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The South Korean Patent Linkage System: A Model for Reforming the United States Hatch-Waxman Act

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THE SOUTH KOREAN PATENT LINKAGE SYSTEM: A MODEL FOR REFORMING THE UNITED STATES HATCH–WAXMAN ACT

ABSTRACT

The Hatch-Waxman Act created the modern pharmaceutical regulatory approval process in the United States. The drafters of Hatch-Waxman sought to balance incentives for branded pharmaceutical company investment in innovative therapies with incentives for accelerated market entry of generic pharmaceuticals. Today, thirty years after enactment, the Hatch-Waxman balance has shifted. Branded pharmaceutical companies routinely exploit Hatch-Waxman loopholes to block generic competitors from entering the market. After much public outcry, United States officials have prioritized closing these loopholes. This Comment proposes Hatch-Waxman reforms which follow South Korea's pharmaceutical regulatory approval process. South Korea modeled its system on Hatch-Waxman yet made it more difficult for pharmaceutical companies to delay generic competitors. The United States need not adopt South Korea's system verbatim. Rather, South Korea's system should be used as a guide for restoring the intended Hatch-Waxman balance, promoting competition in the marketplace, and lowering drug prices in the United States.

INTRODUCTION

The Centers for Disease Control and Prevention estimates that over three million people in the United States are infected with Hepatitis C,[1] a disease that kills more people than HIV/AIDS each year.[2] Prior to Gilead Sciences (Gilead) obtaining U.S. Food and Drug Administration (FDA) approval of Sovaldi® (sofosbuvir) in 2013,[3] traditional therapies offered low cure rates and side effects such as fatigue, nausea, and depression[4] that caused over fifty percent of patients to discontinue treatment prematurely.[5] Sovaldi® (sofosbuvir) has a Hepatitis C

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[1] Kathleen N. Ly et al., *The Increasing Burden of Mortality from Viral Hepatitis in the United States Between 1999 and 2007*, 156 ANNALS INTERNAL MED. 271, 276 (2012).

[2] *Id.* at 273.

[3] Laurie Toich, *Will Hepatitis C Virus Medication Costs Drop in the Years Ahead?*, PHARMACY TIMES (Feb. 8, 2017), https://www.pharmacytimes.com/resource-centers/hepatitisc/will-hepatitis-c-virus-medicaton-costs-drop-in-the-years-ahead; *see also* Richard Knox, *$1,000 Pill for Hepatitis C Spurs Debate Over Drug Prices*, NPR: HEALTH SHOTS (Dec. 30, 2013, 3:22 AM), https://www.npr.org/sections/health-shots/2013/12/30/256885858/-1-000-pill-for-hepatitis-c-spurs-debate-over-drug-prices.

[4] Ewen Callaway, *Hepatitis C Drugs Not Reaching Poor*, 508 NATURE 295, 295 (2014).

[5] Joann LaFleur et al., *High Rates of Early Treatment Discontinuation in Hepatitis C-infected US Veterans*, 7 BMC RES. NOTES 1, 3 (2014), https://bmcresnotes.biomedcentral.com/track/pdf/10.1186/1756-

cure rate of over ninety percent with far fewer side effects.[6] In spite of Sovaldi®'s therapeutic benefits, Gilead was highly criticized for charging $84,000 for a twelve-week regimen (over $1000 per pill),[7] making Sovaldi® the most expensive drug in the United States at that time.[8] In October 2014, Gilead obtained FDA approval for a more effective Hepatitis C combination treatment, Harvoni® (sofosbuvir/ledipasvir), for which Gilead charged an even greater $94,000 for a twelve-week regimen.[9]

In response to public outcry, the United States Senate Finance Committee investigated Gilead's pricing strategies for Sovaldi® and Harvoni®.[10] In 2015, the Committee reported that Gilead's pricing strategy was designed to maximize current and future revenue.[11] However, the report further revealed that Gilead knew that Sovaldi®'s $84,000 price tag would significantly reduce patient access.[12] Public and private health care payers issued substantial restrictions on reimbursement.[13] At least twenty-seven state Medicaid programs limited Sovaldi®'s Hepatitis C treatments to seriously ill patients.[14] Private health care providers also strictly limited Sovaldi®'s use.[15] After public and private health care payers requested rebates or discounts, Gilead agreed to limited reductions,[16] including Medicaid program supplemental rebates of up to 10%.[17] Gilead

0500-7-266?site=bmcresnotes.biomedcentral.com.

6 Toich, *supra* note 3; Knox, *supra* note 3.

7 Toich, *supra* note 3; Knox, *supra* note 3.

8 Emma Court, *This is the Most Expensive Drug in America*, MARKETWATCH.COM (Apr. 14, 2016, 5:45 p.m.), https://www.marketwatch.com/story/this-is-the-most-expensive-drug-in-america-2016-04-09.

9 Toich, *supra* note 3.

10 Medicaid and CHIP Payment and Access Commission (MACPAC), High-Cost HCV Drugs in Medicaid: Final Report (2017) [hereinafter MACPAC]; *see* Press Release, U.S. Senate Comm. on Finance, Wyden-Grassley Sovaldi Investigation Finds Revenue-Driven Pricing Strategy Behind $84,000 Hepatitis Drug (Dec. 01, 2015), https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug.

11 U.S. Senate Comm. on Finance, *supra* note 10.

12 *Id.*

13 *Id.*

14 MACPAC, *supra* note 10, at 5; Michael Ollove, *Are States Obligated To Provide Expensive Hepatitis C Drugs?*, KHN.ORG (Feb. 10, 2016), https://khn.org/news/are-states-obligated-to-provide-expensive-hepatitis-c-drugs/ ("At least 34 states restricted treatment to patients who had reached an advanced stage of liver disease, as determined by the level of scarring on the liver. Thirty-seven states permitted their Medicaid agencies to determine whether the potential recipient was abusing alcohol or drugs, and some required some period of abstinence. And 29 states would only consider approval if the prescriber was a specialist in gastroenterology, hepatology, infectious diseases or liver transplantation.").

15 U.S. Senate Comm. on Finance, *supra* note 10.

16 *Id.*

17 *Id.*

refused requests for further discounts even though few health care payers would provide patient access to Sovaldi® based on such minimal discounts.[18]

While Sovaldi® offered a cure rate of over 90%, the clock was ticking for these patients.[19] The Hepatitis C virus destroys the infected person's liver and causes liver cancer.[20] In 2013, Hepatitis C had put approximately 17,000 Americans on a waitlist for a liver transplant.[21] If greater access to Sovaldi® had been available, many patients would have received early treatment and could have been cured prior to the development of liver scarring.[22] The number of patients seeking early treatment would have expanded the total market for Sovaldi®, Harvoni®, and all future Hepatitis C drugs.[23] Instead, Gilead sought only to gain the highest immediate profit from a limited patient pool.[24]

Gilead's decision highlights the need for more generic drug competition in the United States. Prices often fall dramatically when generic drug competitors are available.[25] Consider the case of Zocor® (simvastatin), a top selling drug for treatment of high cholesterol.[26] After FDA approval of a generic version of simvastatin in 2006, the price of a one-month supply dropped from over $150 for Zocor® to $7 for the generic simvastatin by early 2007.[27] Falling simvastatin prices led to the rise in total prescriptions of simvastatin of more than seventy percent within eighteen months.[28]

Unfortunately, Gilead and other branded pharmaceutical companies routinely exploit loopholes in the Hatch–Waxman Act (Hatch–Waxman),[29] the basis of the United States' pharmaceutical regulatory approval process,[30] to block generic competitors from entering the market. After public outcry over

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18 *Id.*

19 Knox, *supra* note 3.

20 *Id.*

21 *Id.*

22 *Id.*

23 *Id.*

24 *Id.*

25 C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch–Waxman Act*, 77 ANTITRUST L.J. 947, 952 (2011).

26 *Id.*

27 *Id.*

28 *Id.*

29 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §355 and 35 U.S.C. §156, 271 and 282); Yana Perchersky, *To Achieve Closure of the Hatch–Waxman Act's Loopholes, Legislative Action is Unnecessary: Generic Manufacturers Are Able to Hold Their Own*, 25 CARDOZO ARTS & ENT. L.J. 775, 777 (2007).

30 Aaron S. Kesselheim & Jonathan 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, 345–46 (2015).

Gilead's actions, leading United States officials, including President Trump,[31] Congress,[32] and the FDA,[33] have prioritized closing these loopholes. This Comment proposes Hatch–Waxman reforms that follow South Korea's pharmaceutical regulatory approval process.[34] While South Korea modeled its system on Hatch–Waxman, South Korea made it more difficult for pharmaceutical companies to delay generic competitors.[35]

This Comment proceeds in the following order. Following this Part I Introduction, Part II presents an overview of the United States and South Korean pharmaceutical regulatory approval systems. Part III addresses specific loopholes within the United States Hatch–Waxman system and proposes how adopting South Korean provisions would close those loopholes. Part IV summarizes the conclusions and proposals set forth in this Comment.

I. UNITED STATES AND SOUTH KOREAN PHARMACEUTICAL REGULATORY SYSTEMS

To put into context the current loopholes in the Hatch–Waxman system and the solutions to be found within the South Korean patent linkage system, which will be introduced in Part III, Part II begins with an overview of the United States and South Korean pharmaceutical approval systems. Section A presents the origins and key provisions of the Hatch–Waxman Act of 1984, the statute

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[31] Donald J. Trump (@realDonaldTrump), TWITTER, (Mar. 7, 2017, 8:46 AM), https://twitter.com/realdonaldtrump/status/839110000870109184 ("I am working on a new system where there will be competition in the Drug Industry. Pricing for the American people will come way down!"); Remarks in a Cabinet Meeting and an Exchange With Reporters, 2017 DAILY COMP. PRES. DOC. 201700755 (OCT. 16, 2017) ("The drug prices have gone through the roof. . . . The drug companies, frankly, are getting away with murder . . . .").

[32] CREATES Act of 2017, S. 974, 115th Cong. (2017).

