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Pharmaceutical Patent Wars, Reverse-Payment Settlements, and Their Anticompetitive Effects for Consumers

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PHARMACEUTICAL PATENT WARS, REVERSE-PAYMENT
SETTLEMENTS, AND THEIR ANTICOMPETITIVE
EFFECTS FOR CONSUMERS

*Steven Adamson**

Generic drugs have provided considerable cost-savings to consumers. The Hatch-Waxman Act provides economic incentives to both generic and brand-name manufacturers, but it is a complicated piece of legislation scattered across numerous sections of the United States Code. This obfuscation has led to abuse by brand name and generic drug manufacturers, resulting in anticompetitive behaviors for the consumer. Despite attempts to ameliorate the problem, a review of case law makes plain that the judicial and legislative systems are currently inadequate to address this problem.

Litigation typically arises in the context of patented drug filings after a generic drug manufacturer files an Abbreviated New Drug Application, for a generic drug modeled after the patented drug, an act of constructive patent infringement. This then initiates Paragraph IV patent litigation. In order to avoid a finding of patent invalidity, branded and generic manufacturers enter into collusive “reverse-payment” agreements in which the branded manufacturer agrees to pay the generic company to stay out of the market.

*While direct cash payments seem to have been foreclosed in *FTC v. Actavis*,¹ subsequent iterations of reverse payments have evaded this holding, allowing reverse payments to continue to the frustration of many consumers. Finally, the latest mode of manipulation does not involve monetary transfers, but rather manipulates the FDA system via product hopping, risk evaluation monitoring systems, and sham citizen petitions to achieve anticompetitive aims.*

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¹ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2233 (2013).

This Article examines the patenting system for generic drugs, the numerous modes of reverse-payments, and the difficulty of prescribing a bright-line approach to often fluid definitions of “reverse payments.” This is the first article to review the array of reverse payment modes, explaining how legislative and judicial efforts to combat these practices have failed, and arguing for a systemic legislative approach to solve this problem.

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I. INTRODUCTION

Most patients are quick to realize the benefits of generic drugs—due in large part to the creation of the Hatch-Waxman system for generic drug approval. Once a patent term has expired, generic drug manufacturers can begin making a drug available—often at drastically reduced costs to the public. However, easy access to generic drugs has not always been available. Prior to the Hatch-Waxman Act, the system for FDA approval for generic drugs was onerous.

In 1962, following the discovery that thalidomide was prescribed to pregnant women resulting in severe birth defects, drugs needed to be tested for safety and effectiveness before the FDA would approve them for marketing under new amendments to the Federal Food, Drug, and Cosmetic Act.² This required both brand name and generic drug manufacturers to perform expensive and time-consuming clinical trials, despite the fact that a generic drug is defined as pharmaceutically equivalent to the brand-name drug. Generic drugs have the same active ingredient, strength, dosage form, route of administration, and are bioequivalent. A statutory exception allowed generic drugs to be approved with a paper new drug application (NDA), which piggy-backed on published medical studies, thereby eliminating the expense of clinical trials to verify safety and efficacy for the generic manufacturer.³ The chilling effect these regulations had on the generic drug market cannot be understated: there were only fifteen “paper NDAs” between 1962 and 1984, despite at least 150 drugs that were off-patent,⁴ presumably because there were no published studies that the generic companies could use and/or clinical trials were cost-prohibitive, making generic drug manufacturing a venture of limited profitability.

To encourage the introduction of generic drugs onto the consumer market, in 1984 Congress enacted The Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act.⁵ This landmark legislation was remarkably successful in achieving its aims, but is not without criticism.

² Gerald Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD DRUG L.J. 187, 187 (1999).

³ *Id.*

⁴ *Id.*

⁵ Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat 1585 (codified as amended in scattered sections of 21

Although there have been two major and several minor revisions, the complicated pathway for generic drug introduction has made the Hatch-Waxman Act prone to abuse by brand name and generic drug manufacturers alike.⁶

This Article will proceed in six parts. Part I is an introductory section. Part II examines the branded drug patenting process, the role of the FDA, and ultimately how a generic drug can enter the market via the Hatch-Waxman Act. Part III discusses the modes of reverse payments and the complex strategies that have arisen as part of the generic and branded manufacturers' quest to disguise reverse payment schemes. Part IV will review the previous attempts to combat abuse such as legislative amendments, patent office proceedings, and end user litigation. Part V suggests potential reforms to ameliorate the current problems; Part VI is a conclusory section.

II. PATENTS FOR DRUGS

A. Branded vs. Generic Drugs

A prudent place to begin is to describe the difference between brand name and generic drugs. A brand name drug refers to what the FDA calls an "innovator drug," a drug that is the first in its class with a particular therapeutically active ingredient.⁷ Subsequent drug formulations that have the same active ingredient are either a "pharmaceutical equivalent" or "pharmaceutical alternative."⁸ The FDA defines drug products as pharmaceutical equivalents if "they contain the same active ingredient, are of the same dosage form, route of administration and are identical in strength or concentration . . . but may differ in characteristics such as shape, release mechanisms, packaging, excipients (including colors, fla-

U.S.C.).

⁶ Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 42 U.S.C.); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified as amended in scattered sections of 21 U.S.C.).

⁷ Jane Lowers & Robert Howland, *Generic v. Branded Psychiatric Medications: Is There a Difference?*, MEDSCAPE (Apr. 25, 2012), <https://www.medscape.com/viewarticle/762343>.

⁸ *Id.*

vors, preservatives), expiration time, and within certain limits, labeling.”⁹ Drug products are defined as pharmaceutical alternatives, if “they contain the same therapeutic moiety, but are different salts, esters, or complexes of that moiety, or are different dosage forms or strengths.”¹⁰ Similarly, a single manufacturer can produce many different dosage forms (e.g., capsule vs. liquid, extended release vs. standard release), or strengths (e.g., 200mg vs. 1000mg) within the same product line that are considered pharmaceutical alternatives.¹¹

Therefore, a “generic drug” is a drug that is the pharmaceutical equivalent to the brand-name drug, with the same active ingredient, and is identical in strength, dosage form, route of administration, is a bioequivalent.¹² In fact, as discussed *infra* in IIb, bioavailability studies are, with limited exception, the only data the FDA are allowed to request from generic manufacturers. One example is the brand-name drug Paxil, a common antidepressant, where “there are generic versions, or therapeutic equivalents, containing paroxetine hydrochloride, and they are formulated according to the FDA’s bioequivalence standards for generics.”¹³ A similar drug, Paxeva, which is paroxetine mesylate, currently has no generic equivalents.¹⁴ Therefore, Paxil and Paxeva are *not* considered to be pharmaceutically equivalent because of the differences between paroxetine hydrochloride and paroxetine mesylate; therefore pharmacists are not permitted to substitute a generic version of Paxil of a prescription written for Paxeva.¹⁵ Conversely, automatic pharmacy substitution *would* occur for prescriptions written for Paxil.

B. Bioequivalence

Before 1984, a generic drug needed to go through randomized trials to demonstrate safety, efficacy, and tolerability before it

⁹ Nomenclature (as excerpted from the Orange Book), FOOD AND DRUG ADMINISTRATION (Oct. 15, 2016), https://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4137B1_07_Nomenclature.pdf.

