Thirty Years of Flawed Incentives: an Empirical and Economic Analysis of Hatch-Waxman Patent-Term Restoration

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THIRTY YEARS OF FLAWED INCENTIVES:
AN EMPIRICAL AND ECONOMIC ANALYSIS OF
HATCH-WAXMAN PATENT-TERM RESTORATION

Jaime F. Cárdenas-Navia

ABSTRACT

Thirty years ago, the Drug Price Competition and Patent Term Restoration Act (“Hatch-Waxman”) created a new foundation for pharmaceutical innovation by extending patent term for pharmaceutical patents and expanding access to generics. This Article explores the effects of Hatch-Waxman’s patent-term restoration provisions through an empirical and economic analysis and concludes that major structural reforms are needed. The life of a pharmaceutical patent continues to be highly unpredictable and subject to numerous biases and inefficiencies. For example: effective patent term for Hatch-Waxman patents can vary from several months to fourteen years; biologics receive more than a year and a half more patent protection than medical devices; and the implementation of the Uruguay Round General Agreement on Tariffs and Trade (“GATT”) has caused billions of dollars of windfall gains and losses while accelerating reliance on improvements over new products. Moreover, Hatch-Waxman’s unnecessary and heavy-handed incentivization of obtaining FDA approval as quickly as possible places adequate safety and efficacy testing in direct conflict with brand name pharmaceuticals’ profit motives. This Article thus recommends moving towards a system of market exclusivity that provides pre-defined periods of protection for novel pharmaceutical products.
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Imagine a patent system where you did not know how much patent protection you would receive until fifteen years after you filed your patent application. Imagine further that, at the end of the fifteen years, your patent term could range anywhere from several months to fourteen years. Finally, imagine that one in six patents received an incorrect patent term.

Believe it or not, pharmaceutical companies have faced this patent system for three decades. And these conditions are but a sampling of the symptoms of a deeply flawed pharmaceutical patent system.

The patent woes of the pharmaceutical industry trace back to 1938, when the Food and Drug Administration (“FDA”) first required that pharmaceutical manufacturers prove that new products are safe prior to marketing or sale. Since then, patent holders have effectively received less than the statutory patent term for patents covering new pharmaceutical products, as obtaining FDA approval may take up to a decade or more.

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1984 Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman")3 sought to address this departure from the patent system’s norm.4

Representing a compromise between pharmaceutical innovators ("brand names") and duplicators ("generics"), Hatch-Waxman has two major provisions: (1) granting the holders of pharmaceutical patents up to five years of patent-term restoration for time lost while obtaining FDA approval and (2) expanding the use of Abbreviated New Drug Applications ("ANDAs"), thereby enabling generics to compete with brand names immediately after patent protection ends.5 Nearly thirty years later, the precise contours of Hatch-Waxman remain hotly contested in all three branches of government.6

To brand names and their supporters, generics are parasitic free-riders that are choking innovation.7 To generics and their supporters, pharmaceuticals are greedy monopolists, unconcerned with access or affordability.8 As a result, much of the Hatch-Waxman literature focuses on whether Congress struck the correct “balance,”9 or on how “gaming” of legislative loopholes undermines the “balance” between brand names and generics.10

This Article does not wade into that battle. Rather, this Article presents a descriptive, empirical analysis of every patent that has received Hatch-Waxman patent-term restoration through the end of 2013. This analysis reveals (1) unexpected trends in the FDA approval process, patent-term restoration process, and patent term over time; (2) numerous manifestations

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5. See 35 U.S.C. § 156(g)(6) (2012); Morris, supra note 2, at 247; Colleen Kelly, The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond, 66 FOOD & DRUG L.J. 417, 422–26 (2011) (“If the patent expires or if a court rules that the patent is invalid or not infringed, FDA can then immediately approve the ANDA.”).


7. See Bruce N. Kuhlik, The Assault on Pharmaceutical Intellectual Property, 71 U. CHI. L. REV. 93, 94 (2004); see also Morris, supra note 2, at 250.


10. See, e.g., Avery, supra note 8, at 171, 175.
of unpredictability, bias, and instability in the patent-term restoration process; and (3) the effect of the Uruguay Round of the General Agreement on Tariffs and Trade ("GATT"), whose unforeseen and unconsidered implementation has drastically altered patent-term restoration. More broadly, the empirical analysis shows a number of ways in which Hatch-Waxman distorts the incentives for pharmaceutical innovation.

This empirical analysis is followed by (and informs) an economic analysis. This Article analyzes the Hatch-Waxman patent-term restoration provisions in their historical legislative context, describes how the provisions arose and how Congress altered them during negotiations, and how the provisions have played out since enactment. This analysis reveals deep faults in the basic rules of Hatch-Waxman which create perverse incentives and inefficiencies. These flaws are caused by outdated or faulty assumptions and a messy legislative process. Provisions are contradictory, overbearing, and even wholly useless. The implementation of GATT has had an outsized effect, flipping one provision completely on its head. Most shockingly, this analysis reveals a loophole, not just in Hatch-Waxman, but at the nexus of the FDA and the U.S. Patent & Trademark Office ("USPTO"), that existed undiscovered for seventy-five years before being closed by GATT.

Concluding these analyses, this Article outlines a framework for a sounder approach to compensating brand names for their loss of patent term. With the benefits of hard data and hindsight, this Article proposes a regime that provides enhanced stability, reduces opportunities for gaming the law, and lessens the inherent tension between the profit incentives of pharmaceuticals and the health of the public.

To these ends, this Article proceeds as follows: Part II provides a brief history of the FDA and its effect on patent term, and outlines the requirements and timeline of Hatch-Waxman patent-term restoration. It also explains how to calculate patent-term restoration and describes the dataset and methodology used in this Article. Part III presents and analyzes the dataset. Part IV critiques the framework of Hatch-Waxman patent-term restoration. Part V outlines an improved system for incentivizing pharmaceutical innovation, while Part VI concludes.

II. BACKGROUND

A. A BRIEF HISTORY OF THE FDA AND THE DECLINE IN EFFECTIVE PATENT TERM

In the 1930s, there was growing evidence of a need to more effectively regulate U.S. consumer goods, particularly food supply, drugs, cosmetics, and medical devices. A diabetes “cure” was being sold that had no effect whatsoever; toxic eyelash dyes were causing blindness; food was being deceptively packaged and mislabeled; and in a particularly horrific case, a pediatric “wonder drug” killed over one hundred people, many of them children. At that time, the FDA lacked the statutory authority to stop these abuses. In response to public outcry, Congress passed the Food, Drug, and Cosmetic Act (“FDCA”), signed into law on June 25, 1938.

The FDCA introduced many new regulations to protect the public, including label and advertising requirements, food standards, and poisonous substance controls. And for the first time, the FDA required brand names to prove that any new product was safe before it could be sold. This safety requirement led to a de facto loss of patent term for patents covering new products, as many years of patent term may pass before FDA approval is granted. The remaining patent term—from the time the patented product receives FDA approval and may be marketed until the patent expires—is referred to herein as Effective Patent Term (“EPT”).

From 1938 until Congress passed Hatch-Waxman in 1984, the range of products that required FDA approval prior to sale increased as various amendments were made to the FDCA. And in 1962, once again following a horrible tragedy, Congress passed legislation expanding the requirements


13. See FDA History—Part II, supra note 1.


16. See FDA History—Part II, supra note 1.

17. Id.

18. See Grabowski & Vernon, supra note 2.


20. See id. The use of thalidomide worldwide by pregnant mothers as a sleeping pill and to help with morning sickness caused tens of thousands of babies to be born with severe birth defects. The FDA had refused to allow thalidomide sales in the United States, but Congress still responded to the worldwide scare.
for new pharmaceutical products to receive FDA approval.\textsuperscript{21} The Drug Efficacy Amendment ("DEA") of 1962 required companies to prove the efficacy of their products before marketing or sale and applied retroactively.\textsuperscript{22} Thus, all drugs introduced since 1938 must be proven both safe and effective before being sold in the United States.\textsuperscript{23}

The DEA improved the health and safety of the American public.\textsuperscript{24} However, it further accelerated an already-increasing FDA approval period, greatly decreasing EPT.\textsuperscript{25} Academic studies in the early 1980s indicated that, from 1966 to 1979, EPT fell from 13.6 years to 9.5 years.\textsuperscript{26} Later studies found that, for the average pharmaceutical patent, less than half of the seventeen-year patent term remained by the time the drug received FDA approval.\textsuperscript{27}

Patents grant the right to exclude others from making, using, selling, offering to sell, or importing the claimed invention.\textsuperscript{28} This right of exclusivity is essential for brand names to recoup their investment.\textsuperscript{29} It is estimated that bringing a new pharmaceutical product to market today can cost upwards of $1 billion.\textsuperscript{30} Without a guarantee that new products will be protected from generic competition for a substantial period, brand names would be much less willing to undertake the heavy expenditures required to develop, market, and sell new products.\textsuperscript{31} So as EPT continued to decrease in the late 1970s and early 1980s, pro-brand-name forces heavily lobbied Congress for increased patent protection.\textsuperscript{32}

While the DEA led to a decreasing EPT for brand names, it also substantially reduced generic competition. Following the DEA, the FDA created a streamlined procedure for generic versions of pre-1962 products to

\begin{footnotesize}
\begin{itemize}
\item[21.] See FDA History—Part IV, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm055137.htm (last updated June 18, 2009).
\item[22.] See FDA History—Part III, supra note 19. Shockingly, the Drug Efficacy Amendment marked the first time that pharmaceuticals were required to receive informed consent from patients involved in clinical trials.
\item[23.] See Mossinghoff, supra note 4, at 187.
\item[24.] See FDA History—Part II, supra note 1.
\item[25.] See Grabowski & Vernon, supra note 2.
\item[27.] Id.
\item[29.] See Grabowski & Vernon, supra note 2, at 98–99.
\item[30.] Morris, supra note 2, at 254.
\item[31.] See id. at 257–59.
\item[32.] Mossinghoff, supra note 4, at 188.
\end{itemize}
\end{footnotesize}
meet the efficacy requirement and obtain FDA approval. The law, however, did not provide a similar pathway for generics to satisfy the safety and efficacy requirements for post-1962 products. Generics were thus required to incur the time and costs of conducting clinical trials to gain FDA approval for these post-DEA products. As a result, in 1983, 90% of off-patent drugs approved before 1962 faced generic competition, while just 35% of off-patent drugs approved after 1962 faced generic competition. The FDA sought to address this costly oversight by proposing regulations to streamline the approval of generic versions of already-approved products. However, it was uncertain whether these regulations would be implemented.

