

# EARTH TO CONGRESS—THE PHARMACEUTICAL PATENT SYSTEM IS BROKEN—PHARMA PATENTS NEED THEIR OWN SET OF RULES

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## I. INTRODUCTION

Yes, prescription drugs are expensive, but that shows how valuable they are. Besides, our research and development costs are enormous, and we need to cover them somehow. As ‘research-based’ companies, we turn out a steady stream of innovative medicines that lengthen life, enhance its quality, and avert more expensive medical care. You are the beneficiaries of this ongoing achievement of the American free enterprise system, so be grateful, quit whining, and pay up.<sup>1</sup>

This is intended to depict the view of brand name pharmaceutical companies in response to questions as to why pharmaceuticals<sup>2</sup> are so expensive in the United States.<sup>3</sup> The issue is much more complicated and requires an extensive background explanation to fully understand.

Thriving technological innovation in the twenty-first century has enabled drug manufacturers to create innovative drugs to improve the overall quality of patient lives.<sup>4</sup> With this boom in innovation, the cost of pharmaceuticals has grown exponentially, contributing to growing healthcare costs in the United States.<sup>5</sup> As a result, Congress sought to make pharmaceuticals<sup>6</sup> more affordable by creating competition within the

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1. Marcia Angell, *The Truth About the Drug Companies*, N.Y. REV. BOOKS, (July 15, 2004), <http://www.nybooks.com/articles/2004/07/15/the-truth-about-the-drug-companies/> (quoting MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* (Random House, rev. ed. 2005)).
2. The terms “drugs” and “pharmaceuticals” are used interchangeably throughout this Comment.
3. *Id.*; see also *infra* Section III (discussing exponentially rising drug costs).
4. U.S. GOV’T ACCOUNTABILITY OFF. GAO-05-325SP, TWELVE REEXAMINATION AREAS (SECTION 2) OF 21ST CENTURY CHALLENGES: REEXAMINING THE BASE OF THE FEDERAL GOVERNMENT 58 (2005), <http://www.gao.gov/assets/160/157585.pdf>.
5. Brief for Representative Henry A. Waxman at 3–4, as Amici Curiae Supporting Petitioner, *FTC v. Watson*, (No. 12-416), 2013 WL 417736.
6. Note, this Comment only applies to chemically synthesized drugs, which are regulated under the Hatch-Waxman Act of 1984. “Hatch-Waxman applies only to drugs regulated under the Federal Food Drug and Cosmetic Act (“FD&C Act”); these drugs are generally chemically synthesized, small-molecule products, not biologics.” FED. TRADE COMM’N, EMERGING HEALTH CARE

pharmaceutical industry.<sup>7</sup> Congress enacted the Hatch-Waxman Act in 1984, permitting generic pharmaceutical companies to bypass extensive and costly clinical trials, which are required by the FDA to show the drugs' safety and efficacy when seeking approval to market a drug.<sup>8</sup> Basically, this permits generic companies to benefit from the time and money invested by brand name pharmaceutical companies by bringing a generic drug to market quicker and for less cost.<sup>9</sup>

This has been particularly troubling for brand name drug companies because generic drug prescriptions make up approximately 86% of all prescriptions filled,<sup>10</sup> but only account for approximately 27% of all spending.<sup>11</sup> In addition, brand name drug companies have spent approximately \$48 billion annually in research and development over the past ten years; notwithstanding that it takes an average of ten years and \$2.6 billion to bring a single drug to market.<sup>12</sup> Thus, the goal of the Hatch-Waxman Act was to promote competition in order to bring affordable drugs to market, but this procompetitive intent poses challenges to incentivizing development of new drugs.

As a result, over time, brand name pharmaceutical companies have engaged in certain actions to overcome the Hatch-Waxman Act framework

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ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION i (June 2009), <https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf>.

7. Brief for Intellectual Property & Antitrust Professors as Amici Curiae Supporting Plaintiff-Appellee at 8-9, *New York ex rel. Schneiderman v. Actavis, PLC*, 787 F.3d 638 (2d Cir. 2015) (No. 14-4624) [hereinafter IP & Antitrust Professors].
8. Lisa Barons Pensabene et al., *Hatch-Waxman Act: Overview*, PRACTICAL LAW COMPANY 1 (2013), [http://www.fitzpatrickcella.com/wp-content/uploads/HatchWaxman%20Act%20Overview%20pensabene\\_dgregory.pdf](http://www.fitzpatrickcella.com/wp-content/uploads/HatchWaxman%20Act%20Overview%20pensabene_dgregory.pdf).
9. *Id.*
10. Preserve Access to Affordable Generics Act, S. 2019, 114th Cong. §§ 2(a)(2)-(3) (2015).
11. Waxman, *supra* note 5, at 7 (citing IMS INSTITUTE FOR HEALTH INFORMATICS, *THE USE OF MEDICINES IN THE UNITED STATES: REVIEW OF 2011 26* (2012)).
12. PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA, *2015 BIOPHARMACEUTICAL RESEARCH INDUSTRY PROFILE 13* (Apr. 2015), [http://www.phrma.org/sites/default/files/pdf/2015\\_phrma\\_profile.pdf](http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf) (showing the time and money spent represents that of Pharmaceutical Research and Manufacturers of America, which includes "the country's leading biopharmaceutical companies . . ."); Charles Davis, Note, *Take Two and Call Congress in the Morning: How the Biologics Price Competition and Innovation Act May Fail to Prevent Systemic Abuses in the Follow-On Biologics Approval Process*, 81 GEO. WASH. L. REV. 1255, 1267 (2013).  
 These costs include the early development of the drug, the clinical trials process, the application process, legal fees, early marketing, and, most significantly, the costs associated with failed attempts at approval for similar drugs. The substantial costs necessary to bring a successful drug to market are a major cause of the high costs of pioneer drugs that are ultimately passed on to patients.  
*Id.* (citing Donna M. Gitter, *Innovators and Imitators: An Analysis of Proposed Legislation Implementing an Abbreviated Approval Pathway for Follow-On Biologics in the United States*, 35 FLA. ST. U.L. REV. 555, 565-67 (2008)).

to maintain market exclusivity.<sup>13</sup> Such market exclusivity may stem from the right conferred upon Food and Drug Administration (FDA) approved drugs and may exist simultaneously with exclusive rights granted to those drugs deemed worthy of patent protection.<sup>14</sup> One action engaged in to maintain such exclusivity includes entering into reverse payment settlements or “pay-to-delay settlements” to delay generics from entering the market; these settlements have given rise to antitrust scrutiny, which is discussed in this Comment.<sup>15</sup>

Section II introduces the history of the pharmaceutical industry, increasing regulations over the past century, and the current approval process required by the FDA before a drug may be marketed and administered to patients. It also introduces the Hatch-Waxman Act of 1984 and its relevant provisions, including the streamlined approval process for generic drugs. Section III discusses reverse payment settlements, which brand name pharmaceutical companies use to overcome the Hatch-Waxman framework. There is much debate as to whether such acts should be dealt with under the Sherman Antitrust Act, the arguments of which are discussed *infra* in Section III.<sup>16</sup> Lastly, this Comment proposes a solution for the decades-long battle over the Hatch-Waxman framework, which involves separate and distinct rules for pharmaceutical patents.

