \*25–28.

<sup>48</sup> 21 U.S.C. § 355(j)(5)(D)(i)(I) (2006).

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> Ankur N. Patel, *Delayed Access to Generic Medicine: A Comment on the Hatch Waxman Act and the “Approval Bottleneck,”* 78 FORDHAM L. REV. 1075, 1086 (2009).

<sup>52</sup> *Id.*

Thus, even with the amendments contained in the MMA, careful drafting of a settlement agreement can avoid triggering the 180-day period.<sup>53</sup> In addition, it is difficult for later filers to overcome such collusion by obtaining a declaratory judgment due to issues of standing; for example, pioneer drug manufacturers can issue covenants not to sue later filers, taking their causes of action away.<sup>54</sup> Moreover, even if a subsequent ANDA filer was successful in forcing a forfeiture of the 180-day exclusivity period, it would not be able to recover the period for itself.<sup>55</sup> Thus, a subsequent applicant has no bounty of its own to overcome the expenses it would incur in seeking a declaratory judgment of patent invalidity necessary to trigger forfeiture, giving it little incentive to do so.<sup>56</sup>

This combination of mindful settlement drafting between pioneers and first-filing generics, the issuance by pioneer drug manufacturers of covenants not to sue subsequent generic challengers, and the possible lack of means of and/or incentive for later generic filers has greatly diminished the capability of the MMA to right the wrongs of the Hatch-Waxman Act.

### III. THE BENEFITS OF SETTLEMENT AND REVERSE PAYMENTS

Settlements are immensely beneficial. The judicial machinery of a jurisdiction is a scarce, expensive, and often error-prone resource for dispute resolution, and as such the practice of parties coming to agreements outside of court saves both the judiciary and society incalculable amounts of time and money.<sup>57</sup> In effect, trials represent the last resort, which makes a system of private settlement viable. Understanding the value of settlements, legislatures and judiciaries construct rules of civil and criminal procedure to maximize the probability that the parties will settle.<sup>58</sup> This orthodoxy that settlements are efficient and should therefore

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<sup>53</sup> See generally Sandoval, *supra* note 7, at 170–78.

<sup>54</sup> *Id.*

<sup>55</sup> § 355(j)(5)(D)(i)(III).

<sup>56</sup> *Id.*

<sup>57</sup> See Crane, *supra* note 7, at 757–62.

<sup>58</sup> See RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 597–601 (7th ed. 2007).

be encouraged and facilitated where possible is embedded in our legal culture, and it forms the foundation for those who promote settlements in the Hatch-Waxman context.<sup>59</sup>

To be sure, the problems of lengthy and expensive trials are prevalent in the arena of patent law.<sup>60</sup> Patent cases can cost litigants millions of dollars and span years, and such protracted litigation has the potential to cause one or all of the parties serious commercial damage, including the increasing likelihood valuable trade secrets will be divulged through an ongoing discovery process.<sup>61</sup>

A related issue is that of the uncertainty inherent in patent law cases. Questions of patent infringement and validity are exceedingly technical and elaborate, and so it is difficult to predict how judges and juries will digest the information during patent litigation and what determinations they will make. Settlement can stand as a far safer option from the point of view of a party to a patent suit.

Given these traditional efficiencies that settlement supplies to parties in a dispute, some commentators contend that, in the context of the Hatch-Waxman Act, the ledger should not just reference the savings to the court system and those that trickle down from the companies in tallying up the benefits of settlements to society at large—some argue that settlements can be a source of allocative efficiency in that they can facilitate generic entry quicker than litigation.<sup>62</sup>

A patent term has an approximate monetary value, and in settlement bargaining, parties use patent years as currency. A year that the brand-name manufacturer gets to keep its monopoly has a monetary value, and a year that a generic gets to be in the market (with its first six-months as a duopolist) has a different but also

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<sup>59</sup> See Crane, *supra* note 7, at 757–62; Schildkraut, *supra* note 7, at 1049.

<sup>60</sup> See generally MIELE, *supra* note 11, at 15.

<sup>61</sup> See Crane, *supra* note 7, at 757–59; Omri Ben-Sharar & Lisa Bernstein, *The Secrecy Interest in Contract Law*, 109 YALE L.J. 1885, 1886 (2000).

<sup>62</sup> See Dickey et al., *supra* note 10, at 377–85; Schildkraut, *supra* note 7, at 1057–67.

calculable monetary value.<sup>63</sup> As such, many Paragraph IV settlements represent an agreed-upon division in years between the parties of the remaining length of the patent in question. In making the settlement decision, parties calculate what their expected-value of litigation would be (probability of success multiplied by value of favorable outcome), and negotiate within the range of Pareto-superior bargains, which are those bargains that leave both the generic challenger and the brand-name drug manufacturer better off than they would be relative to litigation.<sup>64</sup> The risk aversion of one or both of the parties may expand the bargaining range, in that one or both of the parties may be willing to give some ground in return for the certainty of outcome that the settlement affords.<sup>65</sup>

Given that the bargaining chips are years, there exists within the settlement range pro-competitive settlements, settlements that permit generic entry faster than litigation would. If the chance of a pioneer drug maker winning a Paragraph IV challenge for a ten-year patent is fifty percent, then its expected value of litigation is the same as five years of patent enjoyment. From society's standpoint, that means five years until generic entry.

The argument of Schildkraut and others is that risk aversion renders pioneer drug makers willing to sacrifice some of their expected-value from litigation for certainty.<sup>66</sup> Generally, companies are less risk averse than individuals when dealing with

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<sup>63</sup> See Dickey et al., *supra* note 10, at 377–85; Schildkraut, *supra* note 7, at 1057–67. See generally Robert D. Willig & John Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655 (2004).

<sup>64</sup> See generally Willig & Bigelow, *supra* note 63.

<sup>65</sup> See POSNER, *supra* note 58, at 478 (noting that in general corporations behave in a less risk averse fashion than individuals, although individual firm managers with significant wealth locked up in the corporation may continue to exhibit a low tolerance for risk. Inventors, whether individual or corporate, may be less risk averse than the general population, since the outcome of research and development is often unpredictable although the rewards may be high); Sean T. Carnathan, *Patent Priority Disputes—A Proposed Definition of “First to Invent,”* ALA. L. REV. 755, 808 (1998) (asserting that inventors are likely among the least risk averse people on the planet); Crane *supra* note 7, at 759–62.