With EPT cut in half and generic competition in decline, the need for both patent-term restoration and accelerated generic approval was well-established by the time Hatch-Waxman passed in 1984. Though Hatch-Waxman addresses both issues, this Article focuses exclusively on the patent-term restoration provisions found in 35 U.S.C. § 156.

B. Timeline and Requirements of Hatch-Waxman Patent-Term Restoration

While the basic concepts of Hatch-Waxman patent-term restoration are fairly straightforward, the precise details are somewhat byzantine. A timeline is therefore helpful for understanding its mechanics.

33. See Kelly, supra note 5, at 420 (discussing the FDA’s Drug Efficacy Study Implementation (“DESI”) program, wherein generics needed only submit an Abbreviated New Drug Application (“ANDA”) containing bioavailability and bioequivalence data).
34. Id. (“For post-1962 pioneer drugs, generic drug manufacturers were required to submit a full NDA, including clinical data demonstrating the drug’s safety and efficacy.”).
35. See Nussbaum & Radice, supra note 9, at 231 (2009); see also Mossinghoff, supra note 4, at 187 (discussing the lack of “paper” NDAs).
37. Kelly, supra note 33, at 420 (“In 1983, FDA then proposed a regulation . . . that would create an ANDA process for post-1962 prescription drugs.”).
38. See id. (discussing the lawsuits and controversy surrounding the FDA’s proposed ANDA process for post-1962 drugs).
Figure 1 provides an illustrative timeline of the parallel processes of drug development and patent prosecution that lead to receiving patent-term restoration. Both processes begin with the discovery of a new pharmaceutical product, such as a new active chemical. Brand names conduct screening tests to determine whether new products cause sufficient biological activity to justify further testing. Following a successful screening, pre-clinical trials begin. Pre-clinical trials generally involve testing the product on animals to determine if the product is safe enough for initial use on humans and whether it is effective enough to justify further commercial development. As soon as a statistically significant beneficial use is identified, the brand

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40. Id. at 13–14.
41. See id. at 14.
42. See id. at 13 fig.1.
name may file one or more patent applications with the USPTO. Patent applications may cover the new product itself, the process of making the product, or the method of using the product to treat a condition.

If the pre-clinical trials are successful, the brand name files an Investigational New Drug application ("IND") with the FDA and, unless the FDA objects, human clinical trials begin. The filing of the IND begins the Testing Phase, a key period for computing patent-term restoration, as up to half of the patent term lost during the Testing Phase may be restored.

During the Testing Phase, the brand name attempts to establish product safety and efficacy, and determine appropriate usage, labeling, and manufacturing guidelines for the product. The Testing Phase ends and the Approval Phase begins upon the filing of a New Drug Application ("NDA") with the FDA.

The Approval Phase is largely an administrative process, during which the FDA assesses the safety and efficacy data compiled during the Testing Phase and determines whether or not to allow marketing of the new product, and if so, under what conditions. The FDA can require more testing if it finds the data to be inadequate. The Approval Phase ends when FDA approval is granted, meaning that the product can be marketed and sold.

The Approval Phase is another key period for computing patent-term restoration, as all of these days are eligible for restoration. The sum of the Testing Phase and the Approval Phase—from the filing of the IND until


46. RANDALL, supra note 43, at 7–8.

47. See 35 U.S.C. § 156(c), (g) (2012).


50. See NDA, supra note 48.

51. RANDALL, supra note 43, at 10 ("[I]f the agency has serious concerns about the sufficiency of the drug's safety and efficacy data, it may insist the company do additional studies or data analysis.").

52. Shulman et al., supra note 49, at 64–65.
FDA approval is granted—is the Regulatory Review Period. All in all, one out of every 5000 products that begin pre-clinical testing eventually receives FDA approval.

The patent application(s) covering the new product often issue during the Testing Phase, as shown in Figure 1, though the patent(s) can issue before or after the Testing Phase. The time between the start of the Testing Phase (IND Filing) and the date of patent issuance is the Pre–Patent Issuance Phase. If a patent issues prior to the Testing Phase, then the Pre–Patent Issuance Phase is zero. None of the days in the Pre–Patent Issuance Phase are eligible for restoration.

Once the FDA grants marketing approval, brand names have sixty days to file an application for patent-term restoration with the USPTO. Upon receiving notification of the application from the USPTO, the FDA calculates and publishes the IND filing date, the NDA filing date, the FDA approval date, and the Regulatory Review Period in the Federal Register. The USPTO then determines whether patent-term restoration is merited, and if so, how much. Any patent-term restoration is published in a Certificate of Extension, which becomes part of the record of the patent.

Patents claiming “a product, a method of using a product, or a method of manufacturing a product” are eligible for restoration. Hatch-Waxman defines “product” as comprising drug products, medical devices, and food and color additives subject to regulation under the FDCA. In turn, “drug products” include active ingredients of drugs (“new chemical entities” or “NCEs”), antibiotic drugs, human biological products, and animal or veterinary biological products. To receive restoration, a patent must not

53. Id. Technically, the Regulatory Review Period is defined for a new drug, antibiotic, or biologic in 35 U.S.C. § 156(g) as the sum of these two periods. Since the Testing Phase and the Approval Phase have an overlapping day, the length of the Regulatory Review Period is from the IND filing until FDA approval plus one day.

54. Kuhlik, supra note 7, at 94.

55. See 35 U.S.C. § 156(a) (2012); PATENT-TERM EXTENSION AND THE PHARMACEUTICAL INDUSTRY, supra note 39, at 15 (“[I]t is not unlikely that the patent will be issued during the safety and efficacy testing stage.”).


57. See id.

58. Id. § 156(d).

59. Id.

60. Id. § 156(e).

61. Id.

62. Id. § 156(a).

63. Id. § 156(f)(1)(A)–(B).

64. Id. § 156(f)(2)(A)–(B).
have expired before an application for restoration is submitted. A patent can receive restoration only once, and there can be only one patent restoration per product Regulatory Review Period. Thus, though there are often multiple patents covering a new product, the brand name must choose just one to receive patent-term restoration.

C. Calculating Hatch-Waxman Patent-Term Restoration

Due to concerns about unduly prolonging patent protection for new medical treatments, as generic competition lowers prices, Hatch-Waxman only restores a portion of the patent term that is lost while brand names seek FDA approval. During the negotiations of Hatch-Waxman, some members of Congress also worried that brand names would needlessly delay seeking FDA approval. As a result, Hatch-Waxman contains a variety of provisions that limit the amount of patent-term restoration a given patent may receive and incentivizes brand names to expeditiously obtain FDA approval.

These provisions can be summarized as three distinct steps used to calculate patent-term restoration: (1) calculating the amount of Patent Term Eligible for Restoration based on key dates from the FDA and patent approval processes; (2) applying the two-year, three-year, or five-year caps, if applicable; and (3) applying the fourteen-year limit, if applicable. Each of these steps is described below along with an example.

1. Calculating the Patent Term Eligible for Restoration

The Patent Term Eligible for Restoration is calculated by adding one-half of the Testing Phase plus the Approval Phase, subtracting out the Pre–Patent Issuance Phase and any periods of non-diligence. It is expressed in the formula below:

\[
PTER = \frac{1}{2} (TP \text{–} PPIP_{TP} \text{–} DD_{TP}) + (AP \text{–} PPIP_{AP} \text{–} DD_{AP}),
\]

where “PTER” is the Patent Term Eligible for Restoration, “TP” is the Testing Phase, “AP” is the Approval Phase, “PPIP” is the Pre–Patent Issuance Phase, and “DD” is any period when the applicant failed to act with Due Diligence. The “TP” and “AP” subscripts indicate the portion of the Pre–Patent Issuance Phase and non-diligence that occurred during the

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65. Id. § 156(a)(1). One-year patent term extensions can be granted if the patent is about to expire. Id. § 156(e).
66. Id. § 156(a), (c).
68. See 35 U.S.C. § 156(c), (g) (2012).
69. See id. § 156(e).
70. See id.
Testing Phase and Approval Phase, respectively. All of the values are measured in days.\footnote{See id.}

Deducting any periods of non-diligence from the eligible restoration period discourages delay. And since only half of the Testing Phase is eligible for restoration, brand names are incentivized to conduct their clinical trials as expeditiously as possible, as they can only receive at most one day of patent-term restoration for every two days of clinical trials. Finally, deducting the Pre–Patent Issuance Phase ensures that any time spent seeking FDA approval before the patent issues cannot count towards extending the patent term. These provisions collectively ensure that patent-term restoration is only awarded for time spent diligently pursuing FDA approval for a product covered by an issued patent.