¹⁰ *Id.*

¹¹ *Id.*

¹² Lowers & Howland, *supra* note 7.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

was granted approval.¹⁶ The major scientific tenet of the Hatch-Waxman Act was that bioequivalent drugs are therapeutically equivalent and are, therefore, interchangeable.¹⁷ Bioavailability is “the extent to which a drug is absorbed into the body and is thus available to act upon the drug’s intended target, also known as the ‘site of action’.”¹⁸ For example, an orally ingested drug may be only partially metabolized, leaving less to act upon the target site, whereas intravenous drugs have, generally, much higher bioavailability.¹⁹ Bioequivalence is the “absence of a significant difference between the bioavailability—specifically the extent and rate of absorption—of two pharmaceutical drug equivalents over the course of a period of time, at the same dose and under the same conditions.”²⁰ These data are obtained through a specific set of pharmacokinetic tests set forth in the FDA’s statutory guidance.²¹

In sum, when a manufacturer can demonstrate that its generic drug is bioequivalent to the brand-name drug, statutory provisions allow the manufacturer to forego the extensive clinical studies to demonstrate safety and efficacy, and piggyback off of the clinical studies that the brand-name manufacturer performed in achieving new drug approval. This results in a tremendous cost-savings to generic manufacturers.

C. Pathway for Introduction of Generic Drugs via the Hatch-Waxman Act

The Hatch-Waxman Act is a complex piece of legislation, codified in four different sections of the United States Code.²² Broadly speaking, this act creates a regulatory framework for the approval and marketing of generic pharmaceutical drugs, under which the generic company can submit an Abbreviated New Drug

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ Alexander Gaffney, *Regulatory Explainer: FDA Clarifies Bioequivalence, Bioavailability Approaches for Innovative Drugs* (Mar. 17, 2014), <http://www.raps.org/focus-online/news/news-article-view/article/4774/>; 21 C.F.R. § 320.1(a) (2016).

¹⁹ Gaffney, *supra* note 18.

²⁰ *Id.*

²¹ 21 C.F.R. § 320.1(a) (2016).

²² Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.).

Application (“ANDA”) to seek approval of a drug by the FDA. The ANDA must be a medication bioequivalent to the branded drug and must generally have the same active ingredient, route of administration, dosage form, strength, use indications, and labeling information as the branded drug.²³ A generic company can rely on the branded pioneering drug company’s prior clinical trial data to prove the safety and efficacy of the drug, saving the generic company years of work and expense.²⁴

Furthermore, the Hatch-Waxman Act expressly allows all activity necessary to produce the ANDA, including the use of the patent holder’s data and trial information, as well as samples of the actual drug to test for bioequivalence, without triggering patent infringement.²⁵ This exemption allows generics to be ready for market-entry the moment of patent expiration.²⁶

When branded pioneering drug companies file a New Drug Application (“NDA”) for FDA approval, the law requires the branded company to list all patents that could “reasonably be asserted” against a generic applicant.²⁷ These are then recorded in a document referred to as the “Orange Book.”²⁸ As mentioned above, a generic drug manufacturer is required to make one of four certifications to each of the patents listed for the medication in the Orange Book.²⁹ The first three certifications bring limited litigation, because they represent that patents have expired (Paragraph I), no patents are listed in the Orange Book (Paragraph II), or that the generic manufacturer will wait for patent expiration before market introduction (Paragraph III).³⁰

The most contentious litigation between generic companies and branded pharmaceuticals arise out of Paragraph IV certification, alleging that the listed patent is invalid or would not be infringed by the generic, and is an attempt by the generic to enter the

²³ 21 U.S.C. § 355(j)(2)(A) (2017).

²⁴ Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 506 (2016).

²⁵ *Id.* (explaining that all research activity is statutorily barred from patent infringement up to, and until, Paragraph IV certification is filed, which becomes constructive infringement).

²⁶ *Id.* at 507.

²⁷ 21 U.S.C. § 355(b)(1) (2017).

²⁸ U.S. Food and Drug Admin., *Approved Drug Products with Therapeutic Equivalence Evaluations* (2017).

²⁹ Feldman & Frondorf, *supra* note 24, at 507.

³⁰ *Id.*

market before patent expiration.³¹ After the generic files a Paragraph IV certification, the branded drug company has 45 days to initiate litigation or the FDA must approve the generic drug application.³² If the branded drug company initiates litigation, a 30-month stay is placed on generic drug approval, allowing the infringement suit to work its way through the court system.³³ If the generic is approved, it is granted a 180-day exclusivity before the FDA will consider any subsequent ANDA of the same generic drug.³⁴ If the generic manufacturer loses its patent infringement suit, it also forfeits its 180-day exclusivity and its certification is changed to Paragraph III – agreeing not to enter the market until the expiration of relevant patents.³⁵ Prior research the company has done is barred from patent infringement by the Act.³⁶ This incentive is meant to challenge weak patents, for example, companies that seek to strengthen their intellectual property portfolio through patent evergreening.³⁷

D. Patent Term Extension

As part of a legislative *quid pro quo*, and to compensate patent owners for marketing time lost during the FDA drug approval process, a branded drug manufacturer could receive a patent term extension.³⁸ The Hatch-Waxman provisions allow for the extension of the normal term of a patent for up to five years, and for a total patent term extension of up to fourteen years. Since a generic manufacturer is permitted to file an ANDA that relies on data acquired during a branded company's clinical trials conducted prior to approval of the NDA, the branded pharmaceutical com-

³¹ *Id.*

³² 21 U.S.C. § 355(j)(5)(B)(iii) (2017).

³³ *Id.*

³⁴ Feldman & Frondorf, *supra* note 24, at 502.

³⁵ *Id.* at 509, n.46.

³⁶ *Id.* at 506.

³⁷ Patent evergreening is a legal process of extending intellectual property protection by patenting “multiple aspects of, or incremental improvements to a single drug, so that the last patent expires well after the first.” Rajarshi Banerjee, Note, *The Success of, and Response to, India’s Law against Patent Layering*, 54 HARV. INT’L L.J. 204, 204-05 (2013).

³⁸ 35 U.S.C. § 156(c)(3) (2015).

pany also receives “data exclusivity” (also known as market exclusivity).³⁹ In other words, the FDA will not accept any ANDA for a set period, unless challenged under Paragraph IV certification. For new chemical entities, market exclusivity is granted for up to five years.⁴⁰ For clinical studies leading to new drug indications and formulations, market exclusivity is granted for up to three years.⁴¹ For pharmaceutical drugs targeting rare diseases, market exclusivity is granted for up to seven years.⁴² An additional six months of exclusivity is granted when the FDA requests, and the brand-name pharmaceutical company performs, pediatric clinical studies.⁴³

E. Impact of Hatch-Waxman Act

Judged by almost any metric, the Hatch-Waxman Act has met Congress’ goals of balancing patent protection for pioneering branded drug companies while simultaneously promoting the rapid introduction of generic drugs. Since 1984, more than 10,000 generics have entered the market and the generic market share has risen from 13% in 1980 to approximately 86% in 2013.⁴⁴

Approximately 88% of all U.S. prescriptions are filled using generic medications, which saved consumers approximately \$217 billion in 2012.⁴⁵ It is no wonder that branded drugs face severe financial market competition after generics enter the market. While most generics enter the market at around 80% discounted of the branded drug price, those prices can fall to 10% of the original cost.⁴⁶ Because of automatic pharmacy substitution, branded pharmaceutical companies generally lose 80-90% of their market share within a year of generic introduction.⁴⁷

³⁹ D. Christopher Ohly & Sailesh K. Patel, *The Hatch-Waxman Act: Prescriptions For Innovative And Inexpensive Medicines*, 19 U. BALT. INTELL. PROP. L.J. 107, 113 (2011) (“[A]s consideration for their agreement to the Hatch-Waxman compromise, branded pharmaceutical companies also received ‘data exclusivity,’ a form of additional protection not based on any patents.”).