<sup>66</sup> See Schildkraut, *supra* note 7, at 1057–67.



high stake investments due to their comparatively more diversified investment portfolios, but risk aversion seems likely to be prevalent among pharmaceutical companies in respect to their most valuable drug patents. As alluded to above, many drug patents are either commercially useless because they are attached to a drug which does not gain FDA approval necessary for marketing,<sup>67</sup> or are not so lucrative as to cover the research, development, and regulatory approval costs that went into them.<sup>68</sup> Pharmaceutical companies rely on the profits earned from certain “blockbuster” drugs to subsidize the production and marketing of loss-making or simply less profitable drugs, as well as the research projects that do not yield a marketable drug.<sup>69</sup> Blockbuster drug patents are generally too rare to form part of a diversified portfolio, and, when dealing with them, pioneer drug companies rationally take a more risk averse approach. To have one blockbuster patent eradicated could mean the death of multiple avenues of research along with the possibility of future gain. As such, pharmaceutical companies often expand the range of possible settlement agreements beyond the expected value of litigation according to their desire to maintain with certainty a patent foundational to their company’s success. Litigation costs place the boundary of possible agreements even further beyond the expected value of trials. Recalling that settlement agreements in the Hatch-Waxman context often take the form of a division of remaining patent years between the generic and the pioneer, the fact that the risk and cost

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<sup>67</sup> The FDA will only approve about twenty percent of compounds that make it to human trials, and those compounds are a tiny subset of those that are initially studied. See U.S. DEP’T OF STATE, FOCUS ON: INTELLECTUAL PROPERTY RIGHTS 82 (2006), available at <http://www.america.gov/media/pdf/books/iprbook.pdf#popup>. See generally JAMES O’DONNELL, DRUG INJURY: LIABILITY, ANALYSIS, AND PREVENTION 60 (2d ed. 2005).

<sup>68</sup> See COOK, *supra* note 23, at xv (“For most drugs, the returns from marketing do not exceed the average capitalized costs of development. As a result, for a company’s average returns to exceed its average development costs, the company must discover and market a highly profitable drug from time to time.”).

<sup>69</sup> See FED. TRADE COMM’N, *Business Testimony: Current Innovation Landscape in Selected Industries*, in TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 5 (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>.

aversion of the pioneer broadens the settlement range means that generic entry can often occur sooner than it would under litigation alone. Thus we see one justification for non-aggression pact settlements between pioneers and generics pursuant to Paragraph IV certification suits.

However, commentators argue further that the reverse payments can, in a variety of circumstances, facilitate this welfare-enhancing capability of Hatch-Waxman patent settlements.<sup>70</sup> First, if there exists no connection between the negotiating ranges of the parties due to information asymmetry and mistaken optimism, reverse payments may mend the gap between the ranges by raising the expected value of settlement to the generic drug maker compared to litigation. By way of example, suppose a generic was only willing to accept near-immediate entry, one or two years from settlement, due to mistaken optimism about trial. A reverse payment from a patentee could make the generic willing to wait for a time acceptable to the patentee. In this sense, a reverse payment could be pro-competitive, in that it avoids litigation that would most likely have led to generic entry only after the expiration of the patent, and could lead to generic entry substantially earlier.<sup>71</sup>

In addition to circumstances of mistaken optimism, a reverse-payment bridge between settlement ranges may be called for where a generic is in need of immediate revenue to stay afloat and, therefore, be unwilling to accept a settlement agreement that requires it to wait for a number of years during which it would receive no income.<sup>72</sup> Of course, reverse payments are a double-edged sword in that they also have an anti-competitive potential, with the division of years perhaps often falling outside the consumer-friendly settlement range.

Patent settlements can be valuable not only in terms of allocative efficiency, but also in terms of innovative efficiency. The above discussion relates to how the risk aversion of pioneer drug manufacturers may lead to quicker generic entry of an existing drug, but risk aversion also plays a part in the decision to

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<sup>70</sup> Schildkraut, *supra* note 7, at 1059–65.

<sup>71</sup> *Id.* at 1063.

<sup>72</sup> *Id.* at 1064.

invest in the development of a drug. A firm will sink funds into research and development when the present value of the expected future income stream from the developed product meets or exceeds its development and production costs.<sup>73</sup> In calculating the expected future income stream of the product, the company will account for the possibility that a successful and profitable patent will be declared by a court to be invalid. Settlement operates as a form of insurance against the risk of a declaration of invalidity. By providing a range of certain outcomes, settlement increases the ex ante value of a drug to manufacturers who maintain even a nominal level of risk aversion. Thus, settlements form part of the Hatch-Waxman set of incentives to innovate in the pharmaceutical field, and their removal or restriction in this arena could be damaging in the long term.

In the context of Hatch-Waxman Paragraph IV certification suits, settlements, both with and without reverse payments, can give rise not only to static efficiencies—in that time and money are saved by courts and litigants—but also dynamic allocative and innovative efficiencies. By accelerating generic entry, settlements increase consumer surplus more quickly, and provide an insurance mechanism for the risk averse to encourage them to invest in the creation of new drugs.

#### IV. THE DANGERS OF SETTLEMENTS AND REVERSE PAYMENTS

Settlements in the context of Paragraph IV challenges are the source of considerable vitriol within certain sectors of the legal academy, the FTC, and other factions within congress. In light of the litany of benefits seemingly stemming from settlements that are laid out above, what is the rationale behind this displeasure, and is it justified?

##### A. *Static Allocative Inefficiency*

The most commonly encountered arguments leveled against settlements within Paragraph IV challenges relate to how such settlements may be calibrated so as to hurt consumer welfare by

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<sup>73</sup> See Crane, *supra* note 7, at 762–65.

unnaturally delaying generic entry.<sup>74</sup> The primary focus of this academic discussion is on settlements which contain reverse payments.

Commentators such as Hemphill, Hovenkamp, and Lemley argue that reverse payments are suspicious on the understandable presumption that if a drug maker is willing to pay another to drop a challenge and stay off the market for a number of years, the likelihood seems greater that the patent in question is weak or ill-gotten.<sup>75</sup> Thus agreements involving such payments effectively safeguard bad patents, and force lengthened monopoly and later duopoly prices that society should not have to pay.