To demonstrate the interplay of these provisions, consider the following example, computed in years for simplicity: a product spends six years in clinical trials (six-year Testing Phase), two years seeking FDA approval (two-year Approval Phase), and the product’s corresponding patent issued two years into clinical trials (two-year Pre–Patent Issuance Phase). Assuming the brand name always acted with Due Diligence (DD = zero years), the product has a Patent Term Eligible for Restoration of four years:

\[
\text{PTER} = \frac{1}{2} (6 - 2 - 0) + (2 - 0 - 0) = 4 \text{ years}.
\]

2. Applying the Caps

Once the Patent Term Eligible for Restoration has been calculated, any applicable statutory caps are applied.\footnote{Id. § 156(c), (g).} Caps limit the amount of patent-term restoration, irrespective of how long a product took to receive FDA approval. Hatch-Waxman contains two-year, three-year, and five-year caps on the patent term that can be restored. These caps were believed to be sufficient to encourage innovation without being overly generous to brand names.\footnote{See 98 CONG. REC. H8706 (daily ed. Aug. 8, 1984) (statement of Rep. Waxman) (“Title II of the bill would extend the patents for drugs and other substances subject to premarket approval for up to 5 years. . . . [T]he legislation will create a significant incentive for the development of new products.”); 98 CONG. REC. H8708 (daily ed. Aug. 8, 1984) (statement of Rep. Kastenmeier) (“The OTA also raised several cautions about any patent term legislation. They pointed out that expenditures for research and development appeared to be stable, despite reduced effective patent life. Second, they predicted that drug prices were likely to be higher during a period of patent extension.”).}

Whether a two-year, three-year, or five-year cap applies to a given product depends on, at the time of the enactment of Hatch-Waxman,
whether a corresponding patent had issued and (2) whether an IND had been filed. Products for which a patent had issued and an IND had been filed at enactment (“pipeline” products) were subject to a three-year cap (for animal drugs and veterinary biological products) or a two-year cap (for all other products). These transitional caps represented a balance between the settled expectations of brand names and generics for products already in the pipeline. Products for which either no patent had issued or no IND had been filed are subject to a five-year cap.

The following formula represents this straightforward step in the calculation of patent-term restoration:

**Capped PTER = PTER, unless 2-yr, 3-yr, or 5-yr cap applies**

3. Applying the Fourteen-Year Limit

The final statutory limitation on patent-term restoration is the fourteen-year limit. Whether or not any of the caps limit the Patent Term Eligible for Restoration, the Effective Patent Term With Restoration (“EPTWR”) cannot exceed fourteen years. The EPTWR is the Effective Patent Term (“EPT”) plus any patent-term restoration, represented by the equation below:

\[
EPTWR = EPT + PTR,
\]

where “PTR” is the final Patent Term Restored. If the calculated EPTWR would exceed fourteen years using the Capped PTER, then the PTR is calculated from the above equation, as demonstrated below:

**If: EPT + Capped PTER > 14-year Limit**

**Then:** \( PTR = 14 \text{ years} - EPT \)

**Else:** \( PTR = \text{Capped PTER} \)

Thus, the fourteen-year limit serves a dual role: it prevents patents that receive Hatch-Waxman patent-term restoration from having an EPTWR of more than fourteen years and it precludes patents with EPTs of more than fourteen years from receiving any Hatch-Waxman patent-term restoration. This is why it is referred to as a “limit” rather than a “cap.”

Consider the following example, computed in years for simplicity. A post-Hatch-Waxman patent has a Patent Term Eligible for Restoration of 6.5 years and an EPT of 10 years. The five-year cap will apply to the 6.5-year PTER to yield a capped PTER of 5 years. Additionally, since the EPT plus

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75. Lourie, supra note 26, at 531, 534.
77. Id. § 156(c).
78. Id.
the capped PTER exceeds 14 years (10 + 5 = 15 years), the fourteen-year limit must also apply to limit the EPTWR to 14 years. This will result in a PTR of 4 years (14 years – EPT = 14 – 10 = 4 years). This PTR is added to the existing patent term, and the entire patent remains in force during the period of extension.

The resulting EPTWR is immensely important. This is the period during which brand names recoup their investments, along with a hefty profit. While, contrary to common perception, a patent does not confer a monopoly, given the well-documented market failures in paying for healthcare and the reality that only a few treatments may be available for a given medical condition, a pharmaceutical product patent often confers significant market power. This market power in turn leads to supra-competitive profit margins. Thus, the effect on EPTWR, and the corresponding economic impact, is a recurring focus of this Article.

D. THE DATASET AND METHODOLOGY

The dataset for this Article includes all patents for which a Certificate of Extension was issued by the USPTO, dating from Hatch-Waxman’s enactment through the end of 2013 (1984–2013). This represents 613 commercial products and the corresponding 613 patents.79

It is important to note what is not included in the dataset. Some products that receive FDA approval are unpatentable or the corresponding patent has already expired.80 Additionally, products that receive FDA approval very quickly or for which the corresponding patent issues very late into the Regulatory Review Period may have an EPT of more than fourteen years. Hatch-Waxman does not grant patent-term restoration to these categories of products.81

79. The USPTO generously provided a spreadsheet containing a tremendous amount of data, including all of the patent numbers for which patent term restoration was sought, the name and type of each product, the PTR granted, and the FDA approval date. Additional data was collected from the USPTO’s PAIR website and the Federal Register, including the dates of patent issuance, patent filing, IND filing, and NDA filing. Public PAIR, U.S. PATENT & TRADEMARK OFFICE, http://portal.uspto.gov/pair/PublicPair/ (last visited May 15, 2014); FEDERAL REGISTER, https://www.federalregister.gov/ (last visited May 15, 2014). Various calculations and graphs were then made using Microsoft Excel 2010 to yield the information herein. Special thanks to the USPTO for providing the initial data. The dataset is on file with the Author and can be made available upon request.

80. One-year patent term extensions can be granted if the patent is about to expire (up to five times). 35 U.S.C. § 156(d)(5)(B) (2012).

81. See id. § 156(a), (c).
1. A Note About Figures

The data in the figures below is generally presented in chronological order based on the IND (or equivalent) date. Given how many years the entire patent-term restoration process can take and how the laws, regulations, and practices of the FDA and USPTO have changed over time, an IND-based perspective allows for comparison between products of the same cohort. The data is grouped into intervals of three to five years to smooth out noise and facilitate presentation. When feasible, both the average and the median are presented, as both provide insights into the patent-term restoration system. Providing average values allows brand names to gauge the expected outcomes (e.g., EPTWR) for products entering the FDA approval process during a specific time frame. And given the non-normal distribution of the dataset, the median better reveals the “typical” product’s path to receiving patent-term restoration.

2. The $1 Billion Product

As the time and expense of developing new products increases, brand names increasingly rely on “blockbuster” products to finance their research and development. Some products earn more than $6 billion in yearly revenues in the United States alone. In 2013, fifty-five different drug products had revenues for the year of $1 billion or more in the United States. Despite these enormous figures, it has been estimated that brand names need to create a new blockbuster every two to three years to maintain profitability.

It is often said that time is money, and nothing could be truer when it comes to patent protection for pharmaceutical products. Brand names and generics litigate furiously and at great expense over mere months of patent protection. The reason is that generics tend to dominate the product
market immediately after patent protection ends, sometimes capturing up to 90% of the market within their first year or two after entry.88

Indeed, we are approaching the bottom of the so-called “patent cliff,” in which an unprecedented number of blockbuster products are coming off-patent.89 Between 2007 and 2012, brand names have lost an estimated $67 billion in revenue due to the loss of patent protection and the ensuing generic competition in the United States alone.90 Another estimate puts the loss in sales from 2009 to 2013 worldwide at $137 billion.91 Plavix, Lipitor, and Actos all went off-patent between 2010 and 2013.92 These drugs had annual U.S. revenues in the final years of patent protection of approximately $6.1 billion, $5.3 billion, and $3.3 billion respectively.93

To demonstrate the financial impact that seemingly small differences in EPTWR can make, this Article uses $1 billion as the projected yearly revenues that a blockbuster product would have received during its first year off-patent had the patent remained in effect. Furthermore, this Article makes the conservative assumption that brand names lose 50% of their revenues once patent protection ends.94 Applying this 50% revenue-loss assumption to the $1 billion projected yearly revenues, every year decrease in EPTWR leads to a $500 million decrease in revenues for the brand name, and every lost day of EPTWR corresponds to $1.4 million in lost revenue. This hypothetical product, with its hypothetical revenues and corresponding loss in revenues upon going off-patent, is referred to in this Article as “the $1 Billion Product.”

88. Avery, supra note 8, at 172; see also Grabowski & Vernon, supra note 2, at 106–07.
90. DeRuiter & Holston, supra note 89.
93. See Alazraki, supra note 92.
94. Grabowski & Vernon, supra note 2, at 116 (“By the mid-1990s, major drug products confronting patent expiration typically lost more than half their sales within the first several months to generics entering the markets.”).
The $1 Billion Product is not intended to represent how much revenue the average blockbuster product actually loses in its first year off-patent. Rather, the $1 Billion Product is used in this Article as a tool to highlight how seemingly slight changes in EPTWR can have substantial financial consequences. For example: given that the average patent that was being prosecuted or in force when GATT went into effect received an additional 0.28 years of EPTWR, then the $1 Billion Product received an additional $140 million in revenue due to this extra patent term. This is not to say that any particular product, and certainly not the average product, received $140 million more as a result of GATT; some products’ revenues were unchanged, while others received substantially more than the $1 Billion Product. The point is to demonstrate that for a large brand name with a portfolio of blockbuster products, and certainly for the industry as a whole, the implementation of GATT created a windfall in the billions of dollars. The $1 Billion Product is used throughout this Article for similar effect.

3. Patent-Term Restoration versus Patent Term Adjustment

Finally, to avoid confusion between Hatch-Waxman patent-term restoration and patent term adjustment, “patent term adjustment” herein refers to any increase in patent term under 35 U.S.C. § 154. Essentially, patent term adjustment provisions extend the expiration date of a patent to compensate for certain delays during prosecution at the USPTO, such as appeals or interferences that the patent applicant ultimately wins. Since the fourteen-year limit on EPTWR cannot be exceeded, any patent term adjustment has been taken into account prior to computing Hatch-Waxman patent-term restoration in this dataset.