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13. Jordan Paradise, *REMS as a Competitive Tactic: Is Big Pharma Hijacking Drug Access and Patient Safety?*, 15 HOUS. J. HEALTH L. & POL'Y 43, 52–53, 57 (2015) (discussing “brand name tactics,” namely, product hopping, reverse payment settlements, citizen petitions, and use of REMS); *see also* Matthew J. Seamon, *Antitrust and the Biopharmaceutical Industry: Lessons from Hatch-Waxman and an Early Evaluation of the Biologics Price Competition and Innovation Act of 2009*, 34 NOVA L. REV. 629, 660, 673 (2010).
  14. *Frequently Asked Questions on Patents and Exclusivity*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm> (last updated July 18, 2014) [hereinafter FDA FAQs].
  15. *See* Kimiya Sarayloo, *A Poor Man's Tale of Patented Medicine: The 1962 Amendments, Hatch-Waxman, and the Lost Admonition to Promote Progress*, 18 QUINNIPIAC HEALTH L.J. 1, 26 (2015); Vikram Iyengar, *Should Pharmaceutical Product Hopping Be Subject to Antitrust Scrutiny?*, 97 J. PAT. & TRADEMARK OFF. SOC'Y 663 (2015); *see also* Paradise, *supra* note 13 (discussing brand name drug companies reformulating the drugs through a process known as “product hopping” to prevent generic substitution by pharmacies); *id.* at 64–68 (discussing use of Risk Evaluation Management Systems (“REMS”) to the disadvantage of generic companies, which were created to provide further safety oversight by the FDA; brand name companies have been using them as a weapon to prohibit generic companies from proving the bioequivalence necessary to market generic drugs).
  16. IP & Antitrust Professors, *supra* note 7, at 1–2.

## II. BACKGROUND

### A. History of Pharmaceutical Regulation

Regulation of drug safety did not begin until an unfortunate incident in 1937, when over one-hundred people, including thirty-four children, died from ingesting a drug marketed to treat a myriad of illnesses, including sore throat and gonorrhea.<sup>17</sup> This tragedy highlighted the need for an extensive approval process to ensure drugs were safe for patient consumption.<sup>18</sup> Accordingly, the Federal Food, Drug, and Cosmetic Act of 1938 (“Act”), was implemented, requiring drug manufacturers to demonstrate safety before being approved to market the drug.<sup>19</sup>

Additionally, for the first time, this Act instilled an active role for the FDA, which was previously only involved in challenging marketing fraud by drug manufacturers.<sup>20</sup> Following yet another tragedy, where a sleeping drug was linked to birth defects in Western Europe, Congress implemented the Kefauver-Harris Drug Amendments of 1962 (“the Amendments”), which required pharmaceutical manufacturers to provide evidence of drug efficacy before the drug would be approved for marketing and administration.<sup>21</sup> Additionally, the Amendments tasked the FDA with regulation of drug advertisement, a task formerly held by the Federal Trade Commission (FTC).<sup>22</sup>

Congress has continued to increase regulations among the pharmaceutical industry, addressing safety concerns as they develop and creating more stringent drug labeling and anti-tampering requirements.<sup>23</sup>

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17. Jef Akst, *The Elixir Tragedy, 1937*, THE SCIENTIST (June 1, 2013), <http://www.the-scientist.com/?articles.view/articleNo/35714/title/The-Elixir-Tragedy--1937/>; see also *Promoting Safe and Effective Drugs for 100 Years*, FDA CONSUMER MAG., Jan.-Feb. 2006, <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/PromotingSafeandEffectiveDrugsfor100Years/> (last updated June 18, 2009) (“The S.E. Massengill Co. of Bristol, Tenn., had been marketing the product [titled Elixir Sulanilamide], which was the chemical relative of antifreeze now used in automobiles.”) [hereinafter FDA CONSUMER MAG.].

18. Akst, *supra* note 17.

19. FDA CONSUMER MAG., *supra* note 17.

20. *Id.* The FDA was formerly known as the Bureau of Chemistry in the Department of Agriculture.

21. *Id.*

22. *Id.*

23. *Id.*

In 1966, the Fair Packaging and Labeling Act required all consumer products in interstate commerce to be honestly and informatively labeled, with the FDA enforcing provisions on foods, drugs, cosmetics, and medical devices. In 1970, the FDA required the first patient package insert; oral contraceptives had to contain information about specific benefits and risks in language that patients can understand. Emphasis on OTC labeling came in 1972, when the FDA began reviewing OTC drugs for safety and effectiveness.

*Id.* (“After seven people in Chicago died from swallowing Tylenol capsules laced with cyanide, the FDA issued Tamper-Resistant Packaging Requirements in 1982. The Federal

To address concerns about the slow drug approval process, Congress implemented the Prescription Drug User Fee Act of 1992, which created fee requirements for drug manufacturers “so the FDA could add more resources and speed up drug review times, without compromising standards.”<sup>24</sup>

## B. FDA Drug Approval Process

After decades of congressional actions addressing patient safety concerns, the FDA implemented an extensive and costly application process for pharmaceutical companies seeking to market and administer new medications.<sup>25</sup> During “preclinical development,” once the company determines a drug may be “a viable candidate for further development . . . ,” the pharmaceutical company must compile data of the drug’s pharmacological activity and its “acute toxicity potential in animals” to show that it is “reasonably safe for initial use in humans.”<sup>26</sup> To ensure comprehensive and interstate clinical testing, the pharmaceutical company must submit an Investigational New Drug (IND) application and provide evidence of such preclinical testing.<sup>27</sup> The company may not begin limited dispensing and administering of the drug until thirty days following submission of the IND.<sup>28</sup> For the IND applications that pass into the next stage of development, the drugs must then undergo three phases of clinical testing to ensure patient safety, efficacy, and tolerability.<sup>29</sup>

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Anti-Tampering Act, passed in 1983, makes it a crime to tamper with packaged consumer products.”).

24. *Id.* (“In 1997, the PDUFA was renewed under the Food and Drug Administration Modernization Act and then renewed again in 2002 for five more years.”); *see also A Conversation About the FDA and Drug Regulation with Janet Woodcock, M.D., Deputy FDA Commissioner for Operations*, FDA, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143467.htm> (last updated Aug. 12, 2011).

25. Davis, *supra* note 12, at 1266.

26. *Investigation New Drug (IND) Application*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm> (last updated Aug. 1, 2016) (“[H]aving screened the new molecule for pharmacological activity and acute toxicity potential in animals, wants to test its diagnostic or therapeutic potential in humans.”).

27. *Id.*

28. *Id.* (“Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time, FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.”).