Some have countered this argument by arguing that reverse payments serve a valuable role in negotiation by overcoming the information asymmetries and misplaced optimism that can often bar settlement outside of court.<sup>76</sup> However, the response is incomplete. In spite of the legitimate functions that reverse payments can serve, they can also accommodate the anti-competitive side of the settlement range, providing for later generic entry than would occur under litigation.

The question is then which model is more realistic. While there is something intuitively attractive to the idea that a reverse payment betrays knowledge on the part of the brand-name drug maker that its patent is vulnerable, the highly uncertain nature of patent trials militates against this notion that such payments are necessarily or per se illegitimate. That is not to say they should not be treated with suspicion, and indeed Hemphill provides us with a nuanced argument as to why reverse payments might tend towards being anti-competitive.<sup>77</sup> Hemphill takes the model used by Schildkraut but modifies it to include the *certain* value of the 180-day exclusivity period, which accrues to the first generic filer regardless of success at trial and which is difficult to forfeit; with

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<sup>74</sup> See generally Bulow, *supra* note 7; FELDMAN, *supra* note 7; HOVENKAMP ET AL., *supra* note 7; Carrier, *supra* note 2.

<sup>75</sup> Hovenkamp et al., *supra* note 3, at 1751–57.

<sup>76</sup> See Crane, *supra* note 7, at 759–62; Schildkraut, *supra* note 7, at 60–61; *supra* text accompanying notes 70–71.

<sup>77</sup> Hemphill, *Paying for Delay*, *supra* note 3, at 1588–95.

this extra bargaining chip in place, Hemphill argues that Paragraph IV settlements agreements are more likely to fall beyond the expected-value point of trials on the anti-competitive side of the spectrum.<sup>78</sup>

Buttressing this argument is the realistic observation that, if receiving reverse payments, a generic first filer is largely indifferent to entering the market sooner rather than later,<sup>79</sup> as its exclusivity period and therefore the bulk of its profits, is protected. The generic producer may rationally be happy to accept a payment in compensation for the discounted value of its future profits and stay off the market, while the pioneer may be willing to make such a payment, even if it is substantial, in order to preserve even a fraction of its monopoly rents. This, Hemphill argues, indicates a systemic problem with reverse payments, which should lead us to see them as presumptively, but not per se, illegal.<sup>80</sup>

#### B. *Dynamic Allocative Inefficiency*

Lemley and Hemphill also pointed to the dangers inherent in Hatch-Waxman settlements in terms of dynamic allocative inefficiency.<sup>81</sup> The framers of the Hatch-Waxman Act designed the 180-day exclusivity period as a bounty to entice generic companies to undertake the heavy litigation expenses that go alongside a patent-invalidity suit so that they might effectively police bad patents.<sup>82</sup> Yet effective policing has not resulted from the presence of this bounty. Yes, there have been many Paragraph IV *challenges*, but the challenges do not tend to result in patents being declared invalid.<sup>83</sup> As explained above, the relative certainty of gaining the 180-day exclusivity period has led generic challengers to be somewhat indifferent to the continuation of a patent. A generic, through filing a challenge, can stand to gain more from

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<sup>78</sup> *Id.* at 1590–93.

<sup>79</sup> See Schildkraut, *supra* note 7, at 1058–59 (discussing situations in which the generic is so strapped for cash that it must enter the market immediately).

<sup>80</sup> Hemphill, *Paying for Delay*, *supra* note 3, at 1615.

<sup>81</sup> Hemphill & Lemley, *supra* note 3, at \*20–24 (arguing consumers lose when patent settlements are reached).

<sup>82</sup> Carrier, *supra* note 2, at 41–47.

<sup>83</sup> See Hemphill & Lemley, *supra* note 3, at \*2.

extracting payment from the pioneer drug manufacturer and/or through maintaining a non-aggression pact with the patentee than it might through going the whole nine yards to take the patent down.

Another issue to consider is the practice of rent seeking by generic challengers that aim to game the pioneer manufacturer into giving up as much of the worth of the patent as possible and to block further competition from later ANDA filers.<sup>84</sup> These rents can be greater and more secure than those the generics stand to gain under a successful Paragraph IV challenge. Generics and patentees can construct settlement agreements in such a way that it is very difficult for later ANDA filers to trigger the 180-day period that expedites the transition from monopoly to duopoly to competitive market.<sup>85</sup> As in the static inefficiency case, the blame for the ability of generics and patentees to collude to block further generic entry, and, in a more general sense, for the mutation of the source of rents from being policing patentees to colluding with them, lies with the certainty of the patent.<sup>86</sup> Lemley and Hemphill's solution is to require that the generic challengers "successfully defend" a patent infringement suit born of a Paragraph IV challenge.<sup>87</sup> With this framework in place, the incentives of patentees and generic challengers could be reset to adversarial, thus bringing about more effective policing by generics, alleviating the problem of later ANDA filer bottlenecks, and enhancing consumer welfare.<sup>88</sup>

### C. *Dynamic Innovative Inefficiency*

The focus of this paper is another inefficiency that Paragraph IV settlements may perpetuate, and one that commentators have

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<sup>84</sup> *Id.* at 16–25.

<sup>85</sup> Sandoval, *supra* note 7, at 152–56.

<sup>86</sup> See Hovenkamp et al., *supra* note 3, at 1755–56.

<sup>87</sup> Hemphill & Lemley, *supra* note 3, at \*35–35 (“We do not propose an exact return to the successful defense requirement . . . . The first generic would receive the bounty if it successfully defeats the patent owner, obtains a settlement that permits immediate entry, or receives FDA approval having never been sued.”).