[33] *Administering the Hatch–Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting*, FDA.GOV: DRUGS, https://www.fda.gov/Drugs/NewsEvents/ucm563986.htm (last visited Feb. 11, 2018) ("[This public] meeting [was] held on July 18, 2017 to provide the public an opportunity to submit comments concerning administration of the Hatch–Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) to help ensure the intended balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs is maintained.").

[34] This Comment limits the scope of discussion to South Korean patent linkage provisions which differ significantly from the Hatch–Waxman Act and therefore offer the United States the most guidance. Further, this Comment limits the scope of discussion to the abbreviated generic approval process for chemical synthetic products traditionally covered under the U.S. Hatch–Waxman Act and excludes the analogous process for follow-on biologics covered under the U.S. Biologics Price Competition and Innovation Act of 2009 (BPCI Act). Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7001, 124 Stat. 119, 804 (2010).

[35] Ki Young Kim et al., *The Korean Pharmaceutical Approval-Patent Linkage System: A Comparison with the US Hatch–Waxman Act*, LEXOLOGY 1, 15 (Feb. 16, 2015), https://www.lexology.com/library/detail.aspx?g= 5619213a-4714-4307-8bfd-8e12955841e1.

governing the United States pharmaceutical approval process. Section B presents the South Korean system that was implemented pursuant to the Korean-United States Bilateral Free Trade Agreement, which entered into force in 2012. Section C compares key provisions of Hatch–Waxman to the South Korean system.

A. The United States Hatch–Waxman Act of 1984

1. Hatch–Waxman and the United States Pharmaceutical Industry

The Hatch–Waxman Act has been the cornerstone of the generic drug industry in the United States.[36] In many ways, Hatch–Waxman has been a shining success.[37] In 2016, generic drugs accounted for eighty-nine percent of all United States prescriptions.[38] Further, most other countries have higher generic drug price indexes than the United States.[39] Hatch–Waxman has achieved these results by facilitating approval of new generic drugs and through numerous price competition strategies.[40]

That said, Hatch–Waxman has strengthened patent rights and granted marketing exclusivities to encourage branded drugs to undertake risky, expensive, and lengthy drug development.[41] Branded pharmaceutical manufacturers also command premium prices due to the absence of price controls in the United States.[42] The United States benefits from faster and more widespread use of new drugs compared to other countries.[43] In return, over the past decade the price per capita for branded drugs in the U.S. has risen to the among the highest in the world.[44]

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[36] Kesselheim & Darrow, *supra* note 30, at 295.

[37] Kesselheim & Darrow, *supra* note 30, at 295.

[38] MURRAY AITKEN & MICHAEL KLEINROCK, QUINTILESIMS INST., MEDICINES USE AND SPENDING IN THE UNITED STATES: A REVIEW OF 2016 AND OUTLOOK TO 2021 20 (2017); STEVEN M. LIEBERMAN & PAUL B. GINSBURG, BROOKINGS INST., WOULD PRICE TRANSPARENCY FOR GENERIC PHARMACEUTICALS LOWER COSTS FOR PAYERS AND PATIENTS? 3 (2017).

[39] Patricia M. Danzon & Michael F. Furukawa, *International Prices and Availability of Pharmaceuticals in 2005*, 27 HEALTH AFF. 221, 230-31 (2008), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.27.1.221.

[40] *Id.*; Kesselheim & Darrow, *supra* note 30, at 345.

[41] Kesselheim & Darrow, *supra* note 30, at 305–06.

[42] David R. Francis, The Effect of Price Controls on Pharmaceutical Research, NAT'L BUREAU ECON. RES., https://www.nber.org/digest/may05/w11114.html; *see* Kesselheim & Darrow, *supra* note 30, at 306.

[43] Panos Kanavos et al., *Higher US Branded Pharmaceutical Prices and Spending Compared to Other Countries May Stem Partly from Quick Uptake of New Pharmaceuticals*, 32 HEALTH AFF. 753, 758 (2013).

[44] *Id.* at 758.

This Comment argues that the envisioned market balance between branded and generic pharmaceutical companies is unrealized because of loopholes in the Hatch–Waxman system that branded pharmaceutical companies exploit. This Comment proposes ways to amend Hatch–Waxman to close such loopholes and restore the original purpose of the Hatch–Waxman Act. To add context, the next section reviews the historical origins of the Hatch–Waxman Act and explains the reasons for such a balanced incentive system was created.

2. Origins of Hatch–Waxman

The 1962 Kefauver-Harris Amendments to the Food, Drug, and Cosmetic Act (FDCA) empowered the FDA to require pharmaceutical companies seeking marketing approval to submit evidence of drug safety and efficacy obtained from premarket clinical trials.[45] In 1963, new FDA regulations required pharmaceutical companies to file an Investigational New Drug Application (IND) before initiating clinical trials.[46] This rule established a formal preclinical, Phase I, Phase II, and Phase III clinical trial pathway.[47] In the final stage, pharmaceutical companies were required to submit successful Phase III clinical trial data in a New Drug Application (NDA) to prove drug efficacy and safety.[48]

Preclinical and clinical trials added considerable time and expense for pharmaceutical companies seeking to sell a prescription drug.[49] Further, the FDA rules applied to both branded and generic pharmaceutical manufacturers.[50] An accelerated generic drug approval process was not available for post-1962 drugs.[51] Since greater competition meant that generic drugs were not able to command premium prices, FDA regulations significantly reduced the incentive for generic pharmaceutical companies to enter the market.[52]

By the late 1970s, few generic drugs were commercially available in the United States.[53]

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45 Kesselheim & Darrow, *supra* note 30, at 297.

46 *Id*.

47 *Id*.

48 *Id*. The U.S. Food & Drug Administration (FDA) has interpreted the statutory language—of "adequate and well-controlled investigations"—as preferring two or more separate clinical trials to prove the new drug's efficacy and safety. *Id.*

49 *Id*. at 298.

50 *Id*.

51 *Id*. at 298–99.

52 *Id*. at 299.

53 *Id*. at 300.

Despite being off-patent, approximately 150 branded drugs lacked any generic competition.[54] At that time, generic drugs comprised only 12.4% of all drug prescriptions in the United States.[55] Further, manufacturers only launched generic versions within one year of patent expiration for 15% of the top branded drugs during this period.[56]

Finally, in 1984 the Court of Appeals for the Federal Circuit (CAFC) decided *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (1984), which addressed whether use of a patented drug in pre-clinical or clinical testing by a generic pharmaceutical manufacturer seeking FDA generic drug approval qualified for an experimental use exemption from patent infringement.[57] Bolar had conducted FDA-required testing prior to expiration of Roche's patent for flurazepam (Dalmene).[58] The CAFC held Bolar liable for the mere use of Roche's patented invention and reasoned that the Bolar's commercial incentives counted against a finding of experimental use.[59]

After *Roche*, generic pharmaceutical companies could not begin preclinical or clinical trials until after all relevant branded drug patents had expired.[60] As a result, the *Roche* decision awarded branded pharmaceutical companies a de facto extension of market exclusivity beyond the term of their patents.[61] Congress quickly responded to *Roche* by enacting the Hatch–Waxman Act which, in Section 271(e)(1), created a "Safe Harbor" or "Bolar exemption" from patent infringement for activities done in pursuit of FDA marketing approval.[62]

3. Key Elements of the Hatch–Waxman System

The drafters of the Hatch–Waxman Act sought to balance two competing policy goals: (a) incentives for branded pharmaceutical companies to invest in innovative therapies and (b) accelerated market entry of generic drugs.[63] To branded pharmaceutical companies, Hatch–Waxman grants a patent term

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[54] *Id*.

[55] *Id*.

[56] *Id*.

[57] *See id*. at 299.

[58] *Id*.

[59] *Id*. at 300.

[60] CONG. RES. SERV., R44643, THE HATCH–WAXMAN ACT: A PRIMER 1, 4 (2016), https://www.everycrsreport.com/files/20160928_R44643_1c2fafad2efe96d4c0fe44f2f23308dcfc059f83.pdf.

[61] *Id.*

[62] *Id.* at 2, 5; *see* Anthony Tridico et al., *Facilitating Generic Drug Manufacturing: Bolar Exemptions Worldwide*, 3 WIPO MAGAZINE (June 2014), http://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html.

[63] Kesselheim & Darrow, *supra* note 30, at 306, 336.

extension (PTE) for FDA approval delays.[64] Hatch–Waxman also grants NDA holders data exclusivity for safety or efficacy information submitted for marketing approval of new drugs (five-year) or new clinical information submitted for marketing approval of prior approved products (three-year).[65]

The most controversial Hatch–Waxman provision is "patent linkage"[66] that requires the FDA to delay generic drug marketing approval until (a) after expiration of a branded equivalent's patent term, (b) after a court determines that the branded drug's patent would not be infringed or was invalid, or (c) after the patent owner otherwise consents.[67] Hatch–Waxman created a patent list known as the "Orange Book" where NDA holders register patents covering their FDA approved products.[68] Hatch–Waxman requires generic drug approval applicants to certify whether an FDA approved product's Orange Book listed patents are still in force.[69] If so, generic applicants must notify the NDA holder of the application for generic drug marketing approval.[70] After receiving such notification, an NDA holder may sue the generic drug approval applicant for patent infringement and obtain an automatic thirty-month marketing exclusion period (stay of generic sales).[71]

To accelerate generic drug market entry, Hatch–Waxman created the Abbreviated New Drug Application (ANDA) process (FDCA § 505(j)).[72] ANDA applications require a generic drug to have identical active ingredient, dosage form, dosage strength, administration route, labeling, quality, performance characteristics, and intended use to a previously approved drug.[73] ANDA applicants may rely on an original applicant's clinical data but must supply evidence that a generic drug is bioequivalent to the reference drug.[74] As an added incentive for generic pharmaceutical companies, the FDA offers a 180-day marketing exclusion period for the "first" ANDA filers to challenge an

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64 *Id.* at 306.

65 *Id.* at 305.