III. EMPIRICAL ANALYSIS OF HATCH-WAXMAN PATENT-TERM RESTORATION

A. SUMMARY OF HATCH-WAXMAN PATENT-TERM RESTORATION AND THE FDA APPROVAL PROCESS

All in all, Hatch-Waxman has provided meaningful patent-term restoration. Table 1 summarizes the effects of Hatch-Waxman on Effective Patent Term (“EPT”) for the dataset. For all patents receiving restoration through the end of 2013, the average Patent Term Restored (“PTR”) was 2.7 years, providing an average Effective Patent Term With Restoration

(“EPTWR”) of 11.5 years. The median EPTWR is 12.9 years, over a year longer than the average. The large discrepancy is due to some very low EPTWR values that disproportionately bring down the average. Patents in the dataset lost an average and median patent term of 8.2 years and 7.6 years, respectively.97 Despite the significant PTR, Hatch-Waxman only restores about one-third of the patent term lost while seeking FDA approval.98

Table 1. Summary of Hatch-Waxman Patent-Term Restoration, 1984–2013

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Average</strong></td>
<td>8.8 years</td>
<td>2.7 years</td>
<td>11.5 years</td>
<td>8.2 years</td>
<td>34.9%</td>
</tr>
<tr>
<td><strong>Median</strong></td>
<td>9.6 years</td>
<td>2.3 years</td>
<td>12.9 years</td>
<td>7.6 years</td>
<td>33.9%</td>
</tr>
</tbody>
</table>

Tables 2 and 3 summarize the length of various phases of the Hatch-Waxman patent restoration process, from the filing of a patent application to the issuance of a Certificate of Extension. Looking at Table 2, which summarizes the Regulatory Review Period, the average Testing Phase and average Approval Phase are 5.4 years and 2.2 years, respectively. The average Regulatory Review Period is 7.6 years, well above the maximum PTR allowed of 5 years. Shockingly, the Testing Phase ranges from 0.35 years to 20.0 years, the Approval Phase ranges from 0.01 years (4 days) to 17.2 years, and the Regulatory Review Period ranges from 0.78 years to 21.3 years.

97. The “Patent Term Lost” is the time between a patent’s issuance and FDA approval of the corresponding product.

98. The “Percent of Lost Patent Term Restored” is calculated by dividing a patent’s PTR by the Patent Term Lost.
Table 2. Summary of the FDA Regulatory Review Period for Hatch-Waxman-Eligible Products, 1984–2013

<table>
<thead>
<tr>
<th></th>
<th>Testing Phase</th>
<th>Approval Phase</th>
<th>Regulatory Review Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>5.4 years</td>
<td>2.2 years</td>
<td>7.6 years</td>
</tr>
<tr>
<td>Median</td>
<td>4.8 years</td>
<td>1.6 years</td>
<td>6.9 years</td>
</tr>
<tr>
<td>Min/Max</td>
<td>0.35/20.0 years(^99)</td>
<td>0.01/17.2 years</td>
<td>0.78/21.3 years</td>
</tr>
</tbody>
</table>

Turning now to Table 3, on average 4.7 years passes between when a patent application is filed and when the corresponding product begins the FDA approval process (“Patent Filing to IND Filing”). This large, pre-IND filing period leads to an average of 12.3 years between when a patent application is filed and when FDA approval is granted for the corresponding product (“Patent Filing to FDA Approval”). Surprisingly, it takes an average of 2.9 years from when the FDA approves a product until the USPTO issues a Certificate of Extension for the corresponding patent (“FDA Approval to USPTO Grant”). Though this time period does not affect the EPTWR, it results in an average timeline of 15.2 years from when a patent application is filed until the granting of PTR is assured (“Patent Filing to USPTO Grant”).

The median for each phase of the Hatch-Waxman patent restoration in Tables 2 and 3 is approximately half a year less than the average, due to extraordinary delays for some products and patents at each phase of the process that skew the average in an upwards direction. The Min/Max row of Table 3 shows how much each of these phases can vary and how long the Hatch-Waxman patent-term restoration process can take, with one Certificate of Extension granted nearly thirty years after the patent application was filed.

\(^99\) Nine products had Testing Phases of zero days. These products were excluded when identifying the Min.

<table>
<thead>
<tr>
<th></th>
<th>Patent Filing to IND Filing</th>
<th>Patent Filing to FDA Approval</th>
<th>FDA Approval to USPTO Grant</th>
<th>Patent Filing to USPTO Grant</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Average</strong></td>
<td>4.7 years</td>
<td>12.3 years</td>
<td>2.9 years</td>
<td>15.2 years</td>
</tr>
<tr>
<td><strong>Median</strong></td>
<td>4.0 years</td>
<td>11.8 years</td>
<td>2.5 years</td>
<td>15.0 years</td>
</tr>
<tr>
<td><strong>Min/Max</strong></td>
<td>-13.3/19.4 years(^{100})</td>
<td>4.5/26.9 years</td>
<td>0.83/11.4 years</td>
<td>5.9/29.9 years</td>
</tr>
</tbody>
</table>

\(^{100}\) The negative minimum indicates that some patents receiving PTR were filed after the corresponding IND was filed. These later-filed patents are generally “improvement” patents. See infra Section III.C.
B. **PATENT-TERM RESTORATION TRENDS OVER TIME**

This Section examines trends over time to better understand how Hatch-Waxman patent-term restoration has developed and where it is likely headed.

1. **Effective Patent Term with Restoration**

   **Figure 2. Average Effective Patent Term with and without Restoration**

   ![Bar chart showing average effective patent term with and without restoration over time]

   - **Year of IND Filing**
   - **Average Patent Term Restored (PTR)**
   - **Average Effective Patent Term (EPT)**
Figure 2 above shows the average EPT, PTR, and EPTWR since 1970, grouped into four-year intervals based on the IND filing date. The number of products in each interval is displayed above the respective bar ("N=XX"). As can be seen, average EPTWR increased by about one year every four years from its low of approximately eight years before plateauing from 1986 to 2001 at approximately twelve years. EPTWR declined in the most recent data period, 2002–2008, though the sample size is small. It should be noted that there are no data points beyond 2008 because there are no INDs filed after 2008 that had received patent-term restoration by the end of 2013.

EPTWR increased dramatically from 1970 to 1989 for two main reasons. First, the transitional two-year and three-year PTR caps no longer applied to any of the INDs filed after 1985; only the five-year cap and fourteen-year limit restricted PTR. This allowed for a significant increase in average PTR beginning in 1986, and explains the relatively short PTR from 1970 to 1985.

The second cause of the increase in EPTWR is a sampling bias in the data. The only INDs from the first two data periods (1970–1973, 1974–1977) affected by Hatch-Waxman were those that were still seeking FDA approval at the time of enactment (that is, they had an above-average Regulatory Review Period). For example, an IND filed in 1974 had already spent ten years seeking FDA approval by the time Hatch-Waxman was enacted, well above the average Regulatory Review Period of 7.6 years. An above-average Regulatory Review Period leads to a below-average EPT, as more of the patent term is lost seeking FDA approval. Thus, the data from 1970 to 1977 in Figure 2 is not only drawn from a small sample size (N=15, N=29), making the data points unreliable, but also from a sample size biased towards very low EPTs. The expected result of this sampling bias and the end of the two- and three-year caps—a shorter EPTWR from 1970 to 1985—is exactly what Figure 2 shows.

Conversely, the final data period (2002–2008) is biased towards products that had below-average Regulatory Review Periods. Products filed during this time period had an average Regulatory Review Period of 4.1 years, which is

101. The last data bar encompasses a seven-year period.
102. This graph is based on IND filing date and only includes patents that had received a Certificate of Extension. There are no INDs filed after 2008 that had received PTR by the end of 2013.
103. See 35 U.S.C. § 156(f), (g) (2012). The end of 1985 approximately corresponds with the end of all two-year and three-year limits on restoration. There is not a single cutoff date because of different provisions for animal drugs and veterinary biological products. However, there were no more two-year or three-year limits for any INDs filed after the enactment of the Hatch-Waxman Act. See Hatch-Waxman, supra note 3.
104. See supra Table 1.
3.5 years below the average.105 As a result, one would expect this last data period to have a very high EPT (less patent term lost while seeking FDA approval), but a more modest PTR (less time lost seeking FDA approval, so less time restored). Yet while the average PTR from 2002 to 2008 is short relative to the preceding data periods (2.1 years compared to 3.0 years), the EPT is significantly lower than the preceding data periods when it should be higher (8.2 years compared to 9.2 years). This departure from the sixteen-year plateau is best explained by the implementation of GATT.106

105. See supra Table 2.
106. See infra Section III.C.
The median EPTWR, shown in Figure 3, follows a similar trajectory to the average EPTWR shown in Figure 2, and for the same reasons. There are, however, two notable differences. First, the median EPTWR is generally higher than the average EPTWR, peaking at fourteen years for INDs filed from 1986 to 1989. This indicates that over half of IND applications filed during this time period received the statutory maximum EPTWR. Second, the median EPTWR has been steadily declining ever since, and dropped sharply during the 2002–2008 data period.

Figure 3. Median Effective Patent Term With Restoration
2. Percent of Lost Patent Term Restored

Figure 4: Average Percent of Patent Term Lost While Seeking FDA Approval Restored

Figure 4 shows the percentage of patent term lost during the FDA approval process that the patentee regained through Hatch-Waxman patent-term restoration. This percent restored is calculated by dividing a patent’s PTR by the time between that patent’s issuance and FDA approval of the corresponding product. Similar to EPTWR, the percent restored increased for INDs filed from 1970 to 1989 (from ~20% to ~40%) before plateauing from 1986 to 2001 (~40%) and then sharply decreasing from 2002 to 2008 (~28%). Indeed, the percent restored has dropped to levels not seen since the two-year and three-year PTR caps were in force.