29. Gitter, *supra* note 12, at 565–66.

Phase I clinical trials test for safety and tolerability of the drug in humans; involve about twenty to one hundred healthy, nominally paid volunteers; and generally last between one to three months. Phase II clinical trials continue testing for safety and tolerability and also assess the preliminary efficacy of the drug. Phase II trials often involve several hundred unpaid volunteers diagnosed with a particular condition and generally last about six months to two years. Phase III clinical trials constitute ‘the most costly stage of drug development.’ ‘[D]esigned to evaluate statistically the safety and efficacy of the drug . . . within a larger and typically more diverse population,’

If the drug passes the clinical trial phases, an applicant must submit a New Drug Application (NDA) for the next stage of the approval process.<sup>30</sup> An NDA drug must meet drug labeling and manufacturing requirements, include the results of each phase of the clinical trials to assure the medication's safety and efficacy,<sup>31</sup> and, if applicable, should include all information regarding patents obtained for the drug.<sup>32</sup> Once the FDA approves the NDA, the drug is published in the *Orange Book*,<sup>33</sup> formally known as the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which lists all patent information associated with the drug.<sup>34</sup>

### C. Enactment of the Hatch-Waxman Act of 1984

Before the Hatch-Waxman Act, generic drug options did not exist for approximately 150 drugs with expired patents.<sup>35</sup> Generic pharmaceutical companies had to undergo the same extensive research, development, and clinical trial processes to market and administer a generic drug, which

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these trials involve hundreds to several thousand patients and last an average of four years.

*Id.* (citing Ernst R. Berndt et al., *Opportunities for Improving the Drug Development Process: Results from a Survey of Industry and the FDA*, 6 INNOVATION POL'Y & ECON. 91, 98–100 (2006)); *see also* Jill A. Fisher et al., *Peering into the Pharmaceutical "Pipeline": Investigational Drugs, Clinical Trials, and Industry Priorities*, 131 SOC. SCI. & MED. 322, 322–23 (2015).

30. 21 U.S.C. § 355(b)(1) (2012).

31. *See id.* § 355; *see also* Pensabene et al., *supra* note 8; *How Drugs are Developed and Approved*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/> (last updated Aug. 18, 2015).

32. FDA FAQs, *supra* note 14.

Patent information is required to be submitted with all new drug applications at the time of submission of the NDA. Patent information is published after approval upon receipt of post approval submitted FDA form 3542. For patents issued after approval of the NDA, the applicant holder has 30 days in which to file the patent to have it considered as a timely filed patent. Patents may still be submitted beyond the 30 day timeframe but the patent is not considered a timely filed patent. ANDA holders are not required to make a certification to an untimely filed patent if the generic application is submitted before the patent.

*Id.*

33. *See* FDA, U.S. DEP'T. OF HEALTH & HUMAN SERVS., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS iv (36th ed. 2016), <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf> (“The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the [FDA] under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).”) [hereinafter ORANGE BOOK].

34. *See id.* at add. ADA1.

35. Michael A. Carrier & Steven D. Shadowen, *Product Hopping: A New Framework*, 91 NOTRE DAME L. REV. (forthcoming 2016) (manuscript at 7) [http://www.hilliardshadowenlaw.com/images/uploads/banner/Carrier-Shadowen\\_Product-Hop\\_Framework\\_law\\_review1.pdf](http://www.hilliardshadowenlaw.com/images/uploads/banner/Carrier-Shadowen_Product-Hop_Framework_law_review1.pdf).

likely contributed to the lack of generic drugs.<sup>36</sup> Thus, generic drugs did not enter the market until a couple of years after expiration of the brand name patents because generic drug manufacturers had to wait for such expiration to begin drug trials required for the FDA approval process.<sup>37</sup>

The Hatch-Waxman Act contributed to the growing generic drug market by permitting generic drug companies to perform the necessary bioequivalence testing during the term of the brand name patents and excused any would be infringing activity.<sup>38</sup> The Hatch-Waxman Act and the Abbreviated New Drug Application (ANDA)<sup>39</sup> option purported to substantially lower the cost and time required to bring a generic to market, which naturally incentivized the development of generic drugs.<sup>40</sup>

### 1. Abbreviated New Drug Application

The Hatch-Waxman Act provides generic pharmaceutical companies the opportunity to submit an ANDA for an expedited generic drug approval process.<sup>41</sup> The ANDA must certify bioequivalence of the generic to the original drug, including the same active ingredients, dosage, intended use, and administration, and need only reference the results of clinical trials conducted by the original pharmaceutical company to prove the generic's

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36. Davis, *supra* note 12; see Gitter, *supra* note 12, at 568; Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585; see also Michael F. Werno, *More Questions than Answers? The Uncertainties Surrounding Reverse Payment Settlements in the Post-Actavis World*, 21 B.U. J. SCI & TECH. L. 200, 201 n.4 (2015) (“Prior to the Hatch-Waxman Act, only 35% of these brand-name drugs had generic competition.”) (citing Martha M. Rumore, *The Hatch-Waxman Act—25 Years Later: Keeping the Pharmaceutical Sales Balanced*, PHARMACY TIMES (Aug. 15, 2009), <http://www.pharmacytimes.com/publications/supplement/2009/GenericSupplement0809/Generic-HatchWaxman-0809>).

37. Carrier & Shadowen, *supra* note 35.

38. 35 U.S.C. § 271(e)(1) (2012); see also Carrier & Shadowen, *supra* note 35 (Prior to the Hatch-Waxman Act, “[a] generic company could not even begin the preclinical and clinical process needed for FDA approval of its own version before all of the relevant patents on the brand-name drug expired.”); Aaron S. Kesselheim & Jonathon J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL’Y L. & ETHICS 293, 300 (2015) (“Under 35 U.S.C. section 271(e)(1), it is not patent infringement to conduct otherwise infringing acts necessary to prepare an ANDA.” *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002)).

39. See discussion *infra* Part II.C.1.

40. See 21 U.S.C. § 355(j) (2012); see also Davis, *supra* note 12, at 1268 (“The Hatch-Waxman Act has decreased the cost of bringing a generic drug to market to only \$2 million—as compared to the \$1 billion [in 1984] necessary to complete a full NDA application—leading to a boom in the generic drug industry.”); see also *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) (highlighting that the main purpose of the Hatch-Waxman Act and ANDA was to “get generic drugs into the hands of patients at reasonable prices—fast.”).