66 Ravikant Bhardwaj et al., *The Impact of Patent Linkage on Marketing of Generic Pharmaceuticals*, 18 J. INTELL. PROP. RTS. 316, 317–18 (2013); Kesselheim & Darrow, *supra* note 30, at 303.

67 Bhardwaj et al., *supra* note 66; Kesselheim & Darrow, *supra* note 30, at 303.

68 Bhardwaj et al., *supra* note 66; Kesselheim & Darrow, *supra* note 30, at 303.

69 Kesselheim & Darrow, *supra* note 30, at 303.

70 Kesselheim & Darrow, *supra* note 30, at 303.

71 Allen M. Sokal & Bart A. Gerstenblith, *The Hatch-Waxman Act: Encouraging Innovation and Generic Drug Competition*, https://www.finnegan.com/en/insights/the-hatch-waxman-act-encouraging-innovation-and-generic-drug.html.

72 *What is the Difference Between 505(J) application, 505(B)(2) NDA & 505(B)(1) NDA?*, NCK PHARMA SOL. PRIVATE LTD. (June 12, 2015), https://nckpharma.com/505j-application-505b2-nda-505b1-nda/.

73 *Id*.

74 *Id.*

Orange Book listed patent.[75] Until the 180-day marketing exclusion period expires, the FDA may accept and review but may not approve subsequent generic drug approval requests for the same reference drug.[76]

Unfortunately, the Hatch–Waxman system has been highly susceptible to branded pharmaceutical manufacturer manipulations such as "antitrust violations, further delays in the release of generic drugs, and significant increases in prescription drug prices."[77] In response, Congress enacted the Medicare Prescription Pharmaceutical, Improvement, & Modernization Act of 2003 (MMA).[78] However, the MMA has been criticized for not doing enough to close Hatch–Waxman loopholes.[79]

B. The South Korean Pharmaceutical Regulatory System

This Section presents the rationales for looking to the South Korean pharmaceutical regulatory system for guidance on Hatch–Waxman amendments. It also provides context for Part III, which analyzes loopholes within the U.S. Hatch–Waxman system and the proposed solutions to be found in the South Korean pharmaceutical regulatory system. The political, economic, and historical factors that influenced the adoption of the current South Korean system are discussed, with emphasis on South Korea's decision to give greater weight to the concerns of the generic pharmaceutical industry.

1. The Korea-United States Free Trade Agreement (KORUS FTA)

The KORUS FTA was first signed June 30, 2007 and entered into force on March 15, 2012.[80] Pursuant to Chapter 18 of the KORUS FTA,[81] South Korea agreed to the following provisions: extended patent terms to compensate for Korean Intellectual Property Office (KIPO) patent prosecution delays and Korean Ministry of Food and Pharmaceutical Safety (MFDS) regulatory review delays;[82] data exclusivity requirement for safety or efficacy information

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[75] *Small Business Assistance: 180-Day Generic Drug Exclusivity*, FDA, https://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm069964.htm (last visited Feb. 6, 2019).

[76] *Id.*

[77] Melissa Ganz, *The Medicare Prescription Drug, Improvement, & Modernization Act of 2003: Are We Playing the Lottery with Healthcare Reform?*, 3 DUKE L. & TECH. REV. 1, 6 (2004).

[78] *Id.* at 8.

[79] *Id.* at 13.

[80] *See* Office of the U.S. Trade Representative, *U.S.-Korea Free Trade Agreement*, USTR.GOV, http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta (last visited May 19, 2018).

[81] United States-Korea Free Trade Agreement, Kor.-U.S., June 30, 2007, 46 I.L.M 642, Chapter 18, http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text.

[82] *Id.* art. 18.8.6.

submitted for marketing approval of a new drug (five-year) and for new clinical information submitted in support of marketing approval of a prior approved drug (three-year);[83] and certain patent linkage provisions, including: (a) notifying patentees of the identity of an applicant prior to granting marketing approval of a generic drug in reliance on a patentee's originally submitted safety or efficacy data,[84] and (b) prohibiting marketing approval for a generic drug without consent of the original patent owner during the enforceable term of a valid patent.[85]

2. South Korea's Choice to Depart from Hatch–Waxman

South Korean based their patent linkage system on the United States Hatch–Waxman system, even including provisions not specifically required in the KORUS FTA.[86] Similar to the Hatch-Waxman system, the South Korean Pharmaceutical Affairs Act (PAA)[87] permits an applicant seeking generic drug marketing approval to rely upon a branded drug manufacturer's previously submitted clinical data.[88] However, many provisions of the South Korean patent linkage system provide greater protections for the generic pharmaceutical industry than those found in the Hatch–Waxman system.[89] This choice was partly in support South Korea's historical pharmaceutical industry, which consisted primarily of generic pharmaceutical companies.[90] The heavy reliance of South Korea's national mandatory healthcare system upon a steady supply of generic drugs also influenced the design of the South Korean patent linkage system.[91]

The Korean PAA further modified other patent linkage provisions of Hatch–Waxman to promote generic pharmaceutical competition.[92] First, the Korean patent listing system makes it more difficult to register a patent than its United States counterpart.[93] The Korean patent listing system is strictly policed by the MFDS, while the United States FDA does not intervene in patent listing issues.[94]

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83 *Id.* arts. 18.9.1, 18.9.2.

84 *Id.* art. 18.9.5.

85 *Id.* arts. 18.8.5, 18.9.5.

86 Kim et al., *supra* note 35, at 1.

87 Pharmaceutical Affairs Act, Act No. 300, December 18, 1953, *amended by* Act No. 14328, Dec. 2, 2016, art. 50-4(1) (S. Kor.), *translated in* Korea Legislation Research Institute online database, https://elaw.klri.re.kr/eng_service/lawView.do?hseq=40196&lang=ENG.

88 *Id.* at arts. 50 to 54.

89 Kim et al., *supra* note 35, at 15.

90 *Id*.

91 *Id*.

92 Pharmaceutical Affairs Act, *supra* note 87.

93 Kim et al., *supra* note 35, at 15.

94 *Id.* at 2.

Further, the Korean patent listing system has stricter eligibility standards than the U.S. patent listing system.[95] Unlike in the U,S., generic filers may comment on proposed and amended listings in the Green List and petition the MFDS to correct or remove inaccurate patent information.[96]

Second, South Korea allows a generic pharmaceutical manufacturer to institute administrative hearings before the MFDS to obtain patent scope, invalidity or noninfringement judgments prior to seeking generic drug marketing approval.[97] If the generic drug petitioner receives a favorable judgment, no certification or notification is necessary and the generic applicant for marketing approval avoids costly and lengthy litigation.[98] In the U.S., early proceedings for patent invalidity have limitations while patent scope or noninfringement challenges are only available to ANDA litigation defendants.[99] Third, branded pharmaceutical companies must petition the MFDS for a stay of generic drug sales and the stay lasts nine months.[100] However, in the U.S., once ANDA litigation has been filed, the FDA grants an automatic thirty-month stay of generic drug approval.[101]

Finally, the Korean first-to-file generic drug marketing exclusion period applies to a broader group of applicants than in the U.S.[102] Further, the Korean first-to-file generic drug marketing exclusion period is nine months versus 180-days in the United States.[103] The MFDS has more power than the FDA to revoke first-to-file generic drug eligibility for marketing exclusivity if the first-to-file applicant delays generic drug sales.[104] Thus, branded pharmaceutical manufacturers have less incentive to enter pay-for-delay litigation settlements in South Korea versus the United States.[105]

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95 *Id.* at 4.
96 *Id.* at 3.
97 *Id.* at 5.
98 *Id.* at 7.
99 *Id.* at 5.
100 *Id.* at 6.
101 *Id.*
102 *Id.* at 11.
103 Kim et al., *supra* note 35, at 9; Pharmaceutical Affairs Act, *supra* note 87, at art. 50–9(2).
104 Kim et al., *supra* note 35, at 1–13.
105 *Id.* at 12–13.

II. SOUTH KOREAN PHARMACEUTICAL REGULATORY SYSTEM: MODEL FOR HATCH–WAXMAN REFORM

Part I introduced the major differences between Hatch–Waxman and the Korean pharmaceutical regulatory system. In this section, these differences will be analyzed in greater depth, leading to the conclusion that South Korean provisions provide a useful framework for solving the problems within Hatch–Waxman. With this conclusion in mind, this Comment will now turn to the primary points of difference between Hatch–Waxman and the South Korean pharmaceutical regulatory system: patent listing, patent certification/notification, branded pharmaceutical manufacturer marketing exclusion period (stay of generic drug sales), and first-to-file generic drug marketing exclusion period (stay of later filed generic drug sales).

A. Comparison of Patent Listing Systems

1. Overview of Hatch–Waxman Patent Listing System

Hatch–Waxman created a pathway for branded pharmaceutical manufacturers to obtain a stay of generic drug FDA approval for up to 30 months.[106] First, Hatch–Waxman established an official FDA database known as the "Orange Book" listing all patents relevant to FDA approved drugs.[107] Only patents claiming a listed drug or its method-of-use in which a claim may be "reasonably asserted" in a patent infringement lawsuit are eligible for listing in the official FDA Orange Book.[108] Patents claiming pharmaceutical substance, formulation, composition, and medical uses are eligible for the Orange Book[109] while pharmaceutical manufacturing processes, packaging, metabolites, and intermediates are not.[110]

2. Loopholes in the Hatch–Waxman Patent Listing System

a. Eligibility of Secondary Patents for Orange Book Listing

Patent evergreening is the filing of later issuing patents, often of questionable validity, covering a branded drug and eligible for listing in the

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106 Bhardwaj et al., *supra* note 66; Kesselheim & Darrow, *supra* note 30, at 303.
107 Bhardwaj, et al., *supra* note 66; Kesselheim & Darrow, *supra* note 30, at 303.
108 Kesselheim & Darrow, *supra* note 30, at 303 (citing 21 C.F.R. § 314.53(b) (2014)).
109 *Id.*
110 *See id.* at 303–04.