107. This analysis includes pre-clinical testing and any other factors that may have caused delays during the time between patent issuance and FDA approval.
3. The Regulatory Review Period

As explained above, the Regulatory Review Period consists of the Testing Phase and the Approval Phase.108 The Testing Phase begins when an IND is filed and ends when an NDA is filed; the Approval Phase begins when an NDA is filed and ends when FDA approval is granted.109

Figure 5. Average and Median Testing Phase

Figure 5 shows the average and median Testing Phase length for three-year product groupings based on the IND filing date. IND filings before 1980 and after 2000 have been excluded to avoid the sampling biases and unreliability due to smaller sample sizes discussed above. The average and median Testing Phase has oscillated between about four and six years, with no clear trend, and no clear reason for the oscillations. The average Testing Phase for 1998–2000, the most recent data period for which reliable data

108. See 35 U.S.C. § 156(c), (g) (2012).
109. See id.
exists, is 5.1 years, which is well within the historical range. The median Testing Phase for this data period, at 5.2 years, is near the historical high.

Interestingly, the 1998–2000 data period is the first time that the median Testing Phase was higher than the average Testing Phase. For all preceding periods, the average is significantly above the median, as some very long Testing Phases skewed the average upwards, away from the median. The change may be due to the FDA’s Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review programs, implemented in the 1990s to expedite approval for certain products.110 By significantly decreasing the Testing Phase for eligible products, these programs may have contributed to a higher median Testing Phase than the average Testing Phase, as significantly shorter Testing Phases for these products can skew the average below the median.

Brand names have been sounding the alarm that the Testing Phase has been increasing dramatically.111 But Figure 5 suggests that this is not the case. At the very least, more data is needed to determine if the sharp increase in median Testing Phase of 1.0 years from the 1995–1997 period to the 1998–2000 period is within the historical oscillations or the start of a continuing trend.


111. Morris, supra note 2, at 254–55 (asserting that “clinical trials necessary for FDA approval have increased in size and duration”).
Figure 6 shows the marked decline in the average and median Approval Phase for three-year product groupings based on the NDA filing date. The Approval Phase decreased from approximately three years during the 1983–1985 data period to approximately one year during the 2004–2006 data period. Products for which the NDA was filed before 1983 or after 2006 have been excluded in order to avoid the sampling biases discussed above.

The steady decrease in the Approval Phase coincides with passage of the Prescription Drug User Fee Act (“PDUFA”). First enacted in 1992, PDUFA allows the FDA to collect fees from drug manufacturers to fund the drug approval process. Congress enacted PDUFA in response to concerns that the FDA approval backlog was delaying approval of life-saving

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113. *Id.*
treatments and costing the pharmaceutical industry billions of dollars in lost revenue.\textsuperscript{114} PDUFA has been re-enacted every five years ever since, most recently in 2012.\textsuperscript{115} Each iteration of PDUFA sets new goals for improving the regulatory review process, including new targets for the Approval Phase.\textsuperscript{116} Based on the results in Figure 6, PDUFA has been very successful at expediting FDA approval.

**Figure 7. Average and Median Regulatory Review Period**

![Bar chart showing average and median Regulatory Review Period](chart.png)

<table>
<thead>
<tr>
<th>Year of IND Filing</th>
<th>Average Regulatory Review Period</th>
<th>Median Regulatory Review Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>1980-1982</td>
<td>8.3</td>
<td>7.9</td>
</tr>
<tr>
<td>1983-1985</td>
<td>7.5</td>
<td>7.0</td>
</tr>
<tr>
<td>1986-1988</td>
<td>7.3</td>
<td>7.0</td>
</tr>
<tr>
<td>1989-1991</td>
<td>7.8</td>
<td>7.2</td>
</tr>
<tr>
<td>1992-1994</td>
<td>7.3</td>
<td>6.4</td>
</tr>
<tr>
<td>1995-1997</td>
<td>6.1</td>
<td>6.1</td>
</tr>
<tr>
<td>1998-2000</td>
<td>6.4</td>
<td>5.8</td>
</tr>
</tbody>
</table>

Figure 7 shows the average and median Regulatory Review Periods for three-year groupings of products based on the IND filing date. The total Regulatory Review Period has gradually decreased from an average of 8.3 years and median of 7.9 years to an average of 6.4 years and median of 6.1 years.

\textsuperscript{114} Id.  
\textsuperscript{115} Id.  
\textsuperscript{116} Id.
Several conclusions can be drawn from this data. First, new products are receiving FDA approval significantly faster. As a result, consumers are receiving access to new treatments sooner, potentially saving lives and improving health outcomes. Some have argued, however, that this decrease in FDA approval time is due to a weakening of regulatory vigilance rather than an increase in efficiency.\footnote{See, e.g., Daniel Carpenter et al., Deadline Effects in Regulatory Review: A Methodological and Empirical Analysis 23 (Robert Wood Johnson Found., Working Paper No. 45, 2009), available at http://healthpolicyscholars.org/sites/healthpolicyscholars.org/files/w45_carpenter.pdf (finding a “significant, positive correlation between approval in the two months leading up to a deadline and adverse post-market events”).} Whether or not faster approval has benefitted society as a whole, it has unquestionably benefitted brand names, as a shorter Regulatory Review Period leads to a longer EPTWR.

Second, the entire decrease in the Regulatory Review Period results from the decrease in the Approval Phase.\footnote{Compare supra Figure 5, with supra Figure 6.} The decrease in the Approval Phase only translates into an increased EPTWR if neither the five-year cap nor the fourteen-year limit is reached.\footnote{See 35 U.S.C. § 156(c) (2012).} Since most of the patents in the more recent data periods reach neither the cap nor the limit,\footnote{See infra Figure 8.} many products have received longer EPTWRs as a result of the decreasing Approval Phase.

Finally, any future gains in EPTWR due to a decreased Regulatory Review Period are likely to be minimal. The duration of the Approval Phase has already been reduced about as much as possible, as indicated by the plateau at the end of Figure 6. Moreover, the Testing Phase has oscillated within a defined range for at least twenty years, as shown in Figure 5. More recent versions of PDUFA have focused on decreasing the Testing Phase.\footnote{See Kronquist, supra note 112, at 4–6 (discussing the four congressional reauthorizations of PDUFA).} Although decreasing the testing phase is where the FDAs time and resources should be focused, if the past is indicative of the future, then the Testing Phase is unlikely to change significantly in the near future. The Regulatory Review Period is therefore unlikely to significantly influence EPTWR over the short-to-medium term.
Figure 8 shows the percent of patents that reached a cap or limit for four-year groupings of products based on the IND filing date. Of the products pending at the FDA when Congress enacted Hatch-Waxman, more than 90% were limited by the two-year cap, severely restricting EPTWR. From 1986 to 1989, shortly after Hatch-Waxman was enacted and while the transitional two- and three-year caps were no longer in effect, the five-year cap affected 30% of all patents. The percentage of patents with EPTWR limited by the five-year cap declined along with the decline in the

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122. The percent of patents affected is used rather than an absolute number to control for the difference in sample sizes.


124. See id.
Regulatory Review Period, so far affecting 0% of the INDs filed from 2002–2008. The fourteen-year limit has also applied less frequently since Hatch-Waxman was enacted, dropping from 57% during the time period between 1986 and 1989 to 25% during the most recent period (from 2002 to 2008). This decrease in the fourteen-year limit indicates that despite the decrease in patents whose EPTWR is limited by the five-year cap, fewer patents are reaching the fourteen-year statutory maximum. Less patent protection means less revenue for brand names and potentially more revenue for generics.

4. Putting It All Together: The Impending Decline in Patent Protection for Pharmaceuticals?

The information from Figures 2 to 8 tells a conflicting story. The Regulatory Review Period has been decreasing and there are fewer instances of the five-year cap limiting PTR. These trends are a positive signs for brand names, and should be accompanied by an increasing average and median EPTWR. Yet, the average EPTWR is flat and median EPTWR has been declining. Furthermore, the most recent data shows a steep drop-off in EPTWR, suggesting an impending decline in patent protection for pharmaceuticals. The following Section examines the underlying causes of these trends and explores the likely outcome.

C. The Uruguay Round of GATT, the Increasing Length of Pre-Clinical Trials, and Improvement Patents

The two main causes of the decreasing EPTWR seen in Figures 2 and 3 are the increasing length of pre-clinical trials and the implementation of GATT, particularly the transition from a patent term of seventeen years from issuance to twenty years from filing. These two events have combined to cause the gradual and then sharp decline in EPTWR for INDs filed from 1986 to 2008. However, it appears that brand names have responded to these events by increasing their reliance on “improvement” patents. If this trend continues, a resurgence in EPTWR is more likely than a decline.

125. See supra Figure 7.
126. The number of INDs filed from 2002 to 2008 which have hit the five-year cap is most likely not zero, as there are most likely INDs with longer Regulatory Review Periods that have not yet been granted Hatch-Waxman patent term restoration.
127. See supra Figure 7 and Figure 8.
128. See supra Figure 2 and Figure 3.
129. See id.
1. The Effect of GATT on EPTWR

As part of the Uruguay Round of GATT (“GATT”), the U.S. agreed to make several changes to its patent system, including changing the patent term from seventeen years from the issuance date to twenty years from the filing date. These changes in law went into effect on June 8, 1995. To ease the transition, Congress made special provisions for patents still in force and for patent applications still pending when the changes went into effect. This framework resulted in three tiers of patent term: all patents issued but expired on or before June 7, 1978 (“pre-GATT patents”) retained a term of seventeen years from issuance; all patents still in force or issuing based on an application filed before June 8, 1995 (“transitional patents”) receive a term of either seventeen years from issuance or twenty years from filing, whichever is longer; and all patent applications filed after June 8, 1995 (“post-GATT patents”) receive a patent term of twenty years from the earliest effective filing date.

Because most patents issue in three years or less, and because GATT included patent term adjustment provisions to compensate patent holders for patent term lost due to delays at the USPTO, many in the industry expected that the switch to a twenty years from filing patent term would benefit brand names. Some commentators decried this change in law as a massive and undeserved windfall, while others cautioned that GATT was a double-edged sword whose ultimate effect was unknown. Now that nearly all the eligible transitional patents have received Hatch-Waxman patent


132. GATT Uruguay Round Patent Law Changes, supra note 130; see Uruguay Round Agreements Act § 534, 108 Stat. at 4990 (stating that the new patent term rules apply six months after enactment of the Act).