⁴⁰ Mossinghoff, *supra* note 2, at 190.

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ Feldman & Frondorf, *supra* note 24, at 503.

⁴⁵ *Id.* at 500-01.

⁴⁶ *Id.* at 501.

⁴⁷ *Id.*

Patent litigation is expensive. The American Intellectual Property Law Association's (AIPLA's) 2015 Economic Survey reports that the mean litigation costs *per side* for a patent infringement lawsuit are \$359,000 through the end of discovery and \$1,169,000 through final disposition when less than \$1 million dollars is at risk.⁴⁸ Yet, Hatch-Waxman litigation is even more expensive. The Economic Survey reports Hatch-Waxman patent litigation inclusive costs, including costs associated with discovery, range from \$678,000 for claims with less than \$1 million at risk to \$6.429 million for claims with greater than \$25 million at risk.⁴⁹ Despite these significant litigation costs, the risk-reward analysis still heavily favors proceeding with litigation because the 6-month duopoly can be worth hundreds of millions of dollars to generic drug manufacturers for blockbuster drugs.⁵⁰

Costs to pioneering manufacturers are extraordinarily high and are estimated at \$500-800 million to develop a single brand name drug. This cost can swell to over \$1 billion to include products that have failed along the drug discovery process with only 30% making a good return.⁵¹ It was in this financial landscape, combined with the reduced costs relative to their generic competitors and assured market losses, that the pay-for-delay strategy emerged.

III. REVERSE PAYMENTS MODES

In pay-for-delay settlements, also known as reverse payment schemes, the branded drug company paid the infringing generic manufacturer to delay entry in market. With these reverse payments, the incentives of both the branded pioneering company and the generic manufacturer are aligned so that the branded company enjoys a continued monopoly and the generic manufacturer receives a substantial payment, generally without forfeiting the 180-day exclusivity period.⁵²

⁴⁸ AIPLA, *REPORT OF THE ECONOMIC SURVEY*, I-109 (2015).

⁴⁹ *Id.* at I-129.

⁵⁰ Feldman & Frondorf, *supra* note 24, at 502.

⁵¹ Sheena Ching, "Pay-For-Delay" Settlements Post-Actavis: Why Mediation Can Tackle The "Unreasonable" Antitrust Settlements, 17 CARDOZO J. CONFLICT RESOL. 277, 283 (2015).

⁵² Feldman & Frondorf, *supra* note 24, at 511.

The complexity of the Hatch-Waxman Act certainly breeds abuse in which branded pharmaceuticals enjoy a lengthened monopoly, depriving consumers of generic cost savings. On the other hand, a case can be made that branded drug companies are merely acting on their corporate fiduciary duties. Part of the legislative success in the passage of the Hatch-Waxman Act resulted from marrying branded companies patent extension along with generic drug expedited approval measures through Paragraph IV certification. While intended to tip the balance towards the generic companies (as legislative aims), this is, arguably, no longer necessary and may be counterproductive to the original goals. The next section will broadly explore the complexity of reverse payment schemes and the difficulties legislators have had in detecting and deterring these anticompetitive arrangements.⁵³

A. Generation 1.0

AndroGel, a topical prescription gel for the treatment of low testosterone in men, was developed by Besins Healthcare, S.A.⁵⁴ In August 1995, Besins granted Solvay Pharmaceuticals, Inc. a license to sell AndroGel in the United States, after which Solvay filed a NDA in April 1999, which the FDA approved in February 2000.⁵⁵ The commercial success of AndroGel was extraordinary with U.S. sales between 2000 and 2007 exceeding \$1.8 billion.⁵⁶ Shortly after FDA approval of AndroGel, Solvay filed a patent application—not for the synthetic testosterone whose patent had expired decades earlier—but for a particular gel formulation in order to include the AndroGel patent in the Orange Book.⁵⁷

Two generic drug manufacturers, Watson Pharmaceuticals, Inc. and Paddock Laboratories, Inc. subsequently developed generic versions of this drug and filed Paragraph IV ANDAs in May of 2003, alleging that Solvay's new patent was invalid.⁵⁸ The parties then litigated the patent infringement action, and when the

⁵³ I find Feldman and Frondorf's approach, *supra* note 24, particularly helpful in characterizing reverse payments and, as such, I will adopt their terminology.

⁵⁴ *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1303 (11th Cir. 2012).

⁵⁵ *Id.* at 1304.

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

statutorily-imposed 30-month stay on FDA's approval was nearing its end, concurrent with the generic companies' motions for summary judgment, Solvay faced the real possibility of losing its monopoly in AndroGel and lost profits of \$125 million per year.⁵⁹

The parties came to a settlement agreement in which Solvay agreed to pay Paddock Laboratories \$10 million per year for six years and \$2 million per year for backup manufacturing assistance, and share profits with Watson through September 2015, projected to fall between \$19-\$30 million per year.⁶⁰ After the settlement agreement, the FTC filed an antitrust lawsuit against Solvay, Watson, Par, and Paddock.⁶¹ The Eleventh Circuit Court of Appeals ruled that a reverse payment generally is "immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."⁶² However, the Supreme Court reversed, holding that reverse payments settlement, where large and unjustified, can "bring with it the risk of significant anticompetitive effects."⁶³ Perhaps more importantly, the Court refused to hold that reverse payments are presumptively unlawful, preferring a rule of reason test.⁶⁴ Citing that a presumptive rule "is appropriate only where 'an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets'."⁶⁵

Overall, this may be a pyrrhic victory, as the rule of reason test has largely been described as an onerous burden on plaintiffs and the judicial system, involving complex economic analysis, requiring extensive information about industries, and following amorphous standards.⁶⁶ Many legal scholars have criticized this approach.⁶⁷

⁵⁹ *Id.* at 1304-05.

⁶⁰ *Id.* at 1305.

⁶¹ *Id.*

⁶² *Id.* at 1312.

⁶³ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2233 (2013) (Actavis is formerly known as Watson Pharmaceuticals).

⁶⁴ *Id.* at 2237.

⁶⁵ *Id.*

⁶⁶ Feldman & Frondorf, *supra* note 24, at 513.

⁶⁷ See generally C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009).