Orange Book for the purpose of delaying generic competition.[111] Rather than covering the active ingredient, these secondary patents cover ancillary aspects such as different coatings, salt forms, crystalline structures, or metabolites of the approved pharmaceutical active.[112] Even if secondary patents do not improve the approved pharmaceutical active's safety or efficacy, branded pharmaceutical companies work with doctors directly to convince them to prescribe second-generation pharmaceuticals prior to the expiration of the original patents.[113] Branded pharmaceutical companies also market second-generation drugs directly to consumers through media campaigns and coupons.[114] Physician and patient preferences for second-generation products reduce the incentive to launch a generic version of the original drug.[115]

b. Eligibility of REMS Patents for Orange Book Listing

Under the FDA Amendments Act of 2007 (FDAAA), the FDA is authorized to require pharmaceutical manufacturers to utilize Risk Evaluation and Mitigation Strategies (REMS) to analyze the risks versus the benefits of a pharmaceutical product.[116] REMS are safety strategies that go beyond FDA-approved labeling.[117] In utilizing REMS, a pharmaceutical manufacturer may need to provide information to patients (a medication guide), information for healthcare providers (a communication plan) or may be required to provide "Elements to Assure Safe Use" (e.g., healthcare provider training, patient monitoring, or physician/pharmacy registries).[118] Proprietary REMS are both patentable and eligible for Orange Book listing.[119] Although the FDAAA explicitly prohibits using REMS to block or delay ANDA approval, such REMS patents can be used to trigger thirty-month stays of FDA approval.[120]

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111 *See id.* at 304; *see generally* C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 327–28 (2012) (describing the practice of patent evergreening by branded pharmaceutical companies).

112 Kesselheim & Darrow, *supra* note 30, at 304.

113 LIEBERMAN & GINSBURG, *supra* note 38, at 5, 9.

114 *Id.* at 9.

115 *See id.*

116 Food and Pharmaceutical Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007); Erika Lietzan et al., *The Food and Drug Administration Amendments Act of 2007*, 2 BIO-SCI. L.R. 39, 48 (2006/2007).

117 Lietzan et al., *supra* note 120.

118 *Id.*

119 *See, e.g.*, Thalidomide, FDA ORANGE BOOK, https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm (use "Search by Patent Number" search field; then search "7,141,018").

120 Bhardwaj et al., *supra* note 66.

c. FDA's Ministerial Role Incentivizes Improper Orange Book Listings

The Hatch–Waxman statute lacks an explicit grant of FDA authority to correct or delete any information contained in the Orange Book.[121] Consequently, the FDA has adopted a "purely ministerial" role in operating the Orange Book.[122] The FDA reviews patent listing applications for compliance with formal requirements[123] but declines to determine whether patents in fact properly describe the approved pharmaceutical compounds or their uses.[124] Further, the FDA refuses to correct or delete Orange Book listings that fail to meet statutory requirements.[125] Courts have deferred to the FDA's choice of a neutral administrative position.[126]

Third parties, such as generic manufacturers, do not have a cause of action to force the FDA to correct or delete an improper Orange Book listing and are therefore unable to avoid automatic thirty-month stays of generic approval even when listings in the Orange Book are invalid.[127] The Supreme Court confirmed Congress's intent in the MMA to grant ANDA applicants sued for patent infringement the right to assert a counterclaim against the NDA owner based on an improperly listed patent, but only after an NDA owner has sued an ANDA applicant for patent infringement.[128] Then the ANDA applicant has the burden to prove that a listed patent does not claim the precise pharmaceutical or method which an ANDA applicant seeks to market.[129] Thus, by refusing to police the Orange Book, the FDA has added unnecessary delays and costs for generic manufacturers.

The FDA took a small step toward an agency Orange Book dispute resolution process in its 2016 Final Rule.[130] When ANDA applicants dispute

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[121] *See* 21 C.F.R. § 314.53(b)(1) (2016).

[122] *Prioritizing Public Health: The FDA's Role in the Generic Drug Marketplace: Hearing Before the S. Subcomm. on Agric., Rural Dev., Food and Drug Admin., and Related Agencies, Comm. On Appropriations*, 114th Cong. 10 (2016) (statement of Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, U.S. Department of Health and Human Services).

[123] *Id.*

[124] *Id.*

[125] *Id.*

[126] *See* Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984); Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 407 n.2 (2012).

[127] Bhardwaj et al., *supra* note 66; *see* Caraco, 566 U.S. at 404–07, 424–26 (holding that generic manufacturers could assert a counterclaim against a brand manufacturer, but not against the FDA, to challenge an overbroad Orange Book listing)

[128] *See* Caraco, 566 U.S. at 413–15.

[129] *See id.* Even if the ANDA applicant meets its burden, the onus is on the branded manufacturer to petition the FDA to correct the Orange Book listing.

[130] *See* 21 C.F.R. § 314.53(f)(1)(i) (2016).

Orange Book listings, the FDA requires NDA holders to support the accuracy and correctness of the Orange Book listing in a detailed response to the FDA.[131] While the FDA requires an NDA holder to correct, amend, and defend Orange Book patent listings, the FDA still refuses to review the accuracy of Orange Book listings or to settle disputes by reviewing an NDA holder's detailed response.[132]

The FDA has threatened to establish "a process to review a proposed labeling carve-out with deference to the 505(b)(2) and/or ANDA applicant(s)' interpretation of the scope of the patent" if the current "incremental approach" is ineffective.[133] However, branded pharmaceutical companies are likely to disregard this threat since the FDA chose to omit this requirement from the 2016 Final Rule even though it was part of the original proposed rule.[134]

d. NDA Amendments Block FDA Approval of Skinny Label ANDAs

Often a listed pharmaceutical has multiple FDA-approved uses, and the NDA holder's Orange Book listed patents or FDA exclusivities may only cover a portion of these approved uses.[135] As an added incentive for generic pharmaceutical manufacturers to seek FDA marketing approval, Hatch–Waxman authorized approval of a generic drug under a Section VIII Statement if the generic drug applicant only seeks marketing approval for a method-of-use not covered by Orange Book listed patents or FDA exclusivities.[136]

Section VIII (Skinny Label) marketing approval authorizes generic drug applicants to propose modified labels to exclude "carve out" approved uses still covered by Orange Book listed method-of-use patents or FDA exclusivities.[137] NDA holders are required to list method-of-use patents on a claim-by-claim basis to inform Skinny Label applicants whether listed patent claims cover the sought method-of-use.[138] An applicant may market a generic version of a listed

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131 *Id.* at § 314.53(f)(1)(i)(A).

132 *Id.* The burden remains upon the NDA holder to withdraw or amend patent information in the Orange Book.

133 Abbreviated New Pharmaceutical Applications and 505(b)(2) Applications: Final Rule, 81 Fed. Reg. 69,580, 69,581 (Oct. 6, 2016) (codified at 21 C.F.R. § 314.53) [hereinafter Final Rule].

134 Abbreviated New Pharmaceutical Applications and 505(b)(2) Applications: Proposed Rule, 80 Fed. Reg. 6,802, 6826 (Feb. 6, 2015) (proposing in § 314.53(f)(i) that "the Agency will review the proposed labeling for the 505(b)(2) application or ANDA with deference to the 505(b)(2) or ANDA applicant's interpretation of the scope of the patent.").

135 *See* 21 U.S.C. § 355(j)(2)(A)(viii) (2017); 21 C.F.R. § 314.94(a)(12)(iii)(A) (2016).

136 *See* 21 U.S.C. § 355(j)(2)(A)(viii); 21 C.F.R. § 314.94(a)(12)(iii)(A).

137 *See* 21 U.S.C. § 355(j)(2)(A)(viii); 21 C.F.R. § 314.94(a)(12)(iii)(A).

138 *See* 21 C.F.R. § 314.53(b)(1) ("The applicant must separately identify each pending or approved

drug for those methods-of-use that are not covered by the Orange Book or by FDA exclusivities once the FDA determines that a proposed generic drug product is at least as safe and effective as the Orange Book listed drug for all available uses.[139]

When a branded pharmaceutical manufacturer is allowed to amend an NDA method-of-use prior to ANDA marketing approval, the FDA often must deny a Skinny Label application.[140] The FDA addressed this issue in its 2016 Final Rule by changing the definition of timely filed patent information to within thirty days of patent issuance, corresponding product label change, or change of claim construction ordered by the U.S. Patent and Trademark Office (USPTO) or Federal court.[141] Limits on timely amendments assist Skinny Label applicants to gain market approval for some methods-of-use which differ from first-listed Orange Book methods-of-use.[142] However, by refusing to review the accuracy of Orange Book listings, the FDA has created an incentive for NDA holders to list improper methods-of-use to block Skinny Label applicants.[143] Further, generic drug applicants may not launch a Skinny Label of an original formula if a branded pharmaceutical manufacturer has convinced doctors to switch to a new formula and methods-of-use covered by secondary patents.[144]

3. Lessons from the South Korean Patent Listing System

a. South Korean Green List has Narrower Scope than Orange Book

The Korean PAA created the "Green List,"[145] the South Korean counterpart to the Orange Book in the United States. An applicant for product marketing approval for a new pharmaceutical may apply to the MFDS to have a patent listed on the Green List.[146] The Green List may be sought for patents that (a) are

method of use and related patent claim(s).").

139 21 C.F.R. § 314.127(a)(7) (2017).

140 *See* Caraco, 566 U.S. at 406–07.

141 Final Rule, *supra* note 137.

142 *FDA Issues Final Rule on Abbreviated New Pharmaceutical and 505(b)(2) Applications*, Latham & Watkins Client Alert News Flash, Oct. 6, 2016 at 1–2, https://www.lw.com/thoughtLeadership/FDA-final-rule-abbreviated-new-pharmaceutical-505b2-applications.

143 *See id.*

144 *See* LIEBERMAN & GINSBURG, *supra* note 38, at 9.

145 Keum Nang Park et al., *South Korea's Patent-Approval Linkage System*, IAM MAG., July/August 2014, at 121, http://www.iam-media.com/Magazine/Issue/66/Management-report/South-Koreas-Patent-Approval-Linkage-System.