136. 35 U.S.C. § 154(b) (2012); see also GATT Uruguay Round Patent Law Changes, supra note 130.


138. Id. at 48.

139. See Grabowski & Vernon, supra note 2, at 110–13 (discussing the effect of GATT throughout the 1990s and hypothesizing as to its future impact).
restoration and post-GATT patents are beginning to receive patent
restoration, it is possible to assess the effects of GATT on EPTWR.

Out of the 613 patents comprising this Article’s dataset, 69 are pre-
GATT patents, 490 are transitional patents, and 54 are post-GATT patents.
Of the transitional patents, 28% benefitted from the implementation of
GATT. Each transitional patent that benefitted from GATT received an
average increase in EPTWR of 1.0 year, translating into an average increase
in EPTWR of 0.28 years for all transitional patents. For a $1 Billion Product,
this increase in EPTWR for transitional patents yields an additional $140
million in revenue. Although many of these transitional patents may not have
been blockbuster products and it is unknown how many blockbuster
products received additional EPTWR, it is reasonable to assume that GATT
created a collective windfall for brand names worth billions of dollars.

While brand names received a windfall for transitional patents, they are
now taking a sharp loss on post-GATT patents. Without the ability to take
the longer of seventeen years from issuance or twenty years from filing, 41%
of the post-GATT patents have a shorter EPTWR. Each post-GATT patent
that received a shorter EPTWR lost an average of 2.1 years of patent
protection. On average, post-GATT patents experienced a decrease in
EPTWR of 0.85 years. Thus, the $1 Billion Product receiving the average
post-GATT loss in EPTWR of 0.85 years received $425 million less in
revenue than it would have under the GATT transition rules.

Brand names are not only worse off than they were under the GATT
transitional rules; they are worse off than if the pre-GATT rules had
remained in effect. Only 13% of the post-GATT patents benefit from having
a twenty years from filing patent term (46% are not affected). As a result, the
average post-GATT patent receives 0.70 years less EPTWR than it would
with a seventeen years from issuance patent term. Applying this average
decrease in EPTWR to the $1 Billion Product results in $350 million less
revenue than would have been received under pre-GATT rules.
Table 4. Summary of the Effect of GATT on EPTWR

<table>
<thead>
<tr>
<th></th>
<th>Average Effect Per Affected Patent</th>
<th>Average Effect for All Patents</th>
<th>Percent of Patents with a Shorter EPTWR</th>
<th>Percent of Patents with a Longer EPTWR</th>
<th>Percent of Patents with No Change in EPTWR</th>
</tr>
</thead>
<tbody>
<tr>
<td>GATT Transition Patents</td>
<td>+1.0 years</td>
<td>+0.28 years</td>
<td>0%</td>
<td>28%</td>
<td>72%</td>
</tr>
<tr>
<td>Post-GATT Patents (compared to GATT transition rules)</td>
<td>-2.1 years</td>
<td>-0.85 years</td>
<td>41%</td>
<td>0%</td>
<td>59%</td>
</tr>
<tr>
<td>Post-GATT Patents (compared to pre-GATT rules)</td>
<td>-1.3 years</td>
<td>-0.70 years</td>
<td>41%</td>
<td>13%</td>
<td>46%</td>
</tr>
</tbody>
</table>

Table 4 summarizes the effect of GATT on patent-term restoration. In hindsight, the net negative effect of GATT on patent term should have been obvious, as the average patent prosecution time for pharmaceutical patents exceeds the three-year difference in patent term between pre-GATT and post-GATT patents.\(^{140}\) Predictable or not, unless the average patent prosecution time decreases, it is only a matter of time until the post-GATT losses outstrip the GATT transition windfall. The transition to a twenty-years-from-filing patent term is thus a prime cause of the decrease in EPTWR shown in the final bar of Figures 2 and 3.

2. Evidence of Increasing Length of Pre-Clinical Trials

There is evidence that an increasing pre-clinical trials phase is also decreasing EPTWR. As discussed when describing the Figure 1 timeline of the patent-term restoration process, once a new product is discovered, pre-clinical trials begin soon thereafter. Once pre-clinical trials indicate satisfactory evidence of safety and efficacy, an IND is filed.\(^{141}\) Since a corresponding patent application is filed roughly when pre-clinical trials begin, the time between the filing of a patent application and the filing of an IND is a good proxy for the pre-clinical trials phase. This is helpful information, as data on the length of pre-clinical trials is not readily available.

\(^{140}\) See infra Figure 16; Grabowski & Vernon, supra note 2, at 112 (finding that the average patent prosecution time was 3.8 years and running a simulation suggesting that Hatch-Waxman will have a net negative effect on EPTWR).

\(^{141}\) See PATENT-TERM EXTENSION AND THE PHARMACEUTICAL INDUSTRY, supra note Error! Bookmark not defined., at 13, fig.1.
Figure 9. Average and Median Proxy for Pre-Clinical Trials Phase

Figure 9 shows the average and median time between the filing of a patent and the filing of a related IND, a time period that serves as a proxy for the product’s pre-clinical trials phase. Figure 9 suggests that the pre-clinical trials phase has been increasing. The average and median times have increased from 0.4 years and 2.1 years from 1970 to 1973, respectively, to 8.9 years and 9.6 years from 2002 to 2008, respectively. Even if the approximately nine-year gap between patent filing and IND filing in the most recent data period is an aberration, there is a clear trend upwards.

An increasing pre-clinical trials phase has a direct impact on EPTWR, particularly for post-GATT patents with a patent term of twenty years from the filing date. For these patents, the clock on EPT begins ticking away as soon as the patent is filed. Thus, a nine-year pre-clinical trials phase (as seen above for INDs filed from 2002 to 2008) results in an EPT of eleven years

142. But see Morris, supra note 2, at 252–53 (suggesting that improved screening methods are decreasing the pre-clinical trials phase).
before the Regulatory Review Period has even begun. Add on a six-year Regulatory Review Period (the average for INDs filed from 1998 to 2000\textsuperscript{143}) and the result is an EPT of five years, likely resulting in an EPTWR of $\sim$8.5 years (assuming a five-year Testing Phase and one-year Approval Phase). \textsuperscript{144} Patents with a term of seventeen years from the issuance date face a similar outcome.

So as the length of the pre-clinical trials phase continues to rise, EPTWR will continue to fall. Indeed, the decline in median EPTWR from 1986 to 2008 seen in Figure 3 is most likely a direct result of the growing length of time between patent filing and IND filing. Thus, the implementation of GATT and the increase in the duration of pre-clinical trials has decreased EPTWR.

3. An Anomaly in the Analysis: The Rise of Improvement Patents

There is one glaring and potentially game-changing departure from the general trend toward decreasing EPTWR that is exemplified by the following statistic: post-GATT patents in the dataset have an average and median EPTWR of 13.8 and 14 years, respectively. Thus, although post-GATT patents are receiving less EPTWR than they would have under the pre-GATT or GATT transition rules, post-GATT patents still receive much more EPTWR than Figures 2 and 3 suggest. Astonishingly, the average and median time from the filing of a patent application to the filing of an IND application—the proxy for the pre-clinical trials phase—is a mere two years for post-GATT patents.\textsuperscript{145} This is only a fraction of the approximately nine-year proxy seen in Figure 9 from 2002 to 2008, or even the five to six years from 1994 to 2001. Other critical values, such as the length of patent prosecution and the Regulatory Review Period, hew to the trends seen in Figures 5–7.

The most likely reason for the abrupt decline in the proxy for clinical trials, and the corresponding increase in EPTWR, is the increasingly aggressive use of “improvement” patents, or “evergreening,” by brand names. Evergreening is a pejorative term used to describe the practice by which brand names obtain additional patents to protect modified versions of their original pharmaceutical products.\textsuperscript{146} Thus, when an original product

\textsuperscript{143}. See supra Figure 7.
\textsuperscript{144}. See supra Figures 5–7.
\textsuperscript{145}. This change for post-GATT patents does not show up in Figures 2, 3, or 9 because even the 2002–2008 IND filing data contains mostly GATT transition data patents, which cloaks the change.
\textsuperscript{146}. See Lemley & Moore, supra note 135, at 81–83. This more modern form of evergreening should not be confused with the practice of gaining multiple 30-month stays through the late listing of patents in the Orange Book. See Kelly, supra note 33, at 428–29.
goes off-patent, any generic version must compete with a new and improved version of the product.\textsuperscript{147} Furthermore, in some instances the FDA determines that only the modified version of the product can be sold, and no generic is allowed to enter the market.\textsuperscript{148}

The brand name product OxyContin, a powerful painkiller, provides a recent example of evergreening at work. The active ingredient in OxyContin releases gradually when used as intended, but some users had begun crushing OxyContin pills and snorting or injecting the powder to receive an immediate, powerful hit.\textsuperscript{149} This practice led to overdoses on OxyContin, and, in rare cases, death.\textsuperscript{150} Shortly before OxyContin’s patent term ended, its patent holder released an improved version that is less susceptible to this kind of abuse.\textsuperscript{151} On the day the original OxyContin patent was set to expire, the FDA announced that to reduce the epidemic of prescription drug abuse, it would not approve a generic version of OxyContin.\textsuperscript{152} The FDA determined that the benefits of the original OxyContin formulation outweighed its risks, and that it could not be sold.\textsuperscript{153} Because no generic version can enter the market under the old formulation and the new formulation is still covered by a patent, the brand name has effectively extended its exclusivity over the active chemical in OxyContin.\textsuperscript{154}

Brand names defend this practice as sanctioned by the patent system and beneficial to customers, arguing that updated products have enhanced utility or safety.\textsuperscript{155} Generics argue that the timing of these new formulations is no coincidence and that evergreening is driving up healthcare costs.\textsuperscript{156} For better or worse, the dataset suggests that since GATT went into effect, brand

\begin{footnotesize}
\begin{itemize}
\item This form of evergreening has been eliminated through amendments to Hatch-Waxman. \textit{Id.} at 445.
\item See Lemley & Moore, \textit{supra} note 135, at 81–83.
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.}
\item See Moody, \textit{supra} note 148 (discussing how brand names are able to extend their monopoly by using improvement patents and using OxyContin as an example of the practice).
\end{itemize}
\end{footnotesize}
names have increasingly applied patent-term restoration to improvement patents.