In the year following the *Actavis* decision, the FTC found the number of suspected reverse payment schemes fell from 42 in 2012 to 21 in 2014—the most current fiscal data available.⁶⁸ It remains uncertain whether antitrust cases filed by the justice department are a particularly effective deterrent. In 2015, Teva settled a class action lawsuit brought by purchasers of its drug Provigil, an anti-narcoleptic drug. Purchasers accused Teva of antitrust reverse payment scheme to keep four generic competitors out of the market for six years.⁶⁹ The same month it settled an antitrust claim with the FTC, bringing the total settlement to \$1.2 billion, while Teva accumulated six more years of patent protection and \$3.5 billion in sales, with a net profit of \$2.3 billion dollars after settlement with consumers and the FTC.⁷⁰

B. Generation 2.0

The prototypical Generation 2.0 settlement is similar to that of Generation 1.0 in that cash is exchanged but is disguised as a side-deal. These side deals have evolved with ever-widening complexity and can include promises to promote/market the branded drug, licensing deals allowing manufacture of each other's drugs, "authorized generic" agreements permitted generics to manufacture and sell the brand-name formulation without ANDA approval with profit-sharing attached, agreements to share research and development, and many subsequent iterations.⁷¹

Several examples may be elucidative. As part of an agreement to delay entry of K-Dur, a drug for treating potassium deficiencies, the branded company agreed to buy licenses to multiple medications from the generic, for which it paid \$60 million dollars. K-Dur quickly abandoned their plans to manufacture the generic drugs it had licensed, but leaving their licensing payment intact.⁷²

⁶⁸ 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: Overview of Agreements Filed at Exhibit 1*, <https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf>.

⁶⁹ Feldman & Frondorf, *supra* note 24, at 515.

⁷⁰ *Id.* at 516.

⁷¹ *Id.* at 515; Hemphill, *supra* note 67, at 663-66.

⁷² Feldman & Frondorf, *supra* note 24, at 516; *see also In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

A more recent case is Lipitor, a statin used to lower cholesterol, widely known as the best-selling drug in history with \$125 billion in sales between 1996 and 2011.⁷³ This six-year battle between Pfizer and the generic filer, Ranbaxy, resulted in a legal issues including sham litigation, sham patent obtainment through data falsification, sham Orange Book listing, sham citizen petitions, multiple and staggered suits, multiple settlements, and ANDA approval delay by Ranbaxy by moving its own manufacturing site.⁷⁴ In the 2008 settlement the generic agreed to delay release of its drug until 2011 in exchange for the right to market in 11 international markets.⁷⁵ In coordination with the same settlement, Pfizer reached settlement agreements on two other branded drugs, Accupril and Caduet, with the same generic manufacturer for a paltry \$1 million, although industry estimates put the value of the settlement at closer to \$1.5 billion for the generic.⁷⁶

While Generation 2.0 has given rise to the advent to side deals, many of these deals contain an array of diverse, anti-competitive contractual clauses that serve as indirect payments and bottlenecks to prevent generics from entering the market.⁷⁷ First, consider the fact that a brand-name drug maker can manufacture its own generic. Then, settlement terms may include an “acceleration clause” (also known as a no-authorized generic agreement), which stipulates that the generic may immediately enter the market if another generic files an ANDA and is able to get onto the market before the first-filing generic’s 180-day exclusivity period ends (or even before it begins).⁷⁸ Therefore, the first-filing generic is not locked into its agreed entry date if another generic is able to break through the exclusivity period. Yet, the true value of an acceleration clause is not in the reassurance it provides to the delaying first-filer, but rather the disincentive it creates for prospective generics to subsequently file when faced with immediate competition and no market duopoly.⁷⁹

One similar example is the settlement that arose out of patent litigation suit/Paragraph IV certification between the generic manufacturer King Drug and GlaxoSmithKline over Lamictal, an

⁷³ Feldman & Frondorf, *supra* note 24, at 518.

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.* at 519-20.

⁷⁷ *Id.* at 521.

⁷⁸ *Id.*

⁷⁹ *Id.*

anticonvulsant used to treat epilepsy and bipolar disorder.⁸⁰ Although no cash was exchanged, GlaxoSmithKline allowed the generic to enter the \$50 million market for chewable Lamictal 37 months before patent expiration, but denied entry into the more lucrative \$2 billion market for tablet Lamictal until one day before expiration of exclusivity.⁸¹ In exchange GlaxoSmithKline agreed it would not produce its own generic until after the generic's 180-day exclusivity.⁸² When challenged by a class action suit of purchasers, the Third Circuit agreed, indicating that no-authorized generic agreements may represent an "unusual, unexplained reverse transfer of considerable value" under *Actavis*, allowing antitrust claims to continue."⁸³

C. Generation 3.0

The *Actavis* and *King Drug* decisions were successful knockout punches to Generation 1.0 and 2.0, respectively, through cash pay-for-delay deals, and through large, unexpected payments in multiple settlements combining layers of superfluous deals with valuable contractual clauses.⁸⁴ In Generation 3.0, brand-name drug companies actively obstruct generics from entering the market at every stage of the generic development: before an ANDA submittal, during ANDA approval, after a generic has been approved for marketing, and even once the generic has entered the market.⁸⁵ There are three principle obstructionist strategies that are currently being employed. The first uses product hopping, in which the brand-name drug company takes advantage of its market power to shift consumers to new versions of drugs before a generic drug enters the market and can compete with the "old" version.⁸⁶ A second strategy manipulates FDA guidelines to ensure safe use of dangerous drugs to prevent generic manufacturers from accessing samples for bioequivalence testing.⁸⁷ A third strategy process leverages the ability of the public to file a petition, even

⁸⁰ *Id.* at 523.

⁸¹ *Id.*

⁸² *Id.*

⁸³ *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015).

⁸⁴ Feldman & Frondorf, *supra* note 24, at 524.

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

though meritless, to garner additional delay.⁸⁸ Taken collaboratively, these strategies can yield delay from a few months to several years, in contrast previous modes of reverse payments, which achieved longer monopolies.⁸⁹

i. First Strategy—Product Hopping

Product hopping makes use of patent evergreening, in which a drug manufacturer “make[s] minor variations to existing drugs to extend their patent coverage.”⁹⁰ In order to complete the product hop, the following steps are required. First, the brand name company makes a small change to an existing drug when the patent rights are about to expire and introduces the new formulation onto the market as an entirely new drug, protected by fresh patent grants.⁹¹ Second, the brand name drug company brings about a market shift through significant marketing ad campaign and promotional offers to push doctors to write prescriptions for the new drug.⁹² Simultaneously, the brand name company is providing monetary incentives to drug payers—insurers, HMOs, and pharmaceutical benefit managers—causing these insurers to prefer the use of the new drug over the old in the short-term.⁹³ To complete the product hop, the brand name manufacturer discontinues previous versions of the drug, closes distribution channels and sometimes buys remaining drug inventory back.⁹⁴ Ironically, in some cases the generic is considered to be a “branded” drug for co-pay and reimbursement purposes, since it is the sole drug on the market.⁹⁵ The result of this maneuvering is a generic is unable to gain a toehold in the market, despite the fact that it was supposed to introduce competition for the original brand-name drug.⁹⁶ In a

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ Jonathon Darrow, *Debunking the “Evergreening” Patent Myth*, 131 *Harvard Law Record*, Dec. 8, 2010, at 6, <http://hls.harvard.edu/content/uploads/2009/10/2010-debunking-the-evergreening-patents-myth-harv-l-record.pdf>.

⁹¹ Feldman & Frondorf, *supra* note 24, at 527.

⁹² *Id.*

⁹³ *Id.* at 528.

⁹⁴ *Id.* at 529.