146 *See* NATIONAL INSTITUTE OF FOOD AND PHARMACEUTICAL SAFETY EVALUATION, MINISTRY OF FOOD AND PHARMACEUTICAL SAFETY, KOREA, PUB. REG. NO. 11-1471057-000238-01, GUIDE TO PHARMACEUTICAL APPROVAL SYSTEM IN KOREA 34 (2017) [hereinafter NIFPSE].

not expired based on patent term, patent invalidity, relinquishment, etc.; (b) claim a pharmaceutical substance, dosage, composition, or medical use; (c) directly relate to a pharmaceutical product with marketing approval or amended marketing approval; and (d) has a patent filing date prior to the marketing approval date or amended marketing approval date.[147]

The scope of the Green List is narrower than that of the Orange Book. First, while the South Korean MFDS mandates the creation of REMS for pharmaceutical regulatory approval, REMS patents are not eligible for the Green List.[148] Second, the Green List is limited to patents filed prior to the marketing approval date, which restricts the Green List to patents used in pharmaceutical development.[149] Third, an NDA holder must list patents on a claim-by-claim basis in the Green List while an NDA holder is not required to do so in the Orange Book.[150]

Several current problems in the Hatch–Waxman system may be solved by narrowing the Orange Book scope to more closely resemble that of the Green List. Branded pharmaceutical companies would no longer be able to improperly list patents in the Orange Book, use secondary and REMS patents to extend their patent monopoly, and to amend methods-of-use to block generic Skinny Label ANDA applications.[151]

b. MFDS Polices Green List, FDA Refuses to Manage Orange Book

The Korean MFDS, equivalent to the FDA, oversees all drug marketing approvals in its role to ensure pharmaceutical safety.[152] The MFDS takes a more active role in managing the Green list compared to the FDA's "ministerial" approach to the Orange Book.[153] The MFDS actively enforces the Green List requirements, performing a substantive review of patent listing applications.[154]

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147 *Id.* at 35.

148 *See* Sang Bong Kim, Korea Healthcare Strategy for the Improvement of Access, Ministry of Food and Drug Safety (Apr. 2016), https://apac-asia.com/images/achievements/pdf/5th/ATIM_03_Kim.pdf.

149 *See* Kim et al., *supra* note 35, at 2.

150 Pharmaceutical Affairs Act, *supra* note 87, arts. 31-3(1), 50-2(6); Enforcement Decree of the Pharmaceutical Affairs Act, Presidential Decree No. 20130, June 28, 2007, *amended by* Presidential Decree No. 27673, Dec. 13, 2016, Article 18(2) (S. Kor.), *translated in* Korea Legislation Research Institute online database, https://elaw.klri. re.kr/eng_service/lawView.do?hseq=40268&lang=ENG.

151 *See* Robin Feldman; Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 535–36 (2016).

152 *See* NIFPSE, *supra* note 151, at 1.

153 *See* Kim et al., *supra* note 35, at 2.

154 *Id.*

Such applications must provide considerably more detailed information to demonstrate to the MFDS that all statutory requirements have been met.[155]

A contested requirement is how "directly related" to a pharmaceutical product submitted for marketing approval must a patent be for Green Book listing eligibility.[156] The MFDS often demands supplemental information to determine this issue.[157] The MFDS strictly interprets the phrase "directly related" as to require an exact match between a patent claim and the approved pharmaceutical product.[158] The MFDS will edit listed patent claims to narrow the claim scope to directly match the approved product.[159]

Further, the MFDS will exercise its discretion to delete or amend the Green List if the pharmaceutical no longer meets the listing requirements or the patent was registered "deceitfully or otherwise fraudulently."[160] During the process of deleting or amending the Green List, the MFDS must "seek the opinions of interested persons" in advance, including generic applicants for marketing approval.[161]

Several current problems in the Hatch–Waxman system may be solved by directing the FDA to police Orange Book listings in the same manner that the MFDS manages the Green List. The FDA would have to deny Orange Book listing to initial applications that fail to meet statutory requirements. If the patent status changed for an NDA holder, the FDA would have to correct or remove the Orange Book listing. Further, the opinions of generic pharmaceutical companies would be taken into consideration during such a process. As a result, the number of improper Orange Book entries and their resultant automatic thirty-month stays of generic approval would be expected to decrease. Generic pharmaceutical companies would thus avoid the danger of infringing overly broad, non-related patent claims.

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155 *Id.*

156 *Id.*

157 *Id.*

158 *See* Young Kim, *Patent Linkage System in Korea*, AIPPI.ORG (Sept. 16, 2014), https://aippi.org/wp-content/uploads/2015/09/YKim_Speaker_Pres_Pharma_4_010914.pdf.

159 *See id.* at 10.

160 Pharmaceutical Affairs Act, *supra* note 87, art. 50-3(4).

161 *Id.* arts. 50-3(3), 50-3(4).

B. Comparison of Patent Certification/Notification Systems

1. Overview of Hatch–Waxman Patent Certification/Notification System

In the Hatch–Waxman system's second step toward thirty-month stays of generic FDA approval; each generic applicant must certify the status of Orange Book listed patents of the branded product under one of four certifications:[162]

> [T]hat no patents existed (Paragraph 1); that previous relevant patents were expired (Paragraph II); that they would wait until currently in-force patents expired to market their visions (Paragraph III); or that their versions did not infringe these patents or that the patents were invalid [known as Paragraph IV].[163]

In the Hatch–Waxman system's third step toward thirty-month stays of generic FDA approval, each generic Paragraph IV applicant must notify the brand-name manufacturer.[164] A Paragraph IV certification is a statutory act of infringement,[165] and the branded pharmaceutical manufacturer has forty-five days from notice to file a patent infringement lawsuit.[166] Once a branded pharmaceutical manufacturer files an ANDA lawsuit, the FDA institutes a thirty-month stay of marketing approval on top of any other FDA exclusivity.[167]

2. Loopholes in Hatch–Waxman Certification/Notification System

a. Hatch–Waxman Incentivizes NDA Holders to Institute Litigation

Once a branded pharmaceutical manufacturer timely files a patent infringement lawsuit against an ANDA Paragraph IV filer, the FDA is automatically prevented from approving that ANDA Paragraph IV application until the ANDA filer receives a favorable judgment of patent invalidity or noninfringement or the thirty-month stay has expired.[168] Branded pharmaceutical manufacturers have a great incentive to delay generic competition, thus most NDA holders file such ANDA lawsuits to obtain an

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162 Kesselheim & Darrow, *supra* note 30, at 303.
163 *Id.*
164 *Id.*
165 *Id.*
166 *Id.*; Bhardwaj et al., *supra* note 66.
167 *See* Kesselheim & Darrow, *supra* note 30, at 303.
168 Bhardwaj et al., *supra* note 66, at 317.

automatic thirty-month stay of FDA marketing approval.[169] Such litigation is now the norm in the pharmaceutical industry.[170]

The automatic nature of the thirty-month stay greatly incentivizes branded pharmaceutical manufacturers to file patent infringement suits against ANDA Paragraph IV applicants, even in cases where patents are likely to be judged invalid or noninfringed.[171] The thirty-month stay also provides considerable incentive to engage in patent evergreening—filling the Orange Book with as many secondary and REMS patents as possible, no matter how small the change to the regulated product.[172] This would guarantee that ANDA applicants make Paragraph IV certifications to the secondary patents even after the original patent covering the branded drug has expired.

b. Hatch–Waxman Incentivizes Untimely Orange Book Listings

Prior to the MMA, an ANDA filer seeking generic approval of a branded pharmaceutical also could face multiple thirty-month stays if new patents covering the pharmaceutical were added to the Orange Book after their ANDA filing date.[173] ANDA filers had to submit new Paragraph IV certifications for each new patent, allowing NDA holders to file new patent infringement actions and trigger new thirty-month stays of FDA approval.[174] After the MMA, the FDA broadened the scope of untimely-filed patents to include those submitted on or after an ANDA filing date.[175] While ANDA filers no longer are required to certify untimely-filed patents and no longer are subject to multiple thirty-month stays, untimely-filed patents still may be listed in the Orange Book and contribute to patent evergreening for later filed ANDA applications.[176]

c. Hatch–Waxman Early Patent Challenges are Limited and Ineffective

At the USPTO, the Patent Trial and Appeal Board (PTAB) can institute proceedings to review patentability such as a Post Grant Review (PGR) which

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169 Bhardwaj et al., *supra* note 66.

170 Hemphill & Lemley, *supra* note 25, at 952.

171 Kesselheim & Darrow, *supra* note 30, at 320.

172 *Id.*

173 Meredith H. Boerschlein & Shana K. Cyr, *Intricacies of the 30-Month Stay in Pharmaceutical Patent Cases*, AM. PHARMACEUTICAL REV. (Mar. 25, 2018), https://www.americanpharmaceuticalreview.com/Featured-Articles/348913-Intricacies-of-the-30-Month-Stay-in-Pharmaceutical-Patent-Cases/.

174 *See* Kurt R. Karst, *A Pre-MMA-180-Day Exclusivity Punt? What Gives?*, FDA LAW BLOG (Jan. 8, 2013), http://www.fdalawblog.net/2013/01/a-pre-mma-180-day-exclusivity-punt-what-gives/.