<sup>88</sup> See Hemphill & Lemley, *supra* note 3, at \*38–49.

not so fervently targeted, that of dynamic innovative inefficiency.<sup>89</sup> What I mean by dynamic innovative inefficiency is the inefficiency of too little innovation as a result of the expected value of pharmaceutical patents being insufficient. This notion may appear counter-intuitive, given that one of the arguments proffered by those who favor Paragraph IV settlements is that they preserve or even enhance the expected value of the patent, thus giving greater incentive to innovate.<sup>90</sup> If patents were left to the mercy of trial, the argument goes, the necessary litigation expenses and unavoidable uncertainty would reduce the patent's value, as of course could the court's ruling, perhaps to a significant extent.<sup>91</sup>

Some commentators on the other side of the settlement debate share this intuition that patent settlements preserve or enhance the expected value of patents, but they argue that this preservation is not warranted when balanced against the allocative harm it causes. Hemphill characterizes the Hatch-Waxman Act as a tax on innovation.<sup>92</sup> This analogy is used to make the argument that pay-for-delay settlements should be presumptively illegal in that they generally represent "tax evasion," in the sense that pioneers collude with generics to illegitimately safeguard their patents.<sup>93</sup> So how then could settlements be damaging innovative efficiency by reducing the expected value of patents? In order to see why, we have to broaden our analysis to include not only those patentees who have received bad patents, but also those who have received good patents. Both of these classifications are crude in that determining what is a good or bad patent is left to the United States Patent and Trademark Office (PTO) and the court system, neither of which is an entirely capable arbiter of the elaborate and technical matters at play.<sup>94</sup> We may suspend consideration of problems with this taxonomy for the time being, and proceed with

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<sup>89</sup> It is usually brought up in the context of support for Hatch-Waxman settlements. See, e.g., Crane, *supra* note 7, at 779–96.

<sup>90</sup> *Id.*

<sup>91</sup> See generally Dickey et al., *supra* note 10.

<sup>92</sup> Hemphill, *Paying for Delay*, *supra* note 3, at 1604–06.

<sup>93</sup> *Id.* at 1604–10.

<sup>94</sup> See Douthett, Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 46 (2007).

this categorization to make some initial generalized points about dynamic innovative efficiency within the Hatch-Waxman Act regime.

As Hemphill argues, the intent behind the Hatch-Waxman Act was to effect a compromise between allocative and innovative efficiency.<sup>95</sup> In other words, the aim was to lengthen legitimate patents while at the same time limiting or eradicating bad patents. However, the manner in which the Act makes bad patents vulnerable is not surgical in that it renders many justified patents prone to attack.

We must remember how difficult it is to predict the outcome of a patent case. The PTO and court system are plagued by time constraints, limited understanding, and systematic biases.<sup>96</sup> The objective strength of a patent may not be reflected in a court decision. Thus, if faced with a Paragraph IV challenge, a brand-name manufacturer's confidence in its own patent will not always track its determination as to the probability of success at trial. In the same sense, in challenging a patent, a generic manufacturer need not be sure of the challenged patent's frailty in order to reasonably expect success at trial.

This is why settlement is so prevalent in the Hatch-Waxman context and, indeed, in all patent suits. Each party's call on the probability of success at trial tends towards fifty percent, making settlement, albeit with a substantial range, the more rational option for both. This gravitation towards fifty percent determinations on the probability of success is reflected in the models used by Schildkraut, Dickey et al. and Hemphill.<sup>97</sup> So, if challenged, a

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<sup>95</sup> Hemphill, *Paying for Delay*, *supra* note 3, at 1604–10.

<sup>96</sup> See Devlin, *supra* note 15, at \*33–66.

<sup>97</sup> See Dickey et al., *supra* note 10, at 378 (“[T]he generic manufacturer both believes that it has and in fact has a fifty percent chance of winning the patent case[,] and the brand-name manufacturer also has, and perceives, a fifty percent chance of winning.”); Hemphill, *Paying for Delay*, *supra* note 3, at 1604–10. As Schildkraut has explained:

We can illustrate risk aversion using the example of two litigants negotiating a dispute in 2000 over a patent that expires in 2010. The patent holder believes it has a fifty percent chance of winning, meaning



settlement agreement may diminish the value of even a strong patent. Both the challenger and the patentee know that patent suits can, at worst, be very expensive coin flips, and both know that in this context it is rational for the patentee to spend nearly the full value of the patent to maintain a slice of its monopoly rents—the potential for gaming is manifest. This is the rent that Lemley and Hemphill identified as being sought by generic challengers, and the reason why challenges are so common.<sup>98</sup> A generic need not win a patent invalidity case; it need only challenge and thereafter manipulate the brand-name manufacturer into parting with some of its monopoly profits or allowing it to enter the market sooner than it would under litigation.

Now the problem of dynamic innovative inefficiency becomes clear. Given the certainty of their bounty, generics have little reason to be selective in their challenges, and so they may as well go after the holders of good patents. These patentees may have little choice but to part with some, perhaps a substantial amount, of their profits. This means that patents in the pharmaceutical field are of reduced value. Regardless of strength, they are subject to challenge, and given the unpredictability of patent litigation, pioneer drug manufacturers may lose much of even a good patent's value in order to secure settlement. In other fields, the lack of certain compensation for litigation places a limit on challenges, one that is not present in pharmaceuticals. Thus, the holders of good patents are collateral victims of a policing mechanism that is ineffective at tackling bad patents. Taking Hemphill's characterization of the 180-day bounty as a tax on innovation, we can see that the tax is too high.<sup>99</sup> Yet, we need to localize this issue, and assess its depth.

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that the mean expected outcome of the litigation is that the alleged infringer will enter in 2005.

Schildkraut, *supra* note 7 at 1057–67.

<sup>98</sup> See Hemphill & Lemley, *supra* note 3, at \*3.

<sup>99</sup> See Hemphill, *Paying for Delay*, *supra* note 3, at 1612–16 (“The combined effect of the tax and subsidy reflects contrary forces. Consumer access is promoted by the unique incentive to challenge patents. Innovation is supported by the term extensions, initial delay based upon data exclusivity, and automatic stay.”).

Pursuant to the MMA amendments to the Hatch-Waxman Act, settlements brokered between generics and patents regarding ANDA Paragraph IV filings have to be reported to the FTC.<sup>100</sup> The number of settlements reported has grown steadily from fourteen in 2004 to 156 in 2011.<sup>101</sup> Of the 156 settlements filed in 2011 so far, fifty-four involve first-filing generics.<sup>102</sup> Settlements allowing immediate generic entry have grown from nine in 2004 to twenty-eight in 2011, while the number involving compensation has risen from zero in 2004 to twenty-eight in 2011.<sup>103</sup> Lawsuits have been particularly prevalent on blockbuster drugs such as Cipro, Claratin, Paxil, Pravachol, Prisolec, Prozac, and Zoloft.<sup>104</sup> Of the ten top-selling brand drugs in the United States in 2006, at least seven (Nexium, Pravacid, Singulair, Effexor, XR, Plavix, and Lexapro) were the subject of litigation under the Hatch-Waxman Act in 2008.<sup>105</sup> The twenty-eight pay-for-delay settlements filed with the FTC in 2011 involve twenty-five different branded pharmaceutical products with combined annual U.S. sales of more than nine billion dollars.<sup>106</sup>

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<sup>100</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1112–1113, 117 Stat. 2066 (codified as amended at 21 U.S.C.).