In addition to the very short two-year proxy for pre-clinical trials for post-GATT patents, a large increase in the Pre–Patent Issuance Phase supports the notion that brand names are increasingly relying on improvement patents. As shown in the Figure 1 timeline, patent filing generally takes place soon after a new product is discovered, and pre-clinical trials precede the filing of an IND. Because pre-clinical trials can last several years, new products are likely to have a small or non-existent Pre–Patent Issuance Phase. Improvement products, however, are generally discovered well after discovery of the new product, and so the corresponding patent application will be filed closer to, if not after, the filing of the IND for the original product. Thus, as patent-term restoration is increasingly applied to improvement patents, the Pre–Patent Issuance Phase will rise.

Figure 10 shows the average Pre–Patent Issuance Phase for five-year groupings of patent filing dates. As shown, the Pre–Patent Issuance Phase has nearly doubled for post-GATT patents. For patents filed from 1965 to 1995 (pre-GATT and GATT transition patents), the average Pre–Patent Issuance Phase hovered between 0.85 years and 1.3 years. Yet for patents filed from 1996 to 2002 (post-GATT patents), the Pre–Patent Issuance Phase shot up to 2.2 years. Such a sudden increase strongly suggests increased reliance by brand names on improvement patents. Indeed, Figure 10 suggests that the reliance on improvement patents began after Hatch-Waxman’s enactment in 1984 and skyrocketed for post-GATT patents.

157. The first grouping is ten years and the last grouping is seven years. The patents are grouped to capture all of the data points, of which there are fewer at both ends.

158. Additionally, the length of patent prosecution has remained relatively stable over the years. See infra Figure 16. Thus, the increase in PPIP is not due to delays in obtaining a patent.

159. See Morris, supra note 2, at 273–74 (discussing how Hatch-Waxman most likely caused an increase in improvement patents). Also note that the pre-Hatch-Waxman decline in Pre-Patent Issuance Phase is consistent with an increasing pre-clinical trials phase.
Improvement patents carry risks as well as rewards. Improvement patents are more likely to be invalidated, as they may be found obvious in light of the original product, and they are more likely to be found not infringed, as they tend to be narrower, making it easier for generics to design around the patent. Also, absent FDA intervention, improvement patents do not prevent generic versions of the brand name product from coming to market and competing with the improved product.

Ultimately, the success or failure of improvement patents over the next decade will determine whether GATT and an increasing pre-clinical trials phase will lead to the decline in EPTWR shown in Figures 2 and 3 or whether the drastic resurgence in EPTWR through reliance on improvement patents is the new normal.

160. Morris, supra note 2, at 273–74 (discussing the risks associated with sequential patents, such as frequent challenges to validity under Hatch-Waxman).
161. Id.
162. See supra notes 146–156 and accompanying text.
D. **BIASES AND UNPREDICTABILITY UNDER HATCH-WAXMAN**

Regardless of whether EPTWR is declining or rising, brand names will continue to be subjected to the unpredictable Hatch-Waxman patent-term restoration system. Figures 2 and 3 showed the disparate treatment of products and patents across time. The minimum and maximum rows of Tables 2 and 3 show just how extreme the variations can be. Below, the data is broken down by EPTWR and product type to reveal additional arbitrariness and biases. The accuracy of the USPTO’s Certificates of Extension is also examined.

1. **Variance in EPTWR from Patent to Patent**

   **Figure 11. Effective Patent Term With Restoration, Grouped in Two-Year Increments**

   As shown in Figure 11, over a third of restored patents received an EPTWR of fourteen years, the maximum allowed under Hatch-Waxman; ~25% of restored patents received less than ten years of EPTWR; and just a
single restored patent obtained an EPTWR of less than two years.\footnote{New Chemical Entities (“NCEs”) are given five years of data exclusivity regardless of any patent protection, so in practice, no product receives less than five years on the market before a generic’s entry. Small Business Assistance, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069962.htm (last updated July 1, 2010). A brand name only receives four years of data exclusivity if the generic asserts that the patent is invalid or not infringed. \textit{Id.}} This data supports the conclusion that the majority of brand names receive a substantial period of patent protection (~75% of restored patents have at least ten years of EPTWR). Even so, real harms result from the lack of uniformity.

For the $1 Billion Product, the difference between a fourteen-year EPTWR and a ten-year EPTWR is $2 billion in revenue.\footnote{See Morris, supra note 2, at 254 (discussing the recent increase in FDA approval times and the rise in drug development costs).} Brand names cannot know ex ante what EPTWR a given patent will have, and they may not know for fifteen years or more after a patent application is filed.\footnote{See supra Table 1.} As a result, brand names must hope for the best but plan for the worst. Uncertainty about revenue streams from a particular product is very high until FDA approval is granted, and it persists through the granting of a Certificate of Extension, through any litigation, and until the patent term finally expires. This financial insecurity can result in widespread underinvestment and higher product prices to compensate for the risk.

While some of these risk factors are unrelated to Hatch-Waxman, the variance in EPTWR from product to product is a direct result of its provisions. Thus, rather than being a stabilizing force, Hatch-Waxman’s patent-term restoration provisions largely perpetuate the financial uncertainty resulting from an unpredictable patent term that existed prior to Hatch-Waxman.
2. Variance in EPTWR Based on Product Type

Table 5. Average Effective Patent Term With and Without Restoration Based on Product Type

<table>
<thead>
<tr>
<th>Type of Product</th>
<th>Average Effective Patent Term (EPT)</th>
<th>Average Patent Term Restored (PTR)</th>
<th>Average Effective Patent Term With Restoration (EPTWR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Additive</td>
<td>6.0 years</td>
<td>2.8 years</td>
<td>8.8 years</td>
</tr>
<tr>
<td>Animal Drug</td>
<td>7.3 years</td>
<td>3.0 years</td>
<td>10.3 years</td>
</tr>
<tr>
<td>Medical Device</td>
<td>8.7 years</td>
<td>2.4 years</td>
<td>11.2 years</td>
</tr>
<tr>
<td>Human Drug</td>
<td>8.9 years</td>
<td>2.7 years</td>
<td>11.6 years</td>
</tr>
<tr>
<td>Biologic</td>
<td>10.0 years</td>
<td>2.8 years</td>
<td>12.8 years</td>
</tr>
</tbody>
</table>

As shown in Table 5, there is significant disparity of treatment based on the type of product. Biologics receive by far the most protection, with an average EPTWR of 12.8 years, four years more than food additives receive (8.8 years). This is an enormous difference, representing an average of $2 billion more revenue for developing a biologic rather than a food additive (assuming they are both $1 Billion Products). Animal drugs, medical devices, and human drugs are in the middle, with average EPTWRs of 10.3 years, 11.2 years, and 11.6 years, respectively.

This disparity in patent protection incentivizes certain products over others. For example: brand names can expect to earn significant additional revenue for developing a biologic instead of a medical device because the average EPTWR is 1.6 years longer for biologics than for medical devices. This principle holds for human drugs compared with animal drugs, and so on.

There are many market and regulatory factors that contribute to a brand names’ decision to pursue one type of product over another, including expertise, resources, research goals, market size, and profits margins. But expected differences in EPTWR based on product type, and the corresponding expected additional revenues, remain a powerful incentive. Moreover, the market distortion occurs regardless of whether or not brand names intentionally favor certain product types over others. Developers of biologics will, all other things being equal, reap more profits through the longer EPTWR than developers of medical devices, leading to more resources for biologics research than for medical devices. Thus, whether the facts of Figure 12 directly skew innovation through intentional research...
choices, or the windfall to certain products indirectly skews innovation by funneling enhanced profits back into research, the result is the same: Hatch-Waxman’s failure to standardize EPTWR distorts pharmaceutical research.

All in all, there is significant room to reduce the unpredictability and biases of Hatch-Waxman patent-term restoration. Table 5 breaks down EPTWR by product type, but undoubtedly, the dataset could be filtered in various other ways, such as type of disease, which would reveal additional distortions.\(^\text{166}\) EPTWR, which strongly correlates with profitability, should not vary so significantly from one patent to the next, over time, and based on product type.

3. **Inaccurate Grant of Patent-Term Restoration by the USPTO**

The USPTO’s Certificates of Extension were audited for accuracy, and as mentioned at the very start of this Article, one-sixth of them incorrectly state the amount of patent-term restoration that the applicant is legally entitled to. To be precise, the Certificates of Extension for 104 out of 613 patents, or 17\%, are incorrect. Indeed, eight of the patents in the dataset are not entitled to any patent-term restoration.

The causes of error are an ambiguity in the law,\(^\text{167}\) simple miscalculation,\(^\text{168}\) and GATT.\(^\text{169}\) The ambiguity in the law revolves around the calculation of the Patent Term Eligible for Restoration (“PTER”). The provision for computing PTER can be interpreted either to add one-half of the adjusted Testing Phase to the adjusted Approval Phase (“PTER Equation 1”) or to subtract various periods of time from the Regulatory Review Period (“PTER Equation 2”).\(^\text{170}\)

**PTER Equation 1:**
\[
PTER = \frac{1}{2} (TP - PPI_{TP} - DD_{TP}) + (AP - PPI_{AP} - DD_{AP})
\]

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166. *Accord* Grabowski & Vernon, *supra* note 2, at 108 (“[C]ertain types of drug therapies have significantly shorter expected development times than others (e.g., anti-infectives versus psychotherapeutics).”).
167. *See* 35 U.S.C. § 156(c) (2012) (“[A]fter any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the [Testing Phase] . . . .”).
171. *See id.*
PTER Equation 2:
PTER = RRP – PPIP – DD – ½ TP – PPIPTP – DDTP

This Article uses PTER Equation 1 because it is more elegant than PTER Equation 2. Mathematically, the two are equivalent. However, incongruity can arise when switching between the two equations.