175 Final Rule, *supra* note 137.

176 *Id.*

takes place within nine months of patent grant[177] and an Inter Partes Review (IPR) which takes place after termination of a PGR or at nine months after patent grant.[178] A generic pharmaceutical manufacturer may hesitate to enter into such proceedings which creates estoppel issues in district court ANDA litigation for any issue that was "raised or could have reasonably been raised" at the PTAB.[179]

Further, a March 2017 study indicates that branded pharmaceutical patents usually are upheld by IPRs.[180] Roughly 5% of IPR petitions challenged Orange-listed patents.[181] For such petitions, the PTAB instituted IPRs for 44% (compared to 53% overall) and issued final written decisions in 38% of such petitions.[182] Of such petitions, only 16% resulted in final written decisions finding all claims unpatentable (compared to 23% overall), while 50% resulted in final written decisions holding no claims unpatentable (compared to 7% overall).[183]

An ANDA filer alternatively may petition the court for a declaratory judgment of invalidity or noninfringement of Orange Book-listed patents, but only after an NDA holder fails to bring a patent infringement lawsuit within forty-five days of receiving notice and establishes an Article III "case or controversy[,]"which requires more than a patent listing in the Orange Book.[184]

3. Lessons from the South Korean Patent Certification/Notification System

a. Overview of South Korean Patent Certification/Notification System

Under South Korea's PAA, a generic applicant is only exempt from notifying both the patent owner and the listing party of the filing of a marketing approval application where: (a) relevant patents are expired (equivalent to ANDA Paragraph II Certification); (b) marketing of the generic drug begins

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177 *Post Grant Review*, USPTO, https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/post-grant-review (last visited May 20, 2018).

178 *Inter Partes Review*, USPTO, https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/inter-partes-review (last visited May 20, 2018).

179 *Major Differences between IPR, PGR, and CBM*, USPTO.GOV, https://www.uspto.gov/sites/default/files/ip/boards/. . ./aia_trial_comparison_chart.pptx (last visited Feb. 15, 2019).

180 Steve Brachmann, *Report shows drug patents fare better in IPR proceedings at PTAB*, IPWATCHDOG (July 18, 2017), http://www.ipwatchdog.com/2017/07/18/drug-patents-fare-better-ipr-proceedings-ptab/id=85628/.

181 *Id.*

182 *Id.*

183 *Id.*

184 *See generally* Ronald A. Bleeker & Michael V. O'Shaughnessy, *One Year after MedImmune—The Impact on Patent Licensing & Negotiation*, FED. CIR. B.J. (Oct. 2008).

after relevant patents expire (equivalent to ANDA Paragraph III); or (c) a registered patent owner and patent listing party waive the applicant's notice requirement (so-called "authorized generics").[185] However, if an applicant contests the validity and/or alleges infringement of enforceable patents prior to marketing the generic drug (equivalent to ANDA Paragraph IV Certification),[186] the MFDS requires the applicant to complete such notification prior to granting marketing approval or revised marketing approval.[187]

b. South Korea Incentivizes Early Challenges to Green Listed Patents

The KIPO handles select patent disputes through the Intellectual Property Trial and Appeal Board (IPTAB), the equivalent to the PTAB at the USPTO.[188] The United States' and South Korean patent dispute resolution mechanisms are similar, yet each system operates slightly differently.[189] A generic pharmaceutical manufacturer may challenge a patent before the IPTAB prior to filing for MFDS marketing approval by filing: (a) a "negative scope confirmation" claim seeking a judgment that a generic drug does not infringe the patent;[190] (b) a patent cancellation claim by anyone within six months of issued patent publication on a narrow basis; or (c) a patent invalidation claim any time after patent registration by an "interested party" on a broad basis.[191]

Generic pharmaceutical manufacturers are highly likely to file patent scope confirmation actions, patent cancellation actions, or patent invalidation actions in advance of seeking MFDS marketing approval of a generic pharmaceutical.[192] Once the IPTAB issues a judgment favorable to the generic pharmaceutical manufacturer, a Korean generic applicant is no longer subject to a branded stay of generic sales.[193]

C. Comparison of Branded Pharmaceutical Marketing Exclusion Periods

An action seeking confirmation that a generic drug does not infringe a branded patent is a unique proceeding before the IPTAB unavailable in the

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185 Pharmaceutical Affairs Act, *supra* note 87, art. 50-4(1).

186 *Id.*

187 *Id.* art. 50-4(6).

188 Patent Court of Korea, *About the Court*, SUP. CT. KOR.: PAT. CT. KOR. (Sept. 1, 2018), https://patent.scourt.go.kr/patent_e/intro/intro_01/index.html.

189 Kim et al., *supra* note 35, at 5.

190 *Id.*

191 *New Patent Cancellation System for South-Korea*, LC PATS. (July 25, 2017), https://www.lcpatents.eu/en/news/new_patent_cancellation_system_for_south-korea/21.

192 Kim et al., *supra* note 35, at 5.

193 Kim et al., *supra* note 35.

United States.[194] Several Hatch–Waxman system problems could be solved if similar PTAB proceedings were available to generic pharmaceutical companies to obtain judgments of negative patent scope and noninfringement prior to filing ANDA applications as an alternative to litigation.

1. Loopholes in the Hatch–Waxman Branded Stay of Generic Sales

a. The Cost of Litigation Is a Disincentive for ANDA Filers

Only the largest generic companies can afford ANDA litigation,[195] which adds $10 million or more to an ANDA Paragraph IV challenge.[196] Due to high litigation costs, generic applicants often abandon their challenges, leaving bad patents intact; or, they accept settlements in return for delaying the commercial sales of generic drugs.[197] By 2010, "pay-for-delay" settlements[198] had delayed generic market entry by roughly seventeen months and saved branded pharmaceutical companies at least $20 billion in lost revenues to generics.[199]

The Federal Trade Commission (FTC) has been partially successful in using antitrust laws to deter pay-for-delay settlements.[200] In *FTC v. Actavis, Inc*., the Supreme Court held that a branded pharmaceutical manufacturer pay-for-delay settlement to a generic competitor can violate antitrust laws.[201] However, FTC antitrust proceedings occur after settlements have taken place and involve further burdensome litigation.[202] While legislators have suggested making pay-for-delay contracts illegal,[203] a better solution is to disincentive rather than to punish such agreements.

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194 *Id.*

195 Bhardwaj et al., *supra* note 66, at 317–18.

196 Hemphill & Lemley, *supra* note 25, at 952.

197 Bhardwaj et al., *supra* note 66, at 318.

198 FED. TRADE COMM'N, PAY-FOR-DELAY: HOW PHARMACEUTICAL COMPANY PAY-OFFS COST CONSUMERS BILLIONS 1, (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-pharmaceutical-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

199 *Id.* at 2.

200 *See, e.g.*, FTC v. Actavis, Inc., 133 S. Ct. 2223, 343, 343 (U.S. 2013) [hereinafter FTC].

201 *Id.*

202 *See generally* Directorate for Financial and Enterprise Affairs Competition Committee, *Commitment Decisions in Antitrust Cases*, ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT 1, 2 (June 2, 2016), https://www.justice.gov/atr/file/873491/download.

203 Preserve Access to Affordable Generics Act, S. 124, 115th Cong. (2017) (amending the Federal Trade Commission Act to make pay-for-delay contracts illegal, including monetary payments and any form of benefit to generic manufacturers).

2. Lessons from the South Korean Branded Marketing Exclusion Period

a. South Korean Administrative Proceedings Superior to Litigation

Patent owners of listed drugs have forty-five days from receipt of notice of a generic application for marketing approval to both (a) file patent litigation against generic applicants and (b) apply with the MFDS for a stay of generic sale against the generic pharmaceutical.[204] Patent owners applying for a stay of generic sale must first (a) seek an injunction or action to prevent patent infringement or (b) initiate an action for patent scope confirmation of the listed patent against the generic applicant providing notice.[205] Branded pharmaceutical companies often file "positive [patent] scope confirmation" claims with the IPTAB seeking judgment that a generic pharmaceutical would infringe the listed patent.[206] Disputes are most often filed at the IPTAB than at a district court to settle issues of "generation, amendment, expiry and scope of patent rights . . . ."[207] IPTAB trials are usually shorter than district court trials.[208] Several Hatch–Waxman problems may be solved by requiring branded pharmaceutical manufacturers to petition for stays of generic sales and offering an accelerated and less expensive PTAB pathway for settling patent issues.

b. South Korean Revocable Stay of Generic Sales Promotes Competition

A generic applicant may avoid a branded marketing stay by obtaining favorable judgment of patent invalidity or scope prior to filing for marketing approval with the MFDS.[209] Without a generic favorable judgment, a branded pharmaceutical manufacturer may petition the MFDS for a stay of generic sales against the generic applicant and the MFDS will not approve the generic marketing application for nine months.[210] A stay of generic sales may be denied or cancelled if: (a) a patent owner did not apply within forty-five days from receipt of notice; (b) a Green List patent is ineligible for listing due to an expired, invalid, or fraudulent listings; (c) the generic drug would not infringe the listed

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204 NIFPSE, *supra* note 151, at 36.

205 Pharmaceutical Affairs Act, *supra* note 87, art. 50-5(2).

206 Young Sun Cho et al., *Overview and Implications of the Drug Patent-Approval Linkage System in South Korean Regulation*, WESTLAW (Feb. 1, 2014), https://content.next.westlaw.com/Document/I699f6bf2b36911e398db8b09b4f043e0/View/FullText.html?contextData=(sc.Default)&transitionType=Default&firstPage=true&bhcp=1.

207 *Id.*

208 *Id.*

209 Kim et al., *supra* note 35, at 7.

210 NIFPSE, *supra* note 151, at 36.

patent; or (d) a patent owner violates the Korean Monopoly Regulation and Fair Trade Act.[211]

To solve problems with the current Hatch–Waxman system, the following amendments are recommended: (a) reduce a stay of generic sales from thirty months to nine months; (b) make a stay of generic sales contingent on proper Orange Book listings; (c) narrow the criteria for Orange Book eligibility; (d) require the FDA to correct or delete improper Orange Book listings; and (e) expand pre-ANDA filing USPTO actions for patent invalidity and noninfringement. Limiting the ability of branded pharmaceutical companies to bind generic applicants in ANDA litigation is likely to stimulate greater generic drug competition.