<sup>101</sup> BUREAU OF COMPETITION, FED. TRADE COMM’N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2004 1–3 (2005) [hereinafter AGREEMENTS FILED IN 2004], available at <http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf>; BUREAU OF COMPETITION, FED. TRADE COMM’N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2011 1 (2011) [hereinafter AGREEMENTS FILED IN 2011], available at <http://www.ftc.gov/os/2011/10/1110mmaagree.pdf>.

<sup>102</sup> AGREEMENTS FILED IN FY 2011, *supra* note 101.

<sup>103</sup> AGREEMENTS FILED IN FY 2004, *supra* note 101, at 2; AGREEMENTS FILED IN FY 2011, *supra* note 101; see also Dickey et al., *supra* note 10, at 356–57.

<sup>104</sup> See Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. CORP. L. 309, 331 (2005).

<sup>105</sup> Amended Brief for 28 Professors of Law, Business, and Economics as Amici Curiae Supporting Appellants at 9, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (No. 2008-1097).

<sup>106</sup> See AGREEMENTS FILED IN FY 2011, *supra* note 101.

One of the main problems in interpreting these figures with respect to dynamic innovative inefficiency is that, given that the courts did not have the opportunity to examine the issue of patent validity, we cannot make an instant call on whether these settlements represent bad patentees preserving their ill-gotten gains or good patentees losing out. However, we can make some progress towards assessing the reality of the situation. The first contextual matter to note is that the problem of bad patents in the pharmaceutical industry is not as pronounced as in other fields, such as information technology, and so the percentage of bad patents among these settlements is not likely to be significant.<sup>107</sup>

Second, there are no strong off-setting factors. It could be argued that good patentees can extend or preserve their patents in the same manner as bad patentees do. This would off-set the diminished bad patents, and restore the *ex ante* expected value of pharmaceutical patents. The problem with such an argument is that it neglects the reality of gaming at play. If a first ANDA filer challenges a patent, its preservation or extension will rarely be free, and the pioneer will have to pay the filer some money to compensate it for later entry. As Hemphill and Lemley note, most non-aggression pact settlements (those without pay-for-delay agreements) entail entry before the patent in question is set to expire.<sup>108</sup> In effect, this potential off-setting factor is itself off-set by the money paid to gain it.

The above figures also reveal that the nature of the selection bias of generic Paragraph IV filers is particularly harmful to innovation. As a first generic ANDA filer is relatively unconcerned with the strength of the patent it is challenging, knowing its bounty does not need the support of a favorable court decision, its most rational targets are the most lucrative patents, the blockbusters.<sup>109</sup> For example, pioneer drug manufacturers are most risk averse with respect to their blockbuster patents due to the difficulties of diversification and are eager to settle and not seek a

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<sup>107</sup> See generally Mark Lemley et al., *What to Do About Bad Patents*, 28 REGULATION 10 (2005).

<sup>108</sup> See Hemphill & Lemley et al., *supra* note 3, at \*21.

<sup>109</sup> See Devlin, *supra* note 15, at \*62.

court determination when such patents are the subject of Paragraph IV certifications.

Thus, as a preliminary matter, the first generic filers can be confident that a Paragraph IV suit concerning a blockbuster patent will likely not be taken so far as a decision, which has the potential to go against the filer and rob it of its bounty. However, pioneers could arguably be sufficiently risk averse to desire settlement in cases of weakly profitable patents as well. What makes blockbuster patents so attractive to generic assault is that the risk-aversion of the patentees is severe enough in these circumstances that they would be rationally willing to part with a substantial fraction of the monopoly rents born of the patent in question. The room for generic maneuvering and manipulation is considerable, and they stand to collect a significant ransom from the pioneer drug manufacturers.

Therefore, the more valuable a patent is, the more vulnerable it is, and the more likely it is that its associated rents will have to be relinquished due to a Paragraph IV challenge. This means that pioneers can be severely punished for being successful, and so their incentive for producing popular drugs, which are often the most socially beneficial, stands to be radically diminished. Recalling that the profits from these blockbuster drugs are needed to subsidize the research and development of drugs that stand to make a loss, the threat which generic first filers pose to blockbuster patents could infect a large tract of the innovation landscape, preventing the investment and development of a panoply of drugs.

With these factors in mind, it is reasonable to assert that Paragraph IV settlements represent a mix of good patents being shortened and bad patents being lengthened, and it is arguable that the former constitutes a bigger share if we are happy to make a generalized statement about the bad patent problem being not so severe in the pharmaceutical arena. Probing the unrefined categorization of good and bad patents will reveal a more nuanced picture of the innovative efficiency problem, but, with this rough bifurcation in place, we can say at this stage that good patents are taking a hit from a policing system that is largely ineffective at taking down bad patents.

## V. ANTITRUST AND REGULATORY CONTROL

So what response should the courts and legislature make? This article argues that bringing the consideration of dynamic innovative efficiency to bear on the question of reform, an approach that combines regulatory restructuring together with enhanced antitrust control, is required. Hovenkamp et al.'s suggestion of inquiring into patent validity in determining settlement validity should ease issues of ineffectual policing of bad patents,<sup>110</sup> while Lemley and Hemphill's proposal of earned exclusivity will go towards preventing collateral damage to innovation.<sup>111</sup> In order to frame the discussion of reform, we may now turn to a brief outline of the stances courts have taken with regard to Paragraph IV settlement agreements.

### A. *The Courts' Approach to Hatch-Waxman Settlements*

In the early days of the Hatch-Waxman Act, the courts treated settlements involving reverse payments with the highest suspicion. For example, *In re Cardizem CD Antitrust Litigation*<sup>112</sup> concerned a Paragraph IV certification filed first by Andrx Pharmaceuticals regarding the patent for the drug Cardizem CD, used to treat hypertension and angina, that issued in 1995 to Carderm, which licensed it to Hoechst Marion Roussel.<sup>113</sup> Hoechst sued Andrx in 1996 following its Paragraph IV certification filing, triggering a thirty-month stay on FDA approval.<sup>114</sup> In 1997, The FDA nonetheless granted Andrx provisional approval of their ANDA, which would take full effect upon expiration of the thirty-month period.<sup>115</sup> In response to this tentative approval, an interim agreement between Hoechst and Andrx was brokered, whereby Hoechst agreed to pay Andrx forty million dollars annually in return for its promise not to market its generic of Cardizem CD without a final, unappealable court determination that the patent

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<sup>110</sup> See Hovenkamp et al., *supra* note 3, at 1734–35.