⁹⁵ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

variation of product hopping, AstraZeneca moved Prilosec, a best-selling drug with annual sales of \$6 billion, to an over-the-counter drug, then shifted the prescription market to its newly patented Nexium, which commentators have argued is little different from its predecessor.⁹⁷ Twelve years after its launch, Nexium was the U.S.'s second best-selling drug with just under \$6 billion in sales.⁹⁸

*ii. Second Strategy—Manipulation of FDA Risk Evaluation
Monitory System*

Risk Evaluation and Mitigation Strategy (“REMS”) are risk management and safety plans that the pharmaceutical company implements to inform key stakeholders about drug risks, and Elements to Assure Safe Use (“ETASU”).⁹⁹ ETASU is the most restrictive element of the REMS management plan and directly influence how and when the drug can be used and can include patient monitoring or testing while taking the drug or special certification for prescribers or pharmacies.¹⁰⁰ These are arguably important safety protocols, but they are ripe for abuse. A typical pattern is that a brand-name pharmaceutical company will refuse to sell a small amount of its drug to a generic drug manufacturer for bioequivalence testing on the grounds that it violates their REMS/ETASU policy.¹⁰¹ This is despite the fact that the FDA has repeatedly insisted that the brand-name company is *not* violating the REMS policy.¹⁰² However, a restricted distribution scheme does not even need REMS to be effective in blocking generic competition.

⁹⁷ *Id.* see n.153 (although Prilosec was not completely discontinued, once an over-the-counter version became available, insurers no longer covered it).

⁹⁸ *Id.*

⁹⁹ *Id.* at 533-34.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² See Ctr. For Drug Evaluation & Res., *U.S. Food & Drug Admin., Risk Evaluation and Mitigation Strategy (REMS) Public Meeting 270-72* (July 28, 2010) (Statement by Jane Alexrad, Associate Director of Policy, Ctr. For Drug Evaluation and Res., 315), <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM224950.pdf> (maintaining that REMS is not a barrier to acquiring generic samples for generic bioequivalence testing).

For example, in September 2015, Turing Pharmaceuticals and its founder Martin Shkreli became the subject of intense public hostility after buying the rights to Daraprim, an antimalarial drug commonly used in HIV-positive patients, for \$55 million and immediately raising the price 5,500%, from \$13.50 to \$750 a tablet.¹⁰³ When Turing purchased the rights to Daraprim, it maintained a restricted distribution system for no safety reason whatsoever, making the drug only available through Walgreen's Specialty Pharmacy, and creating access problems for hospitals.¹⁰⁴ However, the real motivation for the price hike was to make it difficult for generics to gain access to samples.¹⁰⁵ Shkreli's previous company, Retrophin, increased the price of the rare kidney-disorder drug Thiola 2000%, from \$1.50 to \$30 a pill, and also created a still-active closed distribution system.¹⁰⁶ Documents that Turing Pharmaceuticals turned over to Congress in anticipation of its February 2016 hearing revealed it was internally known that "exclusivity (closed distribution) creates a barrier and pricing power."¹⁰⁷

iii. Third Strategy—Manipulation of Citizen Petitions

Since 1979, the FDA has allowed the public to request the agency "issue, amend, or revoke a regulation or order to take or refrain from taking any other form of administrative action."¹⁰⁸ Most citizen petitions are benign and request the FDA to certify a brand name drug that is no longer on the market or to allow generic approval with minor variations to the referenced brand name drug.¹⁰⁹ As early as 1999, the FDA and FTC recognized the citizen petition process could be subject of abuse, and so enacted a new rule in 2007 such that when a citizen petition would delay a generic from being approved, the FDA must take final action within 150 days unless the delay is to protect public health.¹¹⁰ Ultimately, the FDA was granted the power to deny a petition if it believed the

¹⁰³ Feldman & Frondorf, *supra* note 24, at 536.

¹⁰⁴ *Id.* at 537.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* at 538.

¹⁰⁷ *Id.*

¹⁰⁸ 21 C.F.R. § 10.30 (1979).

¹⁰⁹ Feldman & Frondorf, *supra* note 24, at 543.

¹¹⁰ Codified at 21 U.S.C. § 355(q) (2017), *amended by* Improving Regulatory Transparency For New Medical Therapies Act, Pub. L. No. 114-89, 1129 Stat. 698 (2015); Feldman & Frondorf, *supra* note 24, at 545-46.

petition was submitted for the purposes of delaying approval and "...does not on its face raise valid scientific or regulatory issues."¹¹¹ However, since its enactment in 2008, the FDA has never summarily denied a citizen petition on these grounds, since proving these requirements can be quite difficult.¹¹² The standard flows from a line of Supreme Court cases from the 1960s that establishes a general right to petition the government without fear of antitrust liability.¹¹³ The legal petition must be *objectively baseless*, which "requires a showing that no reasonable petitioner can realistically expect success on the merits" and *subjectively baseless*, which "requires a showing that the petition tries to conceal an attempt to interfere directly with competition through the administrative process."¹¹⁴ Between the fiscal years 2008 and 2015, 175 citizen petitioning delays were filed and only eight were fully granted yet it is clear that the total number of citizen petitions is increasing.¹¹⁵

One particular successful example is the route taken by GlaxoSmithKline with regard to Flonase, a steroid nasal spray for allergy treatment that had annual sales of \$1.3 billion.¹¹⁶ Through a complicated set of citizen petitions it filed as a staggered series, GlaxoSmithKline was able to keep a generic off the market for more than 23 months, worth approximately \$2.5 billion.¹¹⁷ Even though two class action suits were filed by purchasers, it settled these for a mere \$185 million.¹¹⁸ Even considering that a citizen petition costs the pharmaceutical manufacturer several hundred thousand dollars, GlaxoSmithKline achieved a delay that has been valued at \$2.3 billion.¹¹⁹

¹¹¹ 21 U.S.C. § 355(q)(1)(E) (2017).

¹¹² Feldman & Frondorf, *supra* note 24, at 547.

¹¹³ *United Mine Workers v. Pennington*, 381 U.S. 657, 669-72 (1965); *E.R.R. Presidents Conf. v. Noerr Motor Freight Inc.*, 365 U.S. 127, 144 (1961); Robin Feldman, *Federalism, First Amendment, & Patents: The Fraud Fallacy*, 17 COLUM. SCI. & TECH. L. REV. 30 (2015).

¹¹⁴ Feldman & Frondorf, *supra* note 24, at 547-48.

¹¹⁵ *Id.* at 546-47; U.S. Food & Drug Admin., Eighth Annual Report to Congress on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2015, at 6-7 (2015), <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficesOfMedicalProductsandTobacco/CDER/ReportsBudgets/UCM517279.pdf>.

¹¹⁶ Feldman & Frondorf, *supra* note 24, at 526.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 527.