41. 21 U.S.C. § 355(j); see also Davis, *supra* note 12, at 1268.

safety and efficacy.<sup>42</sup> The ANDA must also include a certification to one of four “paragraphs” regarding the original drug, including (I) that the original drug is not patent protected; (II) that the original drug patent has expired; (III) set forth the expiration date of the original drug; or (IV) that the original drug patent is “invalid or will not be infringed by the manufacture, use, or sale of the new [generic] drug for which the [ANDA] is submitted[.]”<sup>43</sup>

The ANDAs certifying to paragraphs I and II will be approved promptly, so long as all scientific and statutory requirements are met.<sup>44</sup> If certification is sought under paragraph III, assuming all scientific and statutory requirements are met, the ANDA will be approved once the original drug patent expires.<sup>45</sup> ANDAs certifying to paragraph IV must notify the original drug patent owner of its certification;<sup>46</sup> the paragraph IV ANDA will be approved if all scientific and statutory requirements are met unless, within forty-five days following the required notice, the original drug patent owner files an infringement suit against the generic drug manufacturer.<sup>47</sup> The FDA approval process for the ANDA is halted if an infringement suit is filed; the ANDA will not be approved until the earliest of either the patent is found invalid or not infringed, the original drug patent expires, or the passage of thirty months from the date the original drug patent owner received notice of the paragraph IV certification.<sup>48</sup>

In the case of a paragraph IV certified ANDA, regardless of whether the original drug patent is found invalid or not infringed, the first ANDA filer is entitled to 180-days as the exclusive generic on the market.<sup>49</sup> Subsequent ANDA filers will not receive FDA approval to market their generic drug until passage of the 180-days.<sup>50</sup> Rewarding the first ANDA filer is intended to encourage prompt ANDA filings to get more affordable drugs to market quicker.<sup>51</sup> The 180-day market exclusivity “is triggered by

42. 21 U.S.C. § 355(j); see ORANGE BOOK, *supra* note 33, at § 1.4 (calling the original drug the reference listed drug, “mean[ing] the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA.”); 21 C.F.R. § 314.94(a)(3) (2016).

43. 21 U.S.C. §§ 355(j)(2).

44. 5-16 CHISUM ON PATENTS § 16.03[1][d] n.117 (2015) (citing *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1244–45 (Fed. Cir. 2000)).

45. *Id.*

46. 21 U.S.C. § 355(j)(2)(viii)(B)(iii)(I); see also CHISUM ON PATENTS, *supra* note 44.

47. 21 U.S.C. § 355(j)(5)(B)(iii); see CHISUM ON PATENTS, *supra* note 44; see also 35 U.S.C. § 271(e)(2)(A) (2012) (addressing patent infringement by an entity filing an ANDA).

48. CHISUM ON PATENTS, *supra* note 44; see also 21 U.S.C. § 355(j)(2).

49. CHISUM ON PATENTS, *supra* note 44 at n.119; see also 21 U.S.C. § 355(j)(2).

50. CHISUM ON PATENTS, *supra* note 44 at n.119; see also 21 U.S.C. § 355(j)(2).

51. *Davis*, *supra* note 12, at 1268; see also *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008).

As an incentive for generic pharmaceutical companies to challenge suspect Orange Book listed patents, the Hatch-Waxman Act grants the first company to submit a Paragraph IV ANDA a 180-day period of generic marketing exclusivity during which



the earlier of two events: (1) the first Paragraph IV ANDA filer's commercial marketing of a drug product; or (2) a court decision of noninfringement or invalidity."<sup>52</sup> However, the 180-day exclusivity period is not guaranteed and may be forfeited for various reasons, including not marketing the drug within 75 days after the ANDA approval or within 30 months from submission of the ANDA.<sup>53</sup> Nonetheless, if the first generic ANDA filer is awarded the 180-days of market exclusivity, this exclusivity period will likely be very profitable for the generic manufacturer.<sup>54</sup>

There are several provisions of the Hatch-Waxman Act intended to ensure protection of the original pharmaceutical companies' exclusive rights. For instance, The Hatch-Waxman Act does not allow an ANDA to be filed within five years of approval of a new NDA.<sup>55</sup> Similarly, a generic drug will not be approved for marketing while the original pharmaceutical company still holds a valid patent on the original drug, and, thus, the ANDA will only be approved to market the generic drug if the original drug's patents expire or if the patents are held to be invalid or not infringed.<sup>56</sup> Furthermore, to make up for time needed for drug development and FDA approval, the Hatch-Waxman Act provides for "patent term restoration," which adds the development and approval time back to the term of the patent.<sup>57</sup>

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time FDA will not approve a later-filed Paragraph IV ANDA based on the same NDA[.]

*Id.*

52. *Janssen Pharmaceutica*, 540 F.3d at 1356; *see also* 21 U.S.C. § 355(j)(5)(B)(iv).

53. 21 U.S.C. § 355(j)(5)(D); *see* Pub. L. No. 108-173, 117 Stat. 2066 (2003) (discussing the forfeiture provisions, which were added with enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003).

54. Allison Schmitt, *Competition Ahead? The Legal Landscape for Reverse Payment Settlements After Federal Trade Commission v. Actavis, Inc.*, 29 BERKELEY TECH. L. J. 493, 498 (2014).

55. 21 U.S.C. § 355(j)(5)(F)(ii); *see* Davis, *supra* note 12, at 1269; *see also* FDA FAQs, *supra* note 14 (showing that exclusivity varies depending on the type of drug, thus: "Orphan Drug (ODE) – 7 years; New Chemical (NCE) – 5 years; 'Other' Exclusivity – 3 years for a 'change' if criteria are met; Pediatric Exclusivity (PED) – 6 months added to existing Patents/Exclusivity; Patent Challenge (PC) – 180 days (this exclusivity is for ANDAs only)").

56. 21 U.S.C. §§ 355(a), 355(j)(5)(B); *see also* Davis, *supra* note 12, at 1269.

57. 35 U.S.C. § 156(a) (2012); *see also* Kesselheim & Darrow, *supra* note 38, at 306.

In cases in which development and approval took especially long, brand-name manufacturers might find that little or no patent term remained by the time the FDA approved the drug for marketing. The Hatch-Waxman Act addressed this issue by granting brand-name companies 'patent term restoration' or additional time that would be added to the seventeen-year patent term to compensate the patent holder for a portion of the patent term that was lost during the clinical testing phases and FDA review period.

*Id.*

## 2. *Results After More Than Three Decades*

There is some evidence that the Hatch-Waxman Act has achieved its goals for the most part, as generic drugs account for approximately 84% of all prescriptions filled.<sup>58</sup> Moreover, because generic drugs cost substantially less than brand name drugs, it is no surprise that “in 2012, pharmaceutical spending fell 1%, the first decrease in nearly two decades, a trend attributed to more widespread generic drug availability.”<sup>59</sup> Therefore, generic drugs have “dramatically reduced healthcare costs—more than a trillion dollars in the past decade . . . [;]” however, prescription drug and health care costs overall are projected to continue increasing over the next decade.<sup>60</sup> Nonetheless, generic drugs availability has “been shown to promote adherence to medication regimens, enhance access to drugs for lower-income patients, and reduce financial strain caused by illness.”<sup>61</sup> Increased availability of more affordable generic drugs has provided more patients with the opportunities to benefit from proper drug treatments, ultimately leading to “better patient health outcomes.”<sup>62</sup>

### III. DISCUSSION

Though some benefits of the Hatch-Waxman Act are in line with the purported goal of its enactment, not all players are benefiting. This is because when a generic drug enters the market as a result of the Hatch-Waxman Act, the brand name drug manufacturer will most likely suffer a substantial loss in profits and market control.<sup>63</sup> The Hatch-Waxman Act

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58. Preserve Access to Affordable Generics Act of 2015, S. 2019, 114th Cong. §§ 2(a)(2)-(3) (2015); Kesselheim & Darrow, *supra* note 38, at 295.