<sup>111</sup> See generally Hemphill & Lemley, *supra* note 3.

<sup>112</sup> 332 F.3d 896 (6th Cir. 2003).

<sup>113</sup> *Id.* at 899–903 (giving a summary of many of the important facts).

<sup>114</sup> *Id.* at 902.

<sup>115</sup> *Id.*

was not infringed.<sup>116</sup> Subsequent to the FDA's issuing its final approval of Andrx's ANDA in 1998, Hoescht began making quarterly payments of ten million dollars to Andrx pursuant to the interim agreement.<sup>117</sup> Two months later, Andrx reformulated its generic of Cardizem, and the FDA approved this version the following year.<sup>118</sup> The interim agreement was thereafter terminated and a settlement agreement disposing of the infringement suit was put in place with Hoescht paying \$50.7 million to Andrx for total payments of roughly \$90 million.<sup>119</sup>

The Sixth Circuit found this agreement to be per se anti-competitive, in that it guaranteed to Hoechst that "its only potential competitor" would "refrain from marketing its generic version of Cardizem CD even after it had obtained FDA approval."<sup>120</sup> In addition, the court was deeply concerned 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 marketing exclusivity, which Andrx had agreed not to relinquish or transfer."<sup>121</sup> The court concluded that the agreement was "a horizontal agreement to eliminate competition . . . a classic example of a per se illegal restraint of trade."<sup>122</sup>

In *Schering-Plough Corp. v. F.T.C.*,<sup>123</sup> the Eleventh Circuit took a different approach than the *Cardizem* court. Schering-Plough ("Schering") owned the patent to K-Dur 20, a drug used to treat congestive heart disease and high blood pressure. In 1995, Upsher-Smith Laboratories ("Upsher") developed a generic version of K-Dur 20, and sought FDA approval.<sup>124</sup> In the same year ESI Lederle ("ESI") also sought to market a generic version

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<sup>116</sup> *Id.*

<sup>117</sup> *Id.* at 903.

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

<sup>120</sup> *Id.* at 907.

<sup>121</sup> *Id.*

<sup>122</sup> *Id.* at 908.

<sup>123</sup> 402 F.3d 1056 (11th Cir. 2005).

<sup>124</sup> *Id.* at 1058–62 (giving a summary of many of the important facts).

of the drug.<sup>125</sup> After the two Paragraph IV infringement suits were filed, two settlement agreements were made between Schering, Upsher, and ESI.<sup>126</sup> Upsher agreed not to enter the market until September 1, 2001, in return for Schering buying a number of licenses from Upsher.<sup>127</sup> ESI was to stay out of the market until January 1, 2004, and in return would receive a \$10 million payment from Schering upon obtaining FDA approval by a certain date.<sup>128</sup> The FTC condemned the agreements, observing that the licenses paid to Upsher and ESI by Schering greatly exceeded the worth of the products it received, rendering the license fees anti-competitive reverse payments.<sup>129</sup> The Eleventh Circuit reversed the finding of the FTC and condoned the agreements, concluding “that neither the rule of reason nor per se analysis [was] appropriate” for the agreements,<sup>130</sup> and noting that emphasis on anti-competitive effects was “ill-suited” for patent cases which were exclusionary and anti-competitive by nature.<sup>131</sup>

The Eleventh Circuit enunciated a test for the validity of settlement that focused on “(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anti-competitive effects.”<sup>132</sup> Looking to these factors, the court found that the payments by Schering to Upsher and ESI to refrain from commercialization did not exceed the scope of its patent, which granted Schering a right to exclude competitors.<sup>133</sup> The settlement agreements were, in the view of the court, made to dispose of legitimate litigation.

The Second Circuit and the Federal Circuit followed the *Schering* analysis in the cases *In re Tamoxifen Citrate Antitrust Litigation*<sup>134</sup> and *In re Ciprofloxacin Hydrochloride Antitrust*

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<sup>125</sup> *Id.* at 1060.

<sup>126</sup> *Id.*

<sup>127</sup> *Id.* at 1059.

<sup>128</sup> *Id.* at 1060.

<sup>129</sup> *Id.* at 1062.

<sup>130</sup> *Id.* at 1065.

<sup>131</sup> *Id.* at 1065–66.

<sup>132</sup> *Id.* at 1066.

<sup>133</sup> *Id.* at 1076 (noting that the agreements “fell well within the protections of the...patent”).

<sup>134</sup> See 466 F.3d 187, 193 (2d Cir. 2006).

*Litigation.*<sup>135</sup> In the former, Imperial Chemical Industries (ICI) reached a settlement agreement with Barr Laboratories (Barr) and its supplier after Barr filed a Paragraph IV infringement suit for the breast cancer medication tamoxifen.<sup>136</sup> Under the terms of the agreement, Zeneca, a former subsidiary of ICI and the holder of the rights to the tamoxifen patent, would pay Barr twenty-one million dollars and its supplier forty-five million dollars for withdrawing its challenge to the patent and for staying off the market until its expiration by switching its ANDA certification from Paragraph IV to Paragraph III.<sup>137</sup> Barr also agreed to switch back to Paragraph IV in the event of a court declaring the tamoxifen patent invalid, thus delaying further generic entry through its 180-day exclusivity period.<sup>138</sup> The court reiterated the *Schering-Plough* considerations, and, once again, argued that although a patent settlement agreement entails some denial of competition, it is presumed to be valid, provided it does not arise from sham litigation. The Second Circuit admitted that it “seem[s] ‘suspicious’ [for] a patent holder [to] settl[e] patent litigation against a potential generic manufacturer by paying . . . more than either party anticipates the manufacturer would earn by winning the lawsuit and entering the newly competitive market in competition with the patent holder . . . [but] the suspicion abates upon reflection.”<sup>139</sup>

*In re Ciprofloxacin* discussed an agreement between Bayer Pharmaceuticals (Bayer) and Barr Laboratories (Barr), whereby Barr would receive forty-nine million dollars in return for switching its Paragraph IV certification regarding Ciprofloxacin (Cipro), a drug used to treat bacterial illness, to a Paragraph III, and not entering the market until the expiration of Bayer’s patent.<sup>140</sup> The parties also agreed that Barr would not manufacture a generic version of Cipro and that Bayer would “either supply

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<sup>135</sup> See 544 F.3d 1323, 1336 (Fed. Cir. 2008).