¹¹⁹ *Id.*

IV. ATTEMPTS TO COMBAT ABUSE WITHIN THE HATCH-WAXMAN

A. Legislative Approaches

Congress has not been impotent in curbing abuse within this system, most notably by amendments to the Hatch-Waxman through the Medicare Modernization Act in 2003 and the Food and Drug Administration Amendments Act of 2007.¹²⁰ In the first of its major round of amendments to the Hatch-Waxman in 2003, three notable changes were made. The most significant change is that a generic manufacturer loses its six-month duopoly period if it enters into a pay-for-delay settlement.¹²¹ Second, the Medicare Modernization Act all but foreclosed the possibility of multiple 30-month stays, except for a very limited set of circumstances.¹²² Third, an agreement between a brand-name and generic ANDA applicant relying on Paragraph IV certification must be disclosed to antitrust authorities.¹²³

Parties quickly found a work around for the six-month duopoly loss by disguising cash reverse payments as side-deals, which does not trigger the legislative hook.¹²⁴ Settling parties also found a workaround for required disclosure of settlement terms to the FTC, as discussed *infra* § IVb. While the FDA Amendments Act of 2007 made significant shifts in operational aspects to the Hatch-Waxman, including re-authorizing the collection of user fees, broadening the definition of pediatric clinical studies, and requiring registration and reporting of basic results of clinical trials to the FDA, this amendment made no significant attempt to curb abuse within the Hatch-Waxman Act.¹²⁵

¹²⁰ See Medicare Prescription Drug, *supra* note 6.

¹²¹ 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB) (2017); 21 U.S.C. § 355(j)(5)(D)(i)(V) (2017); *Guidance for Industry: Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Questions and Answers* at 10-11 (Oct. 2004), <https://www.fda.gov/ohrms/dockets/98fr/2004n-0087-gdl0001.doc>.

¹²² 21 U.S.C. § 355(j)(5)(B)(iii) (2017); 21 U.S.C. § 355(c)(3)(C) (2017); *Guidance for Industry, supra* note 121, at 8.

¹²³ Medicare Prescription Drug, *supra* note 6.

¹²⁴ Feldman & Frondorf, *supra* note 24, at 512.

¹²⁵ Efthimios Parasidis, *Patients Over Politics: Addressing Legislative Failure In The Regulation of Medical Products*, 2011 WIS. L. REV. 929, 948-49 (2011).

B. PTAB Inter partes Review

The America Invents Act (“AIA”), enacted in 2013, was intended primarily to harmonize the U.S. patent system with the remaining world by moving patent grants from a first-to-invent system to a first-to-file system.¹²⁶ However, in overhauling the patent system, one major set of AIA reforms focused on Patent and Trademark Office (“PTO”) procedural tools used as an alternative to the extremely expensive patent litigation.¹²⁷ The AIA amended the third party submission process to facilitate interested parties’ submissions to challenge patent applications as well as a post-grant review procedure to provide a forum for challenging a patent application at the PTO.¹²⁸ However, a petitioner can challenge a patent’s validity in post-grant review for only nine months after patent issuance.¹²⁹ Because of the narrow window, Congress also created the covered business method review¹³⁰ and the *inter partes* review¹³¹ (“IPR”) in which a petitioner can challenge a patent’s validity after a post-grant window closes.

IPR proceedings have received considerable attention, with respect to their impact on Hatch-Waxman litigation, particularly because, like the other post-grant review proceeding, IPR proceedings were designed to weed out weak patents—the very patents that become part of a Paragraph IV certification when a generic submits an ANDA.¹³² An IPR proceeding can be filed after nine months of the patent’s issuance in which normal post-grant review would take place but it must be filed within a year of any complaint alleging patent infringement.¹³³ IPR proceedings are adjudicative, not merely examinational, and so it is not uncommon to have concurrent proceedings in federal district court and IPR proceedings

¹²⁶ See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (codified as amended in scattered sections of 35 U.S.C. (2011)).

¹²⁷ *Id.*

¹²⁸ Gaia Bernstein, *The Rise of the End User in Patent Litigation*, 55 B.C. L. REV. 1443, 1447 (2014).

¹²⁹ *Id.* at 1448.

¹³⁰ 37 C.F.R. § 42.303 (2012); 35 U.S.C. § 321 (2011); Pub. L. 112-29, 125 Stat. 284, 328 (2011).

¹³¹ 35 U.S.C. §§ 311-19 (2012); Pub. L. 112-29, § 18, 125 Stat. 284, 328 (2011).

¹³² Jaimin Shah, Note, *Pulling the ‘Trigger’ on the Hatch-Waxman Act’s 180-Day Exclusivity Using Inter Partes Review*, 14 J. MARSHALL REV. INTELL. PROP. L. 453, 458 (2015).

¹³³ *Id.* at 458-59.

at the Board of Patent Appeals and Interferences (“BPAI”). Although, the district court will usually stay the court proceedings until the BPAI renders its decision. Unlike post-grant review, parties may challenge the validity of a patent only under prior art and obviousness, and only on the basis of patents and prior patent applications.¹³⁴

There are significant differences between district court litigation and IPR proceedings, which may make them variably attractive. First, the standard for instituting a review is quite low and will be initiated as long as a petition raises a “reasonable likelihood that the petitioner would prevail with respect to at least one of the claims.”¹³⁵ Second, after an IPR is initiated, the patent owner may move to cancel any challenged patent claim or propose substituted claims.¹³⁶ Third, discovery is allowed but is limited to “depositions of witnesses submitting affidavits or declarations” or “what is otherwise necessary in the interest of justice.”¹³⁷ Fourth, IPR proceedings retain the adversarial nature of district court proceedings but jettison the burdensome procedural aspects, guaranteeing the petitioner a decision on the merits no later than eighteen months after filing the petition.¹³⁸ In most cases, this has the effect of mooted the pending district court litigation,¹³⁹ although IPR decisions are appealable.¹⁴⁰ Fifth, there is no presumption of validity as there is in district court. Finally, and perhaps most importantly, unpatentability in an IPR is demonstrated by a preponderance of evidence standard as opposed the higher burden of proof required in district court litigation which finds invalidity by clear and convincing evidence.¹⁴¹ The lower burden on unpatentability and swift timeline of IPR proceedings typically allow a generic manufacturer to be the aggressor, which creates an even stronger incentive on the brand-name manufacturer to generate settlement terms, which are potentially anti-competitive for the public.¹⁴²

¹³⁴ Bernstein, *supra* note 128, at 1477.

¹³⁵ 35 U.S.C. § 314 (2012); 37 C.F.R. § 42.108(c) (2016).

¹³⁶ 35 U.S.C. § 316(d) (2012).

¹³⁷ 35 U.S.C. § 316(a)(5) (2012).

¹³⁸ Shah, *supra* note 132, at 459.

¹³⁹ *Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 721 F.3d 1330, 1340 (Fed. Cir. 2013), *cert. denied*, 134 S. Ct. 2295 (2014).

¹⁴⁰ 35 U.S.C. § 319 (2012).

¹⁴¹ 35 U.S.C. § 316(e) (2012).