59. Kesselheim & Darrow, *supra* note 38, at 318.

60. *Id.* at 295 (citing U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-371R, DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE 4 (2012)); OFF. OF ACTUARY, CTR FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURE PROJECTIONS 2015–2025: FORECAST SUMMARY 1 (2014), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2015.pdf> (“For 2015–25, health spending is projected to grow at an average rate of 5.8 percent per year (4.8 percent on a per capita basis.”) [hereinafter OFF. OF ACTUARY].

61. Kesselheim & Darrow, *supra* note 38, at 316.

62. *Id.*

63. Joel S. Sprout, *Presumptively Illegal: The Supreme Court's Missed Opportunity in FTC v. Actavis, Inc.*, 42 CAP. U. L. REV. 763, 765 (2014).

[E]xample from 2003, drug manufacturer Schering-Plough, the patent holder for drugs including Claritin and Nasonex, reported massive losses of profit as a result of ‘the loss of exclusive selling rights for big sell[ing drugs].’ Generic versions of Schering-Plough’s drugs that entered the market between 2002 and 2003 sold for around 10% of the name-brand price, destroying Schering-Plough’s control of the market and drastically lowering profits.

*Id.* (citing Gardiner Harris, *Schering-Plough is Hurt by Plummeting Pill Costs*, N.Y. TIMES, July 8, 2003, at C1.).

ensures consumers have access to affordable drugs quickly, though creating challenges for brand name companies, while also encouraging the development of new drugs.<sup>64</sup> The research and development needed to develop new drugs requires a substantial investment by brand name companies; thus, there is a dilemma as to how brand name companies can receive the necessary return on investment required to bring such new and innovative drugs to market.<sup>65</sup>

#### A. Overcoming the Hatch-Waxman Act

Ideally, under the Hatch-Waxman framework, inexpensive generic drugs enter the market, coercing brand name companies to come up with even better drugs to advance the overall quality of patient health.<sup>66</sup> Instead, the Hatch-Waxman Act has resulted in survival tactics by brand name drug companies to maintain control of the market, as granted by their exclusive patent rights.

##### 1. Reverse Payment Settlements

Despite provisions of the Hatch-Waxman Act intended to protect brand named drug manufacturers, it was enacted with procompetitive intent.<sup>67</sup> Thus, Congress ultimately created a regulatory regime incentivizing generic drug companies to challenge brand name drug patents in order to market substantially less expensive drugs.<sup>68</sup> Not surprisingly, as a result, brand name drug companies have acted to protect their exclusive patent rights over generic companies.<sup>69</sup>

As one way to maintain their exclusive patent rights, brand name pharmaceutical companies began entering into reverse payment settlement agreements, whereby the generic manufacturer is paid to drop the lawsuit resulting from a paragraph IV ANDA filing and agrees not to enter the market until expiration of the brand name drug patent.<sup>70</sup> Brand name pharmaceutical companies may likely pay all ANDA filers to maintain their market exclusivity.<sup>71</sup> These agreements undermine the purpose of the Hatch-Waxman Act and likely increase drug costs for consumers because

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64. *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370–71 (Fed. Cir. 2002).

65. Sprout, *supra* note 63, at 766.

66. Kesselheim & Darrow, *supra* note 38, at 308–09.

67. Schmitt, *supra* note 54, at 497–98.

68. *Id.* at 498–99.

69. *Id.*

70. *Id.* at 499–500.

71. *Id.* at 500.

consumers would be paying less if generics were available before expiration of the brand name drug patent.<sup>72</sup>

An example demonstrating the effects reverse payment settlements have on the cost of drugs occurred when generics for Provigil, a sleep-disorder drug, attempted to enter the market.<sup>73</sup> The active ingredients patent was issued to Cephalon in 1979 and was set to expire in 2001.<sup>74</sup> In 1997, four years before the active ingredient patent was set to expire, Cephalon was granted another patent claiming a narrower formulation “consist[ing] of a specified distribution of small particles.”<sup>75</sup> As the expiration of the active ingredient patent was nearing, four generic drug companies filed ANDAs.<sup>76</sup> Ultimately, Cephalon entered into reverse payment settlement agreements with all four generic companies, collectively paying them more than \$200 million to maintain market exclusivity until 2012, which resulted in \$4 billion more in revenue.<sup>77</sup>

In addition to paying generic drug companies to delay market entry, brand name pharmaceutical companies may also enter into non-monetary agreements including co-marketing, co-promoting, licensing, supply, and distribution in order to maintain control in the marketplace.<sup>78</sup> Another type of agreement benefiting generic drug companies is “no-authorized generic agreements,” whereby “the brand name company agrees to not market its own generic brand against a generic manufacturer’s product.”<sup>79</sup>

Inherently, reverse payment settlements implicate anticompetitive concerns by undermining the purpose of the Hatch-Waxman Act, which is to bring low cost drugs to market faster in a procompetitive fashion.<sup>80</sup> These settlements benefit the pharmaceutical industry, as the brand name company maintains market exclusivity while generics receive a significant

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72. *Id.* at 501–02 (“[R]everse payment settlements may have the effect of raising costs for consumers, reflected in pharmaceutical prices higher than what consumers would pay if generics could enter the market and decrease prices overall.”).

73. See Michael A. Carrier, *Provigil: A Case Study of Anticompetitive Behavior*, 3 HASTINGS SCI. & TECH. L.J. 441, 441–44 (2011).

74. *Id.* at 442.

75. *Id.* (quoting Complaint for Injunctive Relief at 9, *FTC v. Cephalon, Inc.*, 551 F. Supp. 2d 21 (D.D.C. 2008) (No. 08-0244), 2008 WL 446785, at ¶ 35) (“Unlike the patent on the compound itself, generic firms could easily avoid this narrow formulation patent. As a consultant advised Cephalon in 2002: ‘[A]ll generic companies know [that the patent] may be easily circumvented’ by manufacturing products to contain a different distribution of modafinil particle sizes.”).

76. *Id.*

77. *Id.* at 444.

78. Schmitt, *supra* note 54, at 502 n.47 (citing C. Scott Hemphill, *Drug Patent Settlements Between Rivals: A Survey* 3–4 (Colum. Law Sch., Working Paper, 2007), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=969492](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=969492)).

79. *Id.* at 526.

80. *Id.* at 494.

share of the brand name's profits.<sup>81</sup> However, as the FTC stated in 2012, this is a "lose-lose for everyone else," as these settlements cost consumers roughly \$3.5 billion annually due to only the more expensive name brand drug being available.<sup>82</sup>

## 2. "Rule of Reason" Standard—FTC v. Actavis

*FTC v. Actavis* exemplifies how a paragraph IV ANDA certification followed by a reverse payment settlement is carried out and addresses antitrust scrutiny implicated by these settlements. *Actavis* was decided in 2013, but it has done everything but solve the issue of reverse payment settlements and their restraint on competition.