<sup>136</sup> *In re Tamoxifen*, 466 F.3d at 193–99 (giving a summary of many of the important facts).

<sup>137</sup> *Id.* at 193–94.

<sup>138</sup> *Id.*

<sup>139</sup> *Id.* at 208.

<sup>140</sup> *In re Ciprofloxacin*, 544 F.3d at 1327–30.



Barr with Cipro for resale or make quarterly payments” from 1998 until 2003.<sup>141</sup>

The majority of circuits have moved away from a strict per se treatment of reverse payment settlements to a position of substantial deference to patent scope. The non-aggression pact breed of settlements attracts no judicial concern whatsoever. The courts ground their approach on the importance they attach to the arguments in favor of settlements that are outlined above (i.e., the costs they save and the assistance they render to the incentives to innovate provided by the Hatch-Waxman Act).<sup>142</sup> In addition, the courts lean heavily on the presumption of patent validity as means of avoiding the thorny issue of patent scope. The courts assume that in the absence of a clear sham, the pharmaceutical patents that come before them are valid, and are therefore capable of granting considerable powers of exclusion to the patentees. Within the patent’s zone of discretion, the patentee can essentially do what it pleases in a competitive sense, including paying generics to back off. The courts have also intimated that reverse-payment settlements are a natural element of the Hatch-Waxman regime,<sup>143</sup> and are necessary for its smooth functioning, drawing, once again, from the wealth of arguments in favor of settlements to bolster this claim.

Many see the approach of the courts as a clear failure to attend to the problems of bad patents, one of the chief concerns motivating the construction of the Hatch-Waxman regime.<sup>144</sup> The obedience to the presumption of patent validity is not soundly based given the consensus that the operation of the PTO in granting patents is highly error-prone<sup>145</sup> and that the courts have not analyzed, in depth, the economic arguments against reverse payments since *In re Cardizem*.<sup>146</sup> The courts must adopt a

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<sup>141</sup> *Id.* at 1329.

<sup>142</sup> See Crane, *supra* note 7, at 776–79.

<sup>143</sup> See Carrier, *supra* note 2, at 66.

<sup>144</sup> See Crane, *supra* note 7, at 776–96; Hemphill & Lemley, *supra* note 3, at \*25–30.

<sup>145</sup> See Lemley et al., *supra* note 107; see also *supra* note 96 and accompanying text.

<sup>146</sup> *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

different attitude in order to correct the excesses of Hatch-Waxman settlements. However, it is not certain that antitrust can act alone in restoring the balance, especially with respect to preventing damage to dynamic innovative efficiency, the focus of this paper. Regulatory restructuring is needed to take significant strides in the right direction, but before explaining the precise nature of regulatory reform, I will first discuss the role antitrust should fulfill in this partnership.

B. *A Rule of Presumptive Illegality*

The starting point for determining the course antitrust should take is to recognize that there are both clear economic benefits and clear detriments to settlements within the Hatch-Waxman regime. These benefits and detriments vary widely and independently according to the circumstances at play. Therefore, it would appear that treating either reverse-payment settlements or non-aggression pact settlements as per se illegal would not be consistent with the spirit of the doctrine. Per se illegality is a device to save courts from reassessing the economic merits of a particular practice each time it presents itself where this practice will have damaging, anti-competitive effects. Hatch-Waxman reverse-payment settlements are considered, by even some of their sternest critics, to have the potential to be more efficient than litigation, and so condemning their use wholesale seems inappropriate.

However, in the opinion of Hovenkamp, Hemphill, Lemley and this author, the certainty of the 180-day bounties forces the settlement range in the majority of reverse-payment cases to fall on the anti-competitive side.<sup>147</sup> Hovenkamp et al. thus suggest a rebuttable presumption of illegality to be placed on agreements between pioneers and generics wherein the pioneer pays the generic to refrain from entering the market.<sup>148</sup> This presumption can be rebutted “by showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation

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<sup>147</sup> See Hovenkamp et al., *supra* note 3, at 1756; Hemphill & Lemley, *supra* note 3, at \*17–18.

<sup>148</sup> Hovenkamp et al., *supra* note 3, at 1759.

and collateral costs attending the lawsuit.”<sup>149</sup> This suggestion is echoed by others such as Carrier and Crane,<sup>150</sup> who differ slightly on the details, but who both agree that a quick look into the strength of the pioneer’s patent is needed if the court is to be in some way confident that the settlement was an expression of legitimate risk aversion on the part of the pioneer as opposed to an attempt to extend the life of a patent it had no right to receive in the first place.<sup>151</sup> If this presumption were in place, the pioneer would be cut off from its avenue of manipulation, and generics would be more inclined to complete a Paragraph IV challenge against a weak patent, knowing that it could not gain any greater reward from settlement. The alignment of incentives between the patentee and generic would dissolve, potentially leading to more effective policing and quicker generic entry. However, a presumption would face problems of workability in that a quick look at the strength of a relevant patent may paint only a very crude picture of the reality.<sup>152</sup> Some bad patents may slip through the cracks in rebuttal, but one can say that, in general, the presumption would bring about an improvement in policing. The court would have to be careful not to extend the inquiry into the merits too much, lest the case absorb the invalidity case and add irremovable confusion to the proceedings.<sup>153</sup>

The presumption would not effectively tackle the problem of dynamic innovative efficiency born of the adverse-selection of the generics. As discussed above, it is not weak patents that are the choicest targets for generics, rather it is valuable patents, which may or may not be strong.<sup>154</sup> While valuable but weak patents will be thoroughly policed under a presumption, valuable but strong patents may still come under undeserved attack. If a generic is aware that the presumption can be rebutted by a showing that the patent is more likely valid than invalid, it will be eager to

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<sup>149</sup> *Id.*

<sup>150</sup> See Crane, *supra* note 7, at 776–96; Carrier, *supra* note 2, at 67.

<sup>151</sup> Crane, *supra* note 7, at 776–96.