D. Comparison of First-to-File Generic Marketing Exclusion Periods

1. Overview of Hatch–Waxman 180-day Stays of Later Filed Generics

Under Hatch–Waxman, the FDA offers a 180-day exclusive right to "first-to-file" generic pharmaceutical manufacturers to market the generic drug.[212] The stay of later filed generic sales was designed to encourage ANDA filers to challenge patents asserted by branded pharmaceutical manufacturers, particularly patents of questionable validity and scope.[213] The first-to-file 180-day marketing exclusion period allows generic challengers to recover the cost of ANDA litigation from the greater profits available prior to the arrival of later generic competitors.[214]

The exclusion period allows a first-to-file generic pharmaceutical manufacturer to charge extremely high prices and garner significant profits.[215] Once other generic competitors enter the market, prices fall tremendously and a first-to-file generic pharmaceutical manufacturer often experiences a dramatic drop in sales.[216] Nevertheless, the first-to-file generic pharmaceutical manufacturer benefits from a first-mover advantage that allows early customers to remain in the market even after competitors enter it.[217]

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211 *Id.*; Pharmaceutical Affairs Act, *supra* note 87, art. 50-5(4).
212 Hemphill & Lemley, *supra* note 25, at 953.
213 *Id.*
214 *Id.*
215 *Id.*
216 *Id.*
217 *Id.*

2. *Loopholes in Hatch–Waxman 180-Day Stays of Later Filed Generic Sales*

a. *Insufficient Profit Motive for ANDA Paragraph IV Challengers*

The first-to-file generic 180-day marketing exclusion period is only semi-exclusive given that all ANDA Paragraph IV challengers that file for the same drug on the same day are considered "first applicant[s]."[218] Branded pharmaceutical manufacturers will also license the right to sell generic versions of the listed drug just prior to patent expiration to reduce the potential profits provided to the first generic to file an ANDA Paragraph IV challenge.[219]

b. *Pay-for-Delay Block Later ANDA Paragraph IV Challengers*

The FDA is unable to approve subsequent ANDA applications until the 180-day generic marketing exclusion period expires.[220] The 180-day exclusion period is triggered by the earlier of a "[first] commercial marketing" of a generic drug or a 'court decision' [holding a] patent invalid, unenforceable or not infringed . . . ."[221] Pay-for-delay settlements (a) remove the trigger of "a court decision" and (b) often stipulate that the first-to-file ANDA Paragraph IV applicant must delay "first commercial marketing" until closer to the patent expiration date.[222] Thus, the FDA is effectively blocked from approving later filed ANDA Paragraph IV applications.[223]

c. *Rules for Forfeiture of Eligibility for 180-Day Stay are Ineffective*

The MMA created the basis for a first filing ANDA Paragraph IV applicant to forfeit eligibility for the 180-day marketing exclusion period.[224] Forfeiture events include: "(a) failure to market; (b) withdrawal of application; (c)

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[218] Center for Drug Evaluation and Research (CDER) et al., *Guidance for Industry 180-Day Exclusivity: Questions and Answers* 6 (2003) [hereinafter *180-Day Q&A*], https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM536725.pdf.

[219] Kesselheim & Darrow, *supra* note 30, at 333–34.

[220] CDER, *Small Business Assistance: 180-Day Generic Pharmaceutical Exclusivity*, FDA, https://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm069964.htm (last visited Feb. 11, 2018).

[221] Renu Lal, *Patents and Exclusivity*, FDA/CDER SBIA CHRON. (May 19, 2015), https://www.fda.gov/downloads/drugs/developmentapprovalprocess/smallbusinessassistance/ucm447307.pdf (Section 5 on the "180-Day Exclusivity").

[222] *Health Policy Brief: Patent Settlements*, HEALTH AFFAIRS 1, 1 (2017), https://www.healthaffairs.org/do/10.1377/hpb20170721.583967/full/healthpolicybrief_170.pdf.

[223] *Id.*

[224] *180-Day Q&A*, *supra* note 223, at 4.

amendment of certification; (d) failure to obtain tentative approval; (e) entry into agreement with another applicant, the listed drug application holder, or a patent owner; and (f) expiration of all patents."[225] Upon the occurrence of certain events, first applicants become ineligible for the generic 180-day marketing exclusion period.[226] If no first filing ANDA applicants are eligible for the generic 180-day marketing exclusion period, the FDA will commence with marketing approval of all subsequently filed ANDA applications.[227] However, the FDA only rarely holds forfeiture to have occurred.[228]

First, although pay-for-delay settlements would appear to fall within an "agreement," such a forfeiture event requires the FTC to determine that a specific pay-for-delay settlement had violated antitrust laws.[229] To date, the FDA has never revoked a first filer's 180-day marketing exclusion period on this basis.[230] In *FTC v. Actavis, Inc.*, the Supreme Court held pay-for-delay settlements may violate the antitrust laws but did not declare them illegal per se.[231] Further, the 180-day generic exclusion period will most likely have been triggered and run its course by the time the FTC has ruled a particular pay-for-delay settlement to have violated antitrust laws.[232]

Second, a 180-day generic exclusion period for "failure to market" is extremely difficult to invoke. The MMA forfeiture provisions are a "poorly drafted nuanced web of 'earlier than' and 'later than' language that, when formally applied, leaves a pioneer and first filer almost completely in control and able to thwart Congress's goals."[233] The MMA forfeiture provisions allow for forfeiture if:

> [t]he first applicant fails to market the drug by the later of—
> (aa) [a date determined by the first filer's submission and final approval dates]; or

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225 *Id.* at 4–5.

226 *Id.* at 5.

227 *Id.*

228 *See generally id.*

229 Randi Hernandez, *FDA Clarifies How It Handles 180-Day Exclusivity*, BIOPHARMINTERNATIONAL (Jan. 18, 2017), http://www.biopharminternational.com/fda-clarifies-how-it-handles-180-day-exclusivity.

230 *Id.*

231 FTC, *supra* note 205, at 2; Hernandez, *supra* note 234.

232 *180-Day Q&A*, *supra* note 223, at 24.

233 Brian T. Apel, *An Administrative Meter Maid: Using Inter Partes Review and Post-Grant Review to Curb Exclusivity Parking via the "Failure to Market" Provision of the Hatch–Waxman Act*, 114 MICH. L. REV. 107, 120 (2015).

> (bb) with respect to the first applicant or any other applicant . . . the date that is 75 days after . . . at least 1 of the following has occurred:
>
> (AA) In an infringement action . . . or in a declaratory judgment action . . . a court enters a final decision from which no appeal . . . has been or can be taken that the patent is invalid or not infringed.
>
> (BB) In an infringement action or a declaratory judgment action . . . a court signs a settlement order . . . that includes a finding that the patent is invalid or not infringed.[234]

The MMA states that forfeiture for "failure to market" is triggered when a first-filer fails to market a generic drug by either a date calculated from the first-filer's submission and approval dates, found in subpart (aa) or a date based on a court's final judgment of the patent on the merits, found in subpart (bb), whichever occurs later.[235] According to the FDA's interpretation of the statute, "failure to market" is only triggered when events set forth in both subparts (aa) and (bb) occur.[236] While determining the critical date in subpart (aa) is straightforward, the critical date in subpart (bb) may be triggered by litigation against a first applicant or any other applicant over a period of "seemingly indefinite length."[237]

A branded pharmaceutical manufacturer may readily manipulate such a provision by either settling the lawsuit which avoids a court judgment of patent validity or non-infringement of subpart (bb)(AA).[238] Further, such a settlement can specifically omit any determination of patent validity or non-infringement which avoids the triggering event within subpart (bb)(BB) – except in the unlikely event that a later filed ANDA applicant were to seek such a judgment of patent validity or non-infringement.[239] Consequently, the MMA forfeiture provision "lacks any real teeth."[240]

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234 *Id.* (Brian Apel's interpretion of the original statutory language). For the original statutory language, see 21 U.S.C. § 355(j)(5)(D)(i)(I) (2017).

235 Apel, *supra* note 238 at 120–21.

236 *Id.* at 121.

237 *Id.*

238 *Id.* at 121–22.

239 *Id.* at 121.

240 *Id.*

3. Lessons from South Korean Stay of Later Filed Generic Sales

a. South Korean First-to-File Exclusivity Encourages More Applicants

While the United States offers generic drug first-to-file exclusivity to ANDA applicants but not to 501(b)(2) applicants, Korea extends eligibility for first-to-file exclusivity to all applicants relying on the original applicant's clinical data.[241] The generic drug first-to-file exclusivity acts to bar the sale of later filed generic drugs for nine months calculated from the date a first filer may sell the generic drug.[242]

A generic applicant seeking exclusive priority of sale must file a petition for one of the following proceedings at the KIPO prior to applying for marketing approval: patent invalidity trial (Article 133 of the Korean Patent Act); patent extension invalidity trial (Article 134 of the Korean Patent Act); or patent scope confirmation trial (Article 135 of the Korean Patent Act).[243] Priority of sale is granted to those (a) first to file a marketing approval application; (b) first to file a patent challenge that returns a favorable judgment of patent invalidity, invalidity of term extension, or noninfringement (for at least one listed patent within twelve months); and (c) first to obtain such a favorable judgment in a patent challenge within twelve months.[244] All applicants who file a marketing approval application on the same day are considered first-to-file.[245] Similarly, all applicants filing a patent challenge within fourteen days of the first action are considered first-to-file.[246]

Several Hatch–Waxman problems may be solved by increasing the number of ANDA Paragraph IV challengers eligible to share marketing exclusivity since greater competition will reduce the market price of the generic pharmaceutical more quickly. However, to incentivize ANDA Paragraph IV challengers to seek marketing exclusivity when each challenger's share of potential profits will decrease, Hatch–Waxman will likely need to follow South Korea's example and increase the length of the generic marketing exclusion period (e.g., nine months). Further, Hatch–Waxman will need to create early PTAB proceedings for use by generic pharmaceutical manufacturers seeking to qualify for the generic marketing exclusion period.