Solvay Pharmaceuticals filed an NDA for AndroGel in 1999, which is used to treat men with low levels of testosterone.<sup>83</sup> The NDA was approved the following year, and Solvay obtained a patent on the drug in 2003, which Solvay properly disclosed to the FDA for inclusion in the *Orange Book*.<sup>84</sup> During the same year the patent was obtained and disclosed to the FDA, two ANDAs were filed for generic versions of AndroGel, which were both certified under paragraph IV of the Hatch-Waxman Act.<sup>85</sup> The first one was filed by Actavis, Inc. and another was filed by Paddock Laboratories, joined by Par Pharmaceutical.<sup>86</sup>

Solvay Pharmaceuticals then filed paragraph IV litigation against Actavis and Paddock, which halted the ANDA approval process.<sup>87</sup> Because no decision was reached within thirty months from filing the paragraph IV lawsuit,<sup>88</sup> the FDA approved Actavis' ANDA, granting them the 180-day exclusivity period.<sup>89</sup> However, all parties to the paragraph IV litigation

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81. FED. TRADE COMM'N, FTC STAFF REPORT FINDS 60 PERCENT INCREASE IN PHARMACEUTICAL INDUSTRY DEALS THAT DELAY CONSUMERS' ACCESS TO LOWER-COST GENERIC DRUGS (May 3, 2011), <http://ftc.gov/opa/2011/05/mmreport.shtm> ("Collusive deals to keep generics off the market are already costing consumers and taxpayers \$3.5 billion a year in higher drug prices," said FTC Chairman Jon Leibowitz. "The increasing number of these deals is a win-win proposition for the pharmaceutical industry, but a lose-lose for everyone else.").

82. *Id.*

83. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013); ANDROGEL, <https://www.androgel.com> (last visited Mar. 18, 2016).

84. *Actavis*, 133 S. Ct. at 2229.

85. *Id.*

86. *Id.* ("Par Pharmaceutical, likewise a respondent, did not file an application of its own but joined forces with Paddock, agreeing to share the patent litigation costs in return for a share of profits if Paddock obtained approval for its generic drug.").

87. *Id.*

88. *Id.*

89. *Id.* at 2230–31. The FDA approval process for the ANDA is halted if an infringement suit is filed; the ANDA will not be approved until the earliest of either the patent is found invalid or not infringed, the original drug patent expires, or the passage of thirty months from the date the original drug patent owner received notice of the paragraph IV certification. CHISUM ON PATENTS, *supra* note 44.

settled before Actavis began manufacturing and marketing its generic drug.<sup>90</sup> The agreement reached between the parties permitted Actavis to bring its generic drug to market on August 31, 2015, over five years before the AndroGel patent expired.<sup>91</sup> Paddock, Par, and Actavis similarly agreed to advocate for AndroGel to urologists, and Solvay agreed to pay each of them a substantial amount of money to not market their generic drugs.<sup>92</sup> Specifically, “\$12 million in total to Paddock; \$60 million in total to Par; and an estimated \$19–\$30 million annually, for nine years, to Actavis.”<sup>93</sup>

The FTC filed suit against all parties.<sup>94</sup> The FTC was unconvinced the payments were compensation for the services Paddock, Par, and Actavis agreed to provide for Solvay, as the FTC claimed the payments were to keep them out of the market.<sup>95</sup> The FTC alleged the settlement agreement violated federal antitrust laws “by unlawfully agreeing ‘to share in Solvay’s monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years.’”<sup>96</sup>

The District Court and the Eleventh Circuit disagreed with the FTC’s claims of antitrust violations.<sup>97</sup> The Eleventh Circuit’s reasoning was based on the exclusivity granted to patent owners, specifically that “a reverse payment settlement is immune from antitrust attack” and described patents rights as a “right to cripple competition.”<sup>98</sup> Subsequently, the Supreme Court granted FTC’s petition for certiorari to address differing courts’ conclusions on the matter of whether reverse payment settlements violate antitrust laws.<sup>99</sup>

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90. *Actavis*, 133 S. Ct. at 2229.

91. *Id.* at 2238.

92. *Id.*

93. *Id.*

94. *Id.* at 2229.

95. *Id.*

96. *Id.*

97. *Id.* at 2230.

98. *Id.* (“[A]bsent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”) (quoting *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1310, 1312 (11th Cir. Ga. 2012)).

99. *Id.*

Because different courts have reached different conclusions about the application of the antitrust laws to Hatch-Waxman-related patent settlements, we granted the FTC’s petition. Compare, [*FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (2012)] (settlements generally “immune from antitrust attack”); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323, 1332–1337 (Fed. Cir. 2008) (similar); *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 212–213 (2d Cir. N.Y. 2006) (similar), with *In re K-Dur Antitrust Litigation*, 686 F.3d 197, 214–218 (3d Cir. N.J. 2012) (settlements presumptively unlawful).

*Id.*

The Supreme Court agreed that a patent provides the owner with exclusivity to manufacture and market the drug but reasoned the Eleventh Circuit was wrong to end its analysis there.<sup>100</sup> In bringing the paragraph IV certified ANDA, Paddock, Par, and Actavis sought to potentially invalidate the patent, but that invalidity challenge ended when the parties settled.<sup>101</sup> This is concerning, the Supreme Court reasoned, because “settlements taking this form tend to have significant adverse effects on competition[,]” which *may* implicate antitrust violations, thus requiring analysis of the settlement under antitrust laws as well as patent laws.<sup>102</sup> This type of settlement is problematic because it may create a presumption that the patent is weak and should be held invalid.<sup>103</sup>

Ultimately, the Supreme Court held that reverse payment settlements *may* implicate antitrust violations, leaving it to the lower courts to decide under the “rule of reason” standard.<sup>104</sup> Under this standard, the Court set forth a subjective test to be applied, which states:

[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.<sup>105</sup>

Thus, the Supreme Court created a subjective “rule of reason” standard for lower courts to use in determining whether a reverse payment settlement violates antitrust laws. However, *Actavis* does not pose a solution to the underlying issues of the Hatch-Waxman framework, patent rights, and antitrust laws. Specifically, patents are an exception to antitrust laws so long as the patent owner is acting within the scope of the rights granted by the United States Patent and Trademark Office (USPTO).<sup>106</sup>

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100. *Id.*

101. *Id.* at 2231.

102. *Id.* (“[B]y considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents.”).

103. Michael F. Werno, *More Questions than Answers? The Uncertainties Surrounding Reverse Payment Settlements in the Post-Actavis World*, 21 B.U. J. SCI & TECH. L. 200, 202 (2015).

104. *See Actavis*, 133 S. Ct. 2223 (2013).

105. *Id.* at 2237.

106. *Id.* at 2238 (Roberts, C.J., dissenting).