<sup>152</sup> *Id.* (showing that Crane accepts this limitation, but offers a number of interpretive aids to increase the accuracy of the “quick-look”).

<sup>153</sup> See Hovenkamp et al., *supra* note 3, at 1759.

<sup>154</sup> See Devlin, *supra* note 15, at \*58–66.

manipulate the owners of such a patent into assenting to a harsh settlement agreement. Thus, for strong, valuable patents the status quo would remain essentially unchanged—the generic would still be armed with its 180-day exclusivity period and a knowledge that the pioneer will likely be sufficiently cautious to avoid the full rigor of a patent trial, even if a court has deemed that its *ex ante* likelihood of success is considerable.

The bluntness of the quick look at the merits might, at times, favor the good patentees. In contrast, a court might, at other times, consider the chances of success of the hypothetical good patentee to be insignificant and so force a generic challenger to take an infringement suit to verdict, with the greater analysis of a full patent trial that proves the strength of the patent and saves the pioneer from having to hand over anything to the generic. But which is likelier? Because of this uncertainty, this article argues that a presumption of illegality would not do much to cure the innovation ills and would serve mainly to effect more stringent policing of bad patents and accelerate generic entry.

### C. *Regulatory Reform*

A possible answer to the innovation and adverse-selection problem lies in regulatory reform. Commentators have suggested a variety of possible Hatch-Waxman Act restructurings. Recently, Congress discussed amending the Hatch-Waxman Act in a manner that would codify a presumption of illegality for reverse-payment settlements discussed above, but both bills were voted down.<sup>155</sup> Hemphill and Lemley have put forward an elegantly simple model for reform that is very promising in terms of dealing with issues of policing *and* dynamic innovative efficiency, but the authors only focused on the first matter.<sup>156</sup> They suggest requiring a first generic ANDA filer to earn its 180-day exclusivity period by successfully defending a patent infringement suit born of a Paragraph IV certification, as was the norm prior to 1998.<sup>157</sup> By removing the certainty of bounty, generics would be wise to target

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<sup>155</sup> S. 369, 111st Cong. § 2(b) (2009); H.R. 1706, 111st Cong. § 2(a) (2009).

<sup>156</sup> Hemphill & Lemley, *supra* note 3, at \*30.

<sup>157</sup> See *supra* note 87 and accompanying text.

patents they could expect to successfully take down, enabling them to recover litigation costs through the 180-day period. Thus, the potential for collusion and the preservation of bad patents are substantially reduced. If settling a case means that the generic has to give up its 180-day exclusivity, and hence a substantial percentage of its expected profits, fewer generics are likely to settle, at least on the terms similar to those of the status quo. While some patentees may simply pay the generic more to compensate for the loss of exclusivity, in equilibrium, the narrowing range of joint surplus means that fewer cases settle. In addition, a generic settlement could no longer discourage subsequent ANDA filers because they could now earn the 180-day exclusivity period for themselves, or at least not be excluded by some first-filer that chose to settle.

In addition to making strides to police bad patents, a system of earned exclusivity would have manifest benefits for dynamic innovative efficiency. Owners of deserved and valuable patents would no longer have to fear generic marauders, who would be put in their place, by fear of losing litigation costs. Thus, the expected value of blockbusters would be restored to its pre-1998 level, and the innovation landscape in the pharmaceutical industry markedly improved. By forcing more patent litigation, earned exclusivity creates a situation where more legal certainty can be crafted around the good/bad patent distinction in the pharmaceutical arena.<sup>158</sup> This legal certainty would tend to ameliorate the risk-aversion associated with blockbuster drugs, increasing their expected value even more by instilling greater knowledge in the patentee and more caution in the generics. Generics would be even more honed in on weak patents, garnering incremental boosts in efficacy of patent policing.

Once again, the system is not flawless, as it entails more litigation and the attending litigation costs, but these flaws would be outweighed by the gains achieved in the form of greater investments by pioneers. In addition, there is still the potential for collusion, and savvy generics with sufficiently deep pockets may risk challenging pioneer owners of valuable patents in an attempt

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<sup>158</sup> Hemphill & Lemley, *supra* note 3, at \*38.

to extract lucrative settlement agreements for themselves. However, a system of earned exclusivity would remove the primary facilitator of harmful collusion and undue patentee victimization—the certainty of the 180-day bounty. Pioneers would find it extremely taxing to extend a bad patent, and generics would face daunting risks targeting valuable but strong patents.

#### *D. A Combined Approach*

Perhaps a combination of the two reforms would be stronger than each acting on its own. Earned exclusivity would do the heavy lifting, in that it does not rely on an antitrust court making a rudimentary call on the merits of a highly complex patent case for its operation. Yet, an antitrust regime with a rebuttable presumption of illegality could act as a supplementary check against collusion in an earned exclusivity regime, invalidating those settlements where pioneers, desperate to hold on to their ill-gotten gains, are still willing to pay for generics to stay off the market (even with increased compensation to the generic for the loss of its 180-day exclusivity period). The viability of the antitrust approach in courts would be aided by the greater clarity that would emerge under a system of earned exclusivity because a court's "quick look" at the merits would be all the more informed by an increased number of final opinions assessing patent validity rather than settlement validity.

### VI. CONCLUSION

Settlements in the Hatch-Waxman context represent a complicated and vexing question. In order to solve the problems born of these settlements, we must endeavor to be as circumspect as possible. The purpose of this Article has been to highlight an aspect of the Hatch-Waxman dilemma that is outside popular focus, but which could have serious ramifications if left unnoticed. Dynamic innovative efficiency should be remembered when gauging the desirability of modes of reform. In the opinion of this author, Mark Lemley and Stephen Hemphill's scheme of earned exclusivity is promising in terms of alleviating innovation concerns. Unfortunately, as has been seen recently, legislative reform of this issue is exceedingly difficult to achieve. Antitrust

thus seems like a more likely candidate for change, but the majority of the courts are loath to condemn Hatch-Waxman settlements, and the recent Supreme Court refusal to grant review of the *Cipro* case is indicative of an entrenched commitment within the judiciary to economic arguments in favor of settlements and the presumption of patent validity. Ultimately, from where we stand now, we cannot make a call on the extent of damage being done to innovation by the current regime, but if we continue to wear the beaten path, the future for pharmaceutical invention may not be a bright one.