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241 Kim et al., *supra* note 35, at 9.
242 Pharmaceutical Affairs Act, *supra* note 87, art. 50-9(2).
243 *Id.* art. 50-7(2).
244 Kim et al., *supra* note 35, at 10.
245 *Id.* at 9.
246 *Id.* at 10.

b. South Korean Forfeiture Rules Discourage Pay-for-Delay Deals

Branded pharmaceutical companies have less incentive to offer pay-for-delay settlements in Korea compared to the United States.[247] The MFDS will revoke a generic drug marketing exclusion period if a generic drug applicant fails to begin marketing a generic drug within 2 months of MFDS regulatory approval without justification (Article 50-10(2)(2) of the PAA).[248] The United States could prevent branded pharmaceutical manufacturers from manipulating the indefinite critical dates of the MMA forfeiture provisions by defining forfeiture solely upon the date of FDA marketing approval without reference to any litigation event.[249]

4. Recent KIPO Statistics Reveal Emerging Generic Drug Filing Strategies

a. Substantial Increase in Overall KIPO Filings

The revised South Korean law first permitted patent listings in 2012.[250] While only forty-nine patent listing-related challenges were filed at the KIPO in 2013, this number increased to 216 in 2015; by September 2015, the number increased even more significantly to 1853.[251] Generic drugs were first eligible for generic drug sales exclusivity as of March 2015, which presumably led to the significant rise in KIPO filings in 2015.[252] Further, there is great incentive for generic pharmaceutical manufacturers to file KIPO actions within fourteen days of the actual first filed action to preserve their ability to sell a generic drug during the marketing exclusion period if the challenged patent is eventually invalidated.[253]

b. KIPO Filings Indicate Motive to Preserve First Filer Status

Generic manufacturers have primarily filed patent invalidation actions (61%), followed by PTE invalidation actions (30%), and negative scope confirmation actions (9%).[254] A PTE invalidation action will only shorten or

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247 *Id.* at 13.

248 *Id.*

249 Apel, *supra* note 238, at 121.

250 *Korean Patent-Approval Linkage System – Initial Statistics*, KIM & CHANG: IP NEWSLETTER (Fall/Winter 2015), http://www.kimchang.com/newsletter/201510/ip/en/newsletter_ip_en_fall_winter2015_article07.html.

251 *Id.*

252 *Id.*

253 *Id.*; Kim et al., *supra* note 35, at 13.

254 *Korean Patent-Approval Linkage System*, *supra* note 255.

eliminate additional patent term granted in compensation for MFDS delays in regulatory approval, while the original patent term remains unaffected.[255] One reason for such a large number of PTE filings is that a generic pharmaceutical manufacturer without concrete plans to market a generic drug may file such an action to preserve the right to do so if the invalidation action succeeds.[256] On the other hand, a negative scope confirmation action requires comparison of the branded pharmaceutical with a generic version that exists or will exist.[257] The vast majority (eighty percent) of PTE invalidity actions were for compound claims, suggesting that PTEs were selected over regular patent invalidity actions for compound claims which are generally strong.[258]

c. Generic KIPO Filings Depend on Post-Marketing Surveillance

Mandatory post-marketing safety (PMS) studies in South Korea create "*de facto* data exclusivity period[s]" since generic pharmaceuticals may not be approved until such post-marketing tests have ended.[259] As of 2015, over eighty percent of KIPO filings were challenges to branded drugs whose PMS period would not expire prior to 2017.[260] One reason why KIPO actions are filed so early in the post-marketing surveillance period may be the desire to preserve generic exclusivity rights even without any concrete plans to market a generic.[261] The fact that such actions are mostly of patent invalidation and patent term extension invalidation—as opposed to negative scope confirmation actions—supports this conclusion.[262] Another reason why a generic manufacturer seeking to preserve generic exclusivity rights would file early might be to ensure that any decision in the generic manufacturer's favor falls within nine-month period after the generic application filing date.[263]

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255 *Id.*; Patent Act, Act. No. 950 of 1961, amended by Act No. 14112, Mar. 29, 2016, art. 134 (S. Kor.), *translated in* Korean Intellectual Property Office online database, http://www.kipo.go.kr/upload/en/download/PATENT_ACT_2016.pdf.

256 *Korean Patent-Approval Linkage System*, *supra* note 255.

257 *Id.*; Kim et al., *supra* note 35, at 5.

258 *Korean Patent-Approval Linkage System*, *supra* note 255.

259 *Id.*

260 *Id.*

261 *Id.*

262 *Id.*

263 *Id.*

d. Trends in KIPO Actions Moving Forward

While initial KIPO action filings have steadily increased, such actions might decrease substantially moving forward.[264] As of 2016, roughly thirty to forty percent of such filed actions were later terminated or withdrawn.[265] Such statistics indicate that initial KIPO filings are made to preserve generic exclusivity rights and that generic manufacturers later reconsider a launch of the specific generic pharmaceutical.[266] Further, the MFDS only grants generic exclusivity rights if a generic manufacturer files an application for marketing approval while the challenged patent is still in force.[267] Generic companies may withdraw KIPO filings to resubmit later so that favorable patent invalidity determinations do not precede generic approval application.[268]

South Korea's patent linkage system is still very new and the MFDS is still adjusting the process to encourage generic challenges to branded pharmaceutical patents while not overloading the KIPO with indiscriminate filings.[269] However, early statistics show that the system provides incentives for generic manufacturer to file KIPO actions and to do so prior to filing applications for generic marketing approval to ensure generic marketing exclusivity.[270]

e. Anticipated Results for Hatch–Waxman

Based on South Korea's recent statistics, if Hatch–Waxman allowed early USPTO patent proceedings, a great number of generic pharmaceutical manufacturers would likely participate.[271] Many generic pharmaceutical manufacturers would file such challenges to preserve their right to seek first-to-file generic exclusivity. Many generic pharmaceutical companies are likely to file such proceedings even before fully committing to launching a product in the market. For example, such proceedings would be desirable to later ANDA filers to avoid litigation and stays of generic approval. Therefore, as modeled by South Korea, further refinement may be needed to prevent an overload of merely speculative USPTO patent challenges.

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264 *Id.*
265 *Id.*
266 *Id.*
267 *Id.*; Pharmaceutical Affairs Act, *supra* note 87, art. 50-10(1).
268 *Korean Patent-Approval Linkage System*, *supra* note 255.
269 *Id.*
270 *Id.*
271 *See id.*; Kim et al., *supra* note 35, at 5–9.

CONCLUSION

This Comment has analyzed loopholes within the U.S. Hatch–Waxman system commonly exploited by branded pharmaceutical companies and has proposed adopting certain counterpart provisions of the South Korean pharmaceutical regulatory system as a solution. This Comment predicts that enacting such Hatch–Waxman reforms will increase competition in the market and consequentially lower drug prices in the United States.

There are, of course, several factors which may affect the ultimate outcome of such a proposal which are unpredictable. First, the South Korean patent linkage system is still relatively nascent, and there is scarce information from which to conclude whether it will achieve the desired growth of its generic pharmaceutical industry. Also, since South Korea caps branded and generic pharmaceutical prices, it is impossible to use such data to predict whether adopting South Korea's patent linkage system will reduce U.S. pharmaceutical prices.[272] However, the case of Zocor® gives hope that pharmaceutical prices will fall with greater generic competition.[273]

Another factor to note, this Comment has focused primarily on shifting power away from the branded pharmaceutical industry toward the generic sector in the expectation that this will lower prices to the consumer. However, generic pharmaceutical companies also participate in price gouging strategies.[274] Most notably, in 2016, the price of a two-pack EpiPen rose to $600 from $90 ten years before.[275] In 2015, Marathon Pharmaceuticals sold two heart drugs, Isuprel and Nitropress, to Valeant Pharmaceuticals, who raised their respective prices by 718% and 300%.[276] While competition should reduce all pharmaceutical prices, both branded and generic, this Comment anticipates that additional tailored

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[272] Peter J. Pitts, *The False Promise of Pharmaceutical-Price Controls*, NAT'L REV. (May 19, 2017 4:00 AM), https://www.nationalreview.com/2017/05/drug-price-controls-bad-idea/.

[273] Hemphill & Lemley, *supra* note 25, at 952.

[274] NASHP Staff, *State Lawmaker Will Guzzardi Plots His Next Move to Curb Generic Price Gouging in Illinois*, NASHP: STATE HEALTH POLICY BLOG (Aug. 21, 2018), https://nashp.org/state-lawmaker-will-guzzardi-plots-his-next-move-to-curb-generic-drug-price-gouging-in-illinois/; Jeremy A. Greene, *Cornering the Market on Essential Drugs*, SLATE: MEDICAL EXAMINER (Sept. 23, 2015, 4:31 PM), http://www.slate.com/articles/health_and_science/medical_examiner/2015/09/generic_drug_price_gouging_how_shkreli_and_other_monopolists_cornered_the.html.

[275] Chris Morris, *America's most expensive prescription pharmaceuticals*, CNBC (May 30, 2017, 12:55 PM), https://www.cnbc.com/2017/05/10/americas-10-most-expensive-prescription-drugs.html.

[276] Katie Thomas, *Hospitals Find Valeant Pledge of Drug Discount Hollow*, N.Y. TIMES, May 12, 2016, at B1; *Marathon Pharma sell non-strategic products to Valeant*, THE PHARMA LETTER (Feb. 24, 2015), https://www.thepharmaletter.com/article/marathon-pharma-sells-non-strategic-products-to-valeant.

efforts may be necessary to address problems in the generic pharmaceutical industry.

Potentially serious unintended consequences of such a power shift are a real concern. For example, greater competition from generic drugs may lead to branded pharmaceutical companies choosing to invest less on innovative research. Generic pharmaceutical companies, on the other side, may hesitate to file early ANDA Paragraph IV challenges if the potential profit during the generic market exclusivity period is too diluted by large groups of first filers. If these scenarios arise, future corrections may be needed.

In the thirty years since the enactment of the Hatch–Waxman, the intended balance of branded and generic pharmaceutical companies has shifted—therefore the Hatch–Waxman system will require continual readjustment. This Comment does not propose that the United States adopt South Korea's pharmaceutical regulatory system verbatim. Instead, this Comment points to several ways that the United States would accelerate generic pharmaceutical competition by looking to toward the South Korean system as a guide for the future Hatch–Waxman amendments.

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