## B. Competing Policy Goals: Patent Laws versus Antitrust Laws

By enacting the Hatch-Waxman Act, Congress attempted to balance the conflict between patent laws and antitrust laws to bring affordable drugs to consumers while still encouraging development of new drugs.<sup>107</sup>

Antitrust laws exist to benefit the public by ensuring competition in the marketplace.<sup>108</sup> Section 1 of the Sherman Act states that “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade of commerce among the several States, or with foreign nations, is declared to be illegal.”<sup>109</sup> Section 2 of the Sherman Act states that “[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations . . .” shall be guilty of violating the statutory prohibition on antitrust behavior.<sup>110</sup> Therefore, antitrust laws forbid activities that eliminate competition and impose an unreasonable restraint on trade in the marketplace.<sup>111</sup>

On the other hand, patent laws exist to “promote the progress of science and useful arts, by securing for limited times to . . . inventors the exclusive right to their . . . discoveries.”<sup>112</sup> Patent owners obtain the right to exclude others for the fixed term of twenty years.<sup>113</sup> The public, on the other hand, “benefits from the disclosure of inventions, the entrance into the market of valuable products whose invention might have been delayed but for the incentives provided by the patent laws, and the increased competition the patented product creates in the marketplace.”<sup>114</sup> This exclusive right inherently restrains competition and trade, “but this anticompetitive effect is not unreasonable under the Sherman Act because the exclusivity period encourages and finances ongoing new product development, which ultimately benefits consumers.”<sup>115</sup>

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107. Sprout, *supra* note 63, at 766 (“Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.”) (citing *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370–71 (Fed. Cir. 2002)).

108. *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1203 (2d Cir. Conn. 1981).

109. 15 U.S.C. § 1 (2012).

110. *Id.* § 2.

111. *Id.* § 1 (Antitrust laws forbid “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several [s]tates.”); *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997) (“Although the Sherman Act, by its terms, prohibits every agreement ‘in restraint of trade,’ this Court has long recognized that Congress intended to outlaw only unreasonable restraints.”).

112. U.S. CONST., art. I, § 8, cl. 8.

113. 35 U.S.C. § 154 (2012).

114. *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1203 (2d Cir. 1981).

115. Sprout, *supra* note 63, at 778.



In sum, “[t]he patent-antitrust tension exists because patent law grants a period of time when the new patent holder owns exclusive rights to profit from the patented product, while antitrust law combats monopolistic practices.”<sup>116</sup>

### *1. Patents are an Exception to Antitrust Laws*

The right to prevent others from making and profiting from an invention is at the core of the exclusive patent rights; however, this is what the majority in *Actavis* has potentially allowed to occur.<sup>117</sup> The problem with the majority’s opinion, other than confusing what rights patent owners hold, is that a patent is an exception to antitrust laws.<sup>118</sup> As long as the patent owner is exercising the exclusive right within the scope of the patent, there should be no question as to an antitrust violation.<sup>119</sup> Only when the patent owner is acting outside the scope of the rights conferred by the patent could this implicate an antitrust violation.<sup>120</sup>

The scope of a patent is determined by what is contained in the specification, claims, and drawings.<sup>121</sup> The terms of a patent are well defined and the rights conferred to patent owners allow them to control the use of their patent, whether by license or otherwise.<sup>122</sup> The patent scope approach has also been described as the “walled garden” approach, which protects everything within the scope of a patent from an antitrust violation.<sup>123</sup> These approaches are long-gone in current antitrust disputes, as highlighted by the Supreme Court in *Actavis*.<sup>124</sup>

Historically, when an area of the law was heavily regulated, as with patent law, there was no place for antitrust scrutiny because heavy

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116. *Id.* at 766.

117. The patent infringement statute states, “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.” 35 U.S.C. § 271(a).

118. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2238 (2013) (Roberts, C.J., dissenting).

119. *Id.*

120. *Id.* (citing *United States v. General Elec. Co.*, 272 U.S. 476, 485 (1926)).

121. Herbert Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76 OHIO ST. L.J. 468, 477 (2015).

122. *Id.*; see also *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665–66 (1944) (Patent law “denies to the patentee after issuance the power to use it in such a way as to acquire a monopoly which is not plainly within the terms of the grant.” And “[t]he fact the patentee has the power to refuse a license does not enable him to enlarge the monopoly of the patent by the expedient of attaching conditions to its use.”).

123. Hovenkamp, *supra* note 121, at 472 (citing WARD S. BOWMAN, JR., *PATENT AND ANTITRUST LAW: A LEGAL AND ECONOMIC APPRAISAL* 239–56 (1973)).

124. *Id.* at 477–78 (applying the “rule of reason” standard in place of the “beyond the scope” approach); see also *Actavis*, 133 S. Ct. 2239.

regulation “oust[ed]’ antitrust from the regulated market altogether.”<sup>125</sup> The regulators in that area were in control of the field, which left no room for another governmental agency to intrude.<sup>126</sup> This is still the case today, as the USPTO is the governmental agency responsible for issuing patents and regulating the field.<sup>127</sup> The USPTO may have its own problems, such as issuing poor-quality patents with exceedingly broad claims, but it is not the role of antitrust laws to “police shortcomings in other regulatory agencies.”<sup>128</sup> This is potentially what is being done though, if antitrust laws are used to address the issue of poor quality patents.

### C. Cause and Effect—Solutions to the Pharma Patent Problem

Although some evidence suggests that drug costs have decreased as a result of the Hatch-Waxman Act, the overall cost of drugs has continued to rise and is estimated to rise by an average of 5.8% annually between 2015 and 2025.<sup>129</sup> Thus, even with antitrust scrutiny being imposed on brand name drug companies, there is still a major problem of high drug cost, which is not adequately addressed by the Hatch-Waxman Act.

#### 1. *Making a Profit and Making Drugs*

There are ten major drug manufacturers, five of which are located in the United States.<sup>130</sup> Most of these companies bring in well over \$20 billion in revenue annually, with profit margins ranging from 10% to as high as 42%.<sup>131</sup> Therefore, understandably, courts and the public generally find issue when brand name drug manufacturers essentially “pay off” generic drug companies to maintain their exclusive patent rights; this is especially true considering rising healthcare costs in the United States, since drug prices make up roughly 10% of these increasing costs and are expected to continue rising in years to come.<sup>132</sup>

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125. Hovenkamp, *supra* note 121, at 478 (citing *Hughes Tool Co. v. Trans World Airlines, Inc.*, 409 U.S. 363, 389 (1973)).

126. *Id.*

127. *Id.* at 480.

128. *Id.*

129. OFF. OF ACTUARY, *supra* note 60.

130. *Global 200: The Biggest Drug Companies of 2014*, FORBES, <http://www.forbes.com/pictures/mkg45edhgd/no-1-pfizer/#7cb3ecfa8c7f> (last visited Sept. 15, 2016).

131. Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC (Nov. 6, 2014), <http://www.bbc.com/news/business-28212223>; Liyan Chen, *Best of The Biggest: How Profitable Are The World's Largest Companies?*, FORBES (May 13, 2014), <http://www.forbes.com/sites/liyanchen/2014/05/13/best-of-the-biggest-how-profitable-are-the-worlds-largest-companies/#28dd4e3f4c33>.