¹⁴² When a settlement decision is reached before an IPR proceeding

Perhaps, the most frustrating aspect of IPR litigation is that the settlements are not submitted for antitrust review. The Medicare Modernization Act is clear that any agreement reached between generic and branded pharmaceutical companies should be submitted to the FTC for antitrust review, an “agreement” would presumably include settlements.¹⁴³ However, in order to avoid antitrust scrutiny under *Actavis*, parties are taking full advantage of the PTAB proceedings, relying on claim preclusion rather than an express delay term that prohibits generic entry.¹⁴⁴ For settlements that arise prior to a finding of unpatentability, parties will issue a stipulated consent judgment that the patent(s) are valid and enforceable, would be infringed by the generic manufacturer, and have virtually the same claim-preclusive effect as a court-rendered judgment on the merits.¹⁴⁵ However, unlike the Federal district court, PTAB judges have no jurisdiction to enforce antitrust laws. Therefore, in bypassing the federal court antitrust review, a payment can be made in the settlement terms of the PTAB settlement, which yields essentially the same results as those found in *Actavis*, a de-facto reverse payment.¹⁴⁶

C. Patient Purchasers in Patent Litigation

Whereas the AIA has accomplished many of its significant aims, it largely fails in anticipating the growing role that end-users will play in patent litigation.¹⁴⁷ In some cases, end users are threatened by patent assertion entities (“PAE,” also colloquially known as patent trolls). A typical *modus operandi* is when a PAE, who

reaches conclusion, which would be favored by the brand-name pharmaceutical company, this terminates the proceedings, but because the decision is not on the merits, the district court litigation is still pending. Consequently, the branded and generic manufacturers would file a settlement agreement with the district court, presumptively triggering antitrust review of settlement agreement. However, the intricacies of this interaction are the subject of a future legal commentary for the author and are, as such, beyond the scope of this manuscript.

¹⁴³ Medicare Prescription Drug, *supra* note 6.

¹⁴⁴ Erik Hovenkamp & Jorge Lemus, *Delayed Entry Settlements at the Patent Office*, 21 (July 26, 2016), available at SSRN: <https://ssrn.com/abstract=2814532> or <http://dx.doi.org/10.2139/ssrn.2814532>.

¹⁴⁵ See *e.g.*, *Arizona v. California*, 530 U.S. 392, 414 (2000) (noting that consent decrees will generally trigger claim preclusion).

¹⁴⁶ Hovenkamp & Lemus, *supra* note 144.

¹⁴⁷ See generally Bernstein, *supra* note 128.

may own a patent of dubious enforceability, sends demand letters for licensing fees.¹⁴⁸ More recently, two major U.S. Supreme Court cases were filed on behalf of end users. In 2013, patients and physicians sued Myriad Genetics to invalidate Myriad's breast cancer gene patents in an effort to enhance patients' access to a genetic breast cancer test.¹⁴⁹ The same year, the Supreme Court granted *certiorari* on a case involving farmers sued after reusing genetically engineered seeds by saving of the crops for re-planting the next season.¹⁵⁰ Taken together, these and other cases within the federal circuit reflect the increased willingness for end users to challenge patent validity when competitive interests are not being legally protected by existing statutory patent/FDA architecture. This is because commercial competitor's interests and patent end user's interests increasingly diverge at settlement.¹⁵¹

Although the FTC files suits to challenge anticompetitive settlements,¹⁵² increasingly end users (patients and drug stores) will file suit to independently challenge these settlement agreements.¹⁵³ Many difficulties arise in this area: end users are usually not tech-

¹⁴⁸ For example, in January 2013, Personal Audio, LLC, a PAE, began sending demand letters and suing podcasters, including comedian Adam Carolla, claiming it owned a patent for podcasting technology. See Press Release, Elec. Frontier Found., *EFF Files Challenge with Patent Office Against Troll's Podcasting Patent*, (Oct. 16, 2013), <https://www.eff.org/press/releases/eff-files-challenge-patent-office-against-trolls-podcasting-patent>, archived at <http://perma.cc/S563-PRK7?type=image>.

¹⁴⁹ Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

¹⁵⁰ Bowman v. Monsanto Co., 133 S. Ct. 1761 (2013); see Organic Seed Growers & Trade Ass'n v. Monsanto Co., 718 F.3d 1350, 1353 (Fed. Cir. 2013) ("Between 1997 and 2010, Monsanto brought some 144 infringement suits for unauthorized use of its seed. Approximately 700 other cases were settled without litigation.").

¹⁵¹ Bernstein, *supra* note 128, at 1458.

¹⁵² FTC v. Actavis, 133 S. Ct. 2223, 2226 (2013).

¹⁵³ See e.g. *In re* Cirprofloxacin Hydrochloride Antitrust Litig. 544 F.3d 1323 (Fed. Cir. 2008); *In re* Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003); *In re* Tomoxifen Citrate Antitrust Litig., 277 F. Supp. 2d. 121 (E.D.N.Y. 2003); *In re* Buspirone Patent & Antitrust Litig., 210 F.R.D. 43 (S.D.N.Y. 2002); Valley Drug Co. v. Geneva Pharms. Inc., 350 F.3d 1181 (11th Cir. 2003); *In re* Skelaxin (Metaxalone) Antitrust Litig., 299 F.R.D. 555 (E.D. Tenn. 2014).

nologically savvy, they are one-time players within patent litigation who arrive late in the game, do not have a long-term stake, and lack significant procedural tools.¹⁵⁴ Perhaps the most significant factor can be the financial asymmetry involved between the litigants where end users often have no incentive for long-term resolution. Ironically, these collective factors increasingly drive end users towards a settlement without resolving a claim on the merits.¹⁵⁵

In areas other than pharmaceutical litigation, the role of end users is properly aligned with competitors within the adversarial patent system. For example, a deterrence entity called Unified Patents (“UP”) has filed PTAB petitions, mostly involving computers and wireless communication technology patents, on behalf of subscribers.¹⁵⁶ Technology manufacturing companies pay UP a membership fee and in return UP seeks to invalidate weak patents of non-practicing entities which places the business of subscribing companies at risk. UP will only settle for a transferrable license and never accepts monetary compensation.¹⁵⁷ Conversely, in pharmaceutical litigation, generic and branded manufacturers act to resist the end user’s challenge the settlement agreement. This arises because a settlement aligns both generic and branded manufacturers’ interests.¹⁵⁸

V. PROPOSED REFORMS

The patent system represents a conscious balancing between innovation and competition. A limited governmental monopoly is granted to the inventor in exchange for invention disclosure, provided that statutory requirements for patentability are met, as determined by the USPTO, including novelty, usefulness, and non-obviousness. Therefore, an invalid patent does not meet the statutory requirements. Unfortunately, the patent system is not

¹⁵⁴ Bernstein, *supra* note 128, at 1463-65.

¹⁵⁵ *Id.* at 1465.

¹⁵⁶ Joe Mullin, *Unified Patents Files Legal Challenges Against Top Three Patent Trolls of 2016*, ARSTECHNICA (July 27, 2016), <http://www.arstechnica.com/tech-policy/2016/07/patent-defense-group-seeks-to-knock-out-top-three-trolls-of-2015/>.

¹⁵⁷ *FAQ*, UNIFIED PATENTS, <http://www.unifiedpatents.com/faq/> (last visited on Oct. 30, 2016, 1:08 PM).

¹⁵⁸ Bernstein, *supra* note 128, at 1461.

perfect, and while every patent is presumed valid in litigation,¹⁵⁹ in practice many patents that are litigated end up being invalidated.¹⁶⁰ Practically speaking, patents are “probabilistic” and much of the costs of weeding out bad patents are private.¹⁶¹ Successful patent validity challenges create a social benefit by eliminating restraint on competition, but firms who bring validity challenges capture only a fraction of this benefit.¹⁶² Because of this misalignment of benefits, the judicial and patent systems are not properly aligned to protect consumer interests.