Around four years ago, the USPTO switched from Equation 1 to Equation 2. When it did so, the USPTO changed the way it rounded half-days. The USPTO used to round half-days down, such that, e.g., 512.5 days of PTER became 512 days. Now the USPTO rounds up, such that, e.g., 512.5 days of PTER becomes 513 days. Both methods cannot be correct under Hatch-Waxman.

This Article follows the USPTO’s current practice of rounding half-days up. This approach is both more consistent with the statute and the norms of rounding. As a result, this Article’s audit concluded that every patent in the dataset whose PTER was calculated using Equation 1, whose adjusted Testing Phase was an odd number of days, and whose PTER was not limited by any of the caps or the fourteen-year limit, has an incorrect PTR on its Certificate of Extension.

Another reason for the inaccurate PTRs is simple miscalculation. Whether it is through typos when entering the relevant dates, miscalculation of days when subtracting one date from another, or misapplication of the relevant equations, Certificates of Extension contain human error. For example, the calculation of PTR for U.S. Patent No. 7,037,917 in its Notice of Final Determination contains the correct Testing Phase (2050 days), the correct Pre–Patent Issuance Phase (1608 days), and the correct Approval Phase (185 days), but computes a PTR of 404 days instead of 406.

Ironically, the owner of this patent recently petitioned the USPTO to extend the expiration date listed on the patent’s Certificate of Extension by four

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172. See id.
173. This is true because RRP = TP + AP.
175. 35 U.S.C. § 156(c) (2012).
176. NOTICE OF FINAL DETERMINATION, U.S. Patent No. 7,037,917, supra note 168. The correct calculation: PTER = ½ (2050 – 1608) + 185 = ½ (442) + 185 = 221 + 185 = 406 days.
days to account for patent term adjustment that the USPTO had overlooked.\footnote{Id.} But, neither the USPTO nor the applicant appear to have noticed that the PTR is off by two days, which would further increase the patent’s expiration date.\footnote{Id.} Given the strength of the sales of the product covered by this patent,\footnote{2010 Annual Report: Pharmaceuticals, JOHNSON & JOHNSON, http://www.investor.jnj.com/2010annualreport/chairman/pharmaceuticals.html (last visited May 15, 2014) ("PREZISTA® (darunavir) and INTELENCE® (etravirine) grew sales . . . achieving together more than $1 billion in sales . . .").} these two days of lost PTR could mean millions of dollars in lost revenue.

Errors in PTR due to inconsistent rounding and human error generally result in a loss (or gain) of only a day or two. But applying the $1 Billion Product example, every day of PTR is worth $1.4 million. The absolute sum of these errors is thus potentially tens of millions of dollars.

The final source of error in the calculation of PTR is the usual culprit, GATT. The USPTO issued a number of the Certificates of Extension for GATT transition patents prior to the implementation of GATT.\footnote{See, e.g., NOTICE OF FINAL DETERMINATION, Patent No. 4,868,908, supra note 169.} For these patents, applicants were granted PTR under the assumption that the patent term was seventeen years from the date of issuance, in accordance with the law at the time.\footnote{GATT, supra note 11; see also GATT Uruguay Round Patent Law Changes, supra note 130.} After GATT went into effect, of course, a number of these patents received the longer patent term of twenty years from the date of filing.\footnote{Id.} Thus, these patents have incorrect Certificates of Extension because the rules changed after the certificates issued. Indeed, eight of the patents in the dataset are no longer eligible for patent-term restoration, as their EPT exceeds the fourteen-year limit.\footnote{See, e.g., NOTICE OF FINAL DETERMINATION, U.S. Patent No. 4,868,908, supra note 169.}

Every bureaucracy makes errors from time to time, but one in six is unacceptable. Fortunately, unlike many of the other problems resulting from Hatch-Waxman, this one has an easy fix. The USPTO should conduct an internal audit of its Certificates of Extension and issue corrections. It should also make a final declaration as to whether half-days are rounded up or down, and provide an online calculator so that applicants can double-check their grants of PTR.

\footnote{177. Id.} \footnote{178. Id.} \footnote{179. 2010 Annual Report: Pharmaceuticals, JOHNSON & JOHNSON, http://www.investor.jnj.com/2010annualreport/chairman/pharmaceuticals.html (last visited May 15, 2014) ("PREZISTA® (darunavir) and INTELENCE® (etravirine) grew sales . . . achieving together more than $1 billion in sales . . .").} \footnote{180. See, e.g., NOTICE OF FINAL DETERMINATION, Patent No. 4,868,908, supra note 169.} \footnote{181. GATT, supra note 11; see also GATT Uruguay Round Patent Law Changes, supra note 130.} \footnote{182. Id.} \footnote{183. See, e.g., NOTICE OF FINAL DETERMINATION, U.S. Patent No. 4,868,908, supra note 169.}
IV. ECONOMIC ANALYSIS OF HATCH-WAXMAN PATENT-TERM RESTORATION

To better understand Hatch-Waxman patent-term restoration, this Part identifies the statute’s constituent provisions and analyzes each of them in the context of the law’s legislative history. Specifically, (a) the five-year cap, (b) the fourteen-year limit, (c) the combination of the five-year cap and the fourteen-year limit, (d) the provision that limits PTR to at most half of the Testing Phase, (e) the Due Diligence provision, and (f) the Pre-Patent Issuance Phase are each assessed.

The purpose of this analysis is to demonstrate how these provisions, individually and collectively, affect brand names’ incentives. This Part argues that as brand names responded to the Hatch-Waxman framework, such as by strategically altering their behavior to maximize EPTWR, the incentives for innovation became skewed in undesirable ways. Furthermore, the implementation of GATT, which was not anticipated when Hatch-Waxman was enacted, has significantly altered how the constituent parts of Hatch-Waxman affect EPTWR. Thus, this Article argues that GATT has further changed the incentives of brand names to the detriment of pharmaceutical innovation.

At a broader level, this inquiry reveals that Congress too often modified one part of the legislation without considering how other parts were affected, fundamentally misunderstood the incentives of brand names, and by demanding more and more concessions from brand names to garner legislative support, created contradictory provisions. Interestingly, while the implementation of GATT fixed a major loophole in Hatch-Waxman, it otherwise aggravated the mistakes and faulty assumptions of Hatch-Waxman.

184. Hatch-Waxman has very limited legislative history. See Allan M. Fox and Alan R. Bennett, The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984, at v (1987) (“[T]here is almost none of the usual legislative history to this bill. There are no Senate reports, for example, and floor statements were extremely limited and dealt with only a small number of technical points. To really understand the intent of this legislation, one almost had to be there as it was negotiated.”); Kelly, infra note 33, at 421. As a result, this Section relies largely on the personal accounts of individuals involved in drafting and negotiating the legislation.

185. Two-year and three-year caps are not analyzed because they were temporary measures which only affected pipeline products, thus the ability of brand names to respond to the changed incentives was limited.
A. **The Five-Year Cap**

The road to Hatch-Waxman was long and winding.186 The first patent-term restoration legislation to be voted on, the Patent Term Restoration Act of 1982, did not include complementary legislation to promote generic entry;187 it was focused solely on restoring patent term.188 It was also relatively simple.189 The Patent Term Restoration Act of 1982 allowed brand names to receive up to seven years of patent-term restoration, but capped total patent life at twenty-seven years from the date of filing anywhere in the world.190 The underlying assumptions were that seven years would fully compensate most brand names for their loss of patent term and that a total patent life of more than twenty-seven years from the filing date would be due to the brand names’ own delays, and therefore not justified.191

The bill passed the Senate, but due to arcane rules, a two-thirds vote of approval was required in the House of Representatives.192 Facing inclement weather, several representatives who supported the legislation could not fly into the Capitol to cast their vote.193 The bill failed by five votes.194

Following the failure of the Patent Term Restoration Act of 1982, pro-generic provisions became a necessary part of any patent-term restoration legislation.195 The generic industry and other public interest groups that sought faster access to more affordable treatments applied significant pressure on Congress.196 In addition to inserting legislation creating ANDAs, pro-generic legislators had the seven-year maximum patent-term restoration cut to five years, resulting in the five-year cap.197

Figure 12 shows the theoretical effect of only a five-year cap.198 A five-year cap fully restores the first five years of lost patent term, but provides no

186. See Lourie, supra note 26, at 527 (“One thing is certain, however, and that is that all those who were involved in the lengthy legislative battle are surely pleased to have it behind them.”).
187. Id. at 533.
188. Id. at 527.
189. See id. at 528 (“The bill emphasized administrative simplicity . . . .”)
190. Id. at 530.
191. Id.
192. Id. at 532.
193. Id.
194. Id.
195. Id. at 533.
196. See id. at 533–34 (discussing the political back and forth that occurred on the road to Hatch-Waxman).
197. Id. at 534, 548.
198. Figures 12–14 assume a seventeen-year patent term and that the patent issued right as an IND was filed, such that each year of the Regulatory Review Period translates into a
additional restoration thereafter. Thus, a patent subject to only a five-year cap would receive a full seventeen-year EPTWR if anywhere from zero to five years were lost while the patentee sought FDA approval for the corresponding product, but every day of lost patent term over five years would result in a lost day of EPTWR. Given that the median patent term lost is 7.6 years, corresponding to an EPTWR of 14.4 years, a five-year cap would handily restore most of the lost patent term for most Hatch-Waxman patents.

Figure 12. Theoretical Effective Patent Term With Restoration (EPTWR) Using a Five-Year Cap

lost year of patent term. Though patents now have a twenty-year from filing patent term and patent issuance does not always correspond with the filing of an IND, the conclusions of these analyses remain valid. For example, if the corresponding patent issued two years prior to the filing of an IND, then the curve in Figure 13 would shift downwards, as 100% of the patent