132. Waxman, *supra* note 5, at 3–4.

There has been some evidence of decreasing pharmaceutical costs<sup>133</sup> since the increased availability of generics resulting from the Hatch-Waxman Act; thus, it is not surprising that demand for brand name drugs has been suppressed while the price of brand name drugs has continued to rise.<sup>134</sup> Increased innovation encouraged by the Hatch-Waxman Act likely requires increased time and costs for research and development of new drugs. It makes sense that brand name drugs prices seem to be increasing, especially where generics make up such a large percentage of prescriptions filled.

Brand name drugs costs are high because brand name drug manufacturers are in the business of making a profit, but they are also in the business of making drugs.<sup>135</sup> Turning a profit is crucial for survival, as brand name companies are often controlled by corporate board members and shareholders, which desire a return on their investment in the company.<sup>136</sup> Accordingly, large pharmaceutical companies seek to profit from their drug for as long as they can in order to satisfy investors.<sup>137</sup>

Thus, if not for the increased brand name drug prices, would brand name companies be able to fund the research and development (R&D) necessary to bring new, breakthrough drugs to market? The answer to this question can be inferred from the fact that brand name drug companies only spend approximately 18% of their sales revenue on R&D costs, while spending twice that amount to market their drugs.<sup>138</sup> Research and development is important, as drug companies would not exist if not for the

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133. See discussion *supra* Section II.C.2.

134. Waxman, *supra* note 5, at 6.

135. John LaMattina, *Do Drug Companies Make Drugs, or Money?*, FORBES (July 29, 2014), <http://www.forbes.com/sites/johnlamattina/2014/07/29/do-drug-companies-make-drugs-or-money/#8ec24887f9fc>.

136. *Id.*

137. *Id.*

As crass as it may sound, the companies responsible for discovering and developing the next medical breakthroughs have to do so in a way that generates significant profits. If they don't do that, investors will turn to other places to invest their money, and the companies will shrivel up and either be sold to another company or die . . . . A pharma company's business is making drugs—and, in doing so it had better make profits.

*Id.*

138. PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA, *supra* note 12, at i; Ana Swanson, *Big Pharmaceutical Companies are Spending Far More on Marketing Than Research*, WASH. POST WONKBLOG (Feb. 11, 2015), <https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/> (“The biggest spender, Johnson & Johnson, shelled out \$17.5 billion on sales and marketing in 2013, compared with \$8.2 billion for R&D.”) (citing *Last Week Tonight with John Oliver: Marketing to Doctors* (HBO broadcast Feb. 8, 2015)).

drugs they develop, but marketing the drugs is crucial for drug companies' survival.<sup>139</sup>

## 2. *Strengthening the Patent System*

There has been a large movement in recent years to strengthen the U.S. patent system. Congress implemented the America Invents Act of 2012 (AIA), which was intended to create a more efficient USPTO so that inventions are brought to market sooner for less cost, which purported to encourage greater innovation.<sup>140</sup> Another purpose, of particular importance to the issue of reverse payment settlements and secondary patents, the AIA purported to address is the issue of poor quality patents.<sup>141</sup> At the time AIA was implemented, reverse payment settlements were not a new phenomenon, as there were a number of U.S. Court of Appeals decisions addressing the legality of these settlements.<sup>142</sup>

Brand name drug companies engage in acts such as reverse payment settlements to protect their exclusive patent rights, which is not beyond the scope of their patent if their patent is still in effect.<sup>143</sup> So, as in *Actavis*, by settling with generic drug companies, the patent owners were simply protecting their exclusive patent right.<sup>144</sup> Declining to carry out a challenge to a patent or settling a patent litigation dispute has never violated antitrust laws.<sup>145</sup> In fact, several new proceedings under the AIA give parties the option and incentive to settle before the Patent and Trademark Appeals Board issues a decision on the patent's validity.<sup>146</sup>

Therefore, it is reasonable for Congress to interject and address the unique issues surrounding pharmaceutical patents. There are separate and distinct rules for design<sup>147</sup> and plant<sup>148</sup> patents, so it is feasible to create

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139. MIN DING, INNOVATION AND MARKETING IN THE PHARMACEUTICAL INDUSTRY 2 (Springer Science+Business 2014) ("A [pharmaceutical] firm without strong marketing capabilities will not fully unlock the value of innovation and thus it stands to miss out on billions of dollars for its stakeholders and on the resources needed to sustain continued innovation.").

140. Press Release, The White House, Office of the Press Secretary, President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs (Sept. 16, 2011), <https://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim>.

141. *Id.* ("The Patent and Trademark Office has re-engineered its quality management processes to increase the quality of the examinations and has issued guidelines that clarify and tighten its standards for the issuance of patents.").

142. *See supra* note 99.

143. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2240 (2013) (Roberts, C.J., dissenting).

144. *See id.*

145. *Id.* at 2239 (Roberts, C.J., dissenting) (citing *Standard Oil Co., Ind. v. United States*, 283 U.S. 163, 171 (1931)).

146. *Inter partes* review and post-grant review allow parties to settle before PTAB has instituted its decision on the patentability of the claims at issue. *See* 35 U.S.C. §§ 317, 327 (2012).

147. *Id.* § 171.

separate and distinct rules for pharmaceutical patents. These rules should ensure that drug patents are being granted for new, innovative drugs. Additionally, these rules should prevent drug patents for compounds that are not innovative but are being pursued merely to maintain market exclusivity of an expiring drug patent.

If new rules are implemented, which will require new procedures to address pharmaceutical patents, there will be an uproar by the pharmaceutical industry, and it will take all parties time to adjust, but it will advance the recurring theme of strengthening the patent system and ensuring issuance of high quality patents. Creating distinct rules for drug patents might not alleviate high drug costs, but it will ensure consumers are receiving the highest quality drugs, as opposed to paying the cost of a secondary drug—the patent of which was only granted because it met all statutory requirements but was actually a lesser version of the original drug patent.

Perhaps another alternative to challenging reverse payment settlements is to grant shorter terms for drug patents. This will allow brand name companies to maintain their exclusive patent right but will provide the public with access to the generic sooner. A shorter drug patent term could also be imposed under separate and distinct drug patent laws. This will certainly require greater innovation, as companies will be forced to create breakthrough products to maintain drugs to compete in the marketplace. But there is also the possibility that drug companies will engage in potentially unlawful tactics to maintain market exclusivity of their drug patents beyond the scope of their patent. Therefore, specific drug patent rules should address every scenario that could possibly occur.

#### IV. CONCLUSION

In sum, patent laws exist to ensure continuing technological development and innovation to benefit the general public. Antitrust laws exist to maintain competition in the marketplace to also ensure public benefits. These laws clash, as courts have attempted to restrain what brand name drug companies can do to protect the rights conferred by their drug patents. Creating an innovative drug, obtaining FDA approval to market it, and obtaining a patent on such drug is costly and time consuming. Therefore, pharmaceutical companies are in the business to make a profit, so they are able to continue bringing innovative drugs to market. They engage in activities, such as reverse payment settlements, which are properly disguised under the rights inferred in their drug patents. To adequately address such activities, Congress should create separate and

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148. *Id.* § 161.

distinct rules for drug patents. This will address the unique issues surrounding drug patents and eliminate future patent and antitrust conflicts.