A. Redraft the Hatch-Waxman Act

The first step in redrafting the behemoth of legislation is to ruthlessly simplify it – not an easy task for policy analysts and lawyers who are trained to see nuance in the minutia. But, it is abundantly evident that complexity breeds opportunity for manipulation. A simplified system would provide far fewer opportunities for legal maneuvering and require fewer resources.

Moreover, redrafting the Hatch-Waxman Act would provide legislators with an opportunity to apply a systems approach, which would avoid “death by tinkering,” a problem plaguing the patent system.¹⁶³ Legislators often address difficult questions by adjusting legal doctrines in bits and pieces, without comprehensive

¹⁵⁹ 35 U.S.C. § 282(a) (2012).

¹⁶⁰ Dunstan Barnes, Note, *Technically speaking, Does it matter? An Empirical Study Linking the Federal Circuit Judges’ Technical Backgrounds to How They Analyze the Section 112 Enablement and Written Description Requirements*, 88 CHI.-KENT L. REV. 971 (2013) (“[P]anels were more likely to invalidate patents in cases that reached the Federal Circuit on appeal from the BPAI (a patent invalidation rate of 78.4%) than on appeal from federal district court (a patent invalidation rate of 52%).”); Amy Simpson & Hwa Lee, *PTAB Kill Rates: How IPRs Are Affecting Patents*, LAW360 (Sept. 15, 2015, 9:44 AM), <http://www.law360.com/articles/699860/ptab-kill-rates-how-iprs-are-affecting-patents> (Eighty-eight percent of petitions with final written decisions resulted in at least one claim being invalidated, 21% resulted in complete invalidation of the patent).

¹⁶¹ Mark Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSPECTIVES 75, 85-86 (2005) (accessible at <http://pubs.aea-web.org/doi/pdfplus/10.1257/0895330054048650>).

¹⁶² *Id.* at 89-90.

¹⁶³ Robin Feldman, *A Conversation on Judicial Decision-Making*, 5 HASTINGS SCI. & TECH. L.J. 1, 2 (2013).

logic of the legal implications, ultimately causing the entire doctrinal framework to dissolve under its own weight.¹⁶⁴

A systems approach is used in modern medicine to describe cancer treatment.¹⁶⁵ Physicians used to target a tumor by attempting to shrink its size, but tumors are adaptive and can network and develop work-arounds.¹⁶⁶ A systems approach examines and targets the many ways that tumors are networks in a system-wide fashion and systems-approach based therapy shrinks the tumor while also targeting the genetic networks by which the tumor may develop work-arounds.¹⁶⁷

While arguably not without controversy, a systems-approach has been successful and widely adopted in other areas of law. For example, it would be difficult to understate the influence of the American Law Institute (“ALI”) upon jurisprudence in developing the model penal code, the uniform commercial code, or numerous other restatements, from which most other state legislators and judges rely upon.¹⁶⁸ The ALI is an independent group of legal scholars that work to clarify, modernize, and improve the law. Perhaps, the task of re-drafting the Hatch-Waxman Act would be one that is achievable by this or a similar group.

B. PTAB Settlements that Occur Among Competitors Should be Submitted to the FTC for Antitrust Review

There is a strong need for antitrust scrutiny and settling parties should not be allowed to manipulate PTAB IPR proceedings to avoid scrutiny. While not all settlements are detrimental to the public and may simply reflect changes in perceived strength of the parties’ position, a PTAB judge should be more skeptical in accepting settlement terms that preserve a patent’s validity in this context. Currently, the disclosure of agreements is mandated only in district court settlements. Therefore, prudent revision may be that any settlement agreement between branded and generic manufacturers must be submitted to the FTC for antitrust review, either by the PTAB judge or a district court judge. Moreover, if proposed district court litigation coincides with the settlement of a

¹⁶⁴ Feldman & Frondorf, *supra* note 24, at 557.

¹⁶⁵ *Id.* at 556.

¹⁶⁶ *Id.*

¹⁶⁷ *Id.* at 557.

¹⁶⁸ *About ALLI*, THE AMERICAN LAW INSTITUTE, <https://www.ali.org/about-ali/> (last visited Oct. 30, 2016 10:26 PM).

PTAB petition between parties, a federal district court judge should view these as consolidated agreements, and review the entirety of the claim on antitrust grounds.¹⁶⁹

*C. Move Away from Supreme Court's Rule of Reason Analysis
for Pharmaceutical Deals Involving Generic
Manufacturers*

In granting certiorari for the *Actavis* decision, the Supreme Court had three possible standards of antitrust review derived from circuit splits: (1) per se illegality, (2) scope of the patent test, and (3) rule of reason analysis.¹⁷⁰ A majority of federal courts which had analyzed reverse payment settlements according to the scope of the patent test, which presumes the legality of settlements due to the limited monopoly granted to the patent holder.¹⁷¹ In other words a reverse payment settlement is presumptively valid as long as the settlement is not outside the scope of the patent holder's monopolistic limited grant.¹⁷² Instead of the strict per se illegality or a more lenient "scope of the patent" test, the Supreme Court opted for middle ground in mandating the rule of reason test when analyzing whether a reverse payment settlement incurs antitrust liability.¹⁷³

This decision has been widely criticized because of the onerous burden placed on prosecutors. Under the rule of reason test, courts consider factors if the "questioned practice imposes unreasonable restraint on competition."¹⁷⁴ Such factors may include "relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect."¹⁷⁵ Moreover, the antitrust plaintiff carries the initial burden in establishing market power and anticompetitive effect.¹⁷⁶ This burden remains high for antitrust plaintiffs. Congress should place the burden on the settling pharmaceutical companies, requiring them to show that

¹⁶⁹ Hovenkamp & Lemus, *supra* note 144.

¹⁷⁰ Ching, *supra* note 51, at 289.

¹⁷¹ Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1310 (11th Cir. 2003).

¹⁷² *Id.*

¹⁷³ FTC v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013).

¹⁷⁴ State Oil Co. v. Khan, 522 U.S. 3, 10 (1997).

¹⁷⁵ Schering-Plough Co. v. FTC, 402 F.3d 1056, 1065 (11th Cir. 2005).

¹⁷⁶ *Id.*

they are proper and not anticompetitive through appropriate legislative enactments, as discussed *supra* in § V(a)-(b).

VI. CONCLUSIONS

The Hatch-Waxman Act revolutionized the generic drug market by providing incredible incentives to generic manufacturers to challenge weak patent claims and thus allowing speedy delivery of generic drugs to the market by introducing competition and dramatically lowered prices for consumers. However, the complexity resulting from these regulations and any ensuing delay to the generic drugs entering the market through creative legal strategies has yielded extraordinary profits for branded pharmaceutical companies.

Pharmaceutical manufacturers, brand-name or generic, have corporate fiduciary duties to their shareholders. They are in the business of maximizing returns to their shareholders and, to the legal extent possible, they will find ways to do so. But the hide-and-seek games that pharmaceutical manufacturers play with the court, FDA, FTC, and PTO are incredibly wasteful. Patents were granted “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.”¹⁷⁷ When pharmaceutical companies settle upon terms that are anti-competitive, this is counterproductive to their Constitutional grant of a limited monopoly and provides no societal benefit. The proposed reforms are an effort to simplify an overly complex piece of legislation in an effort to avoid what we have seen over the past two decades—a cat and mouse game across the regulatory provisions.

¹⁷⁷ U.S. CONST. art. I, § 8, cl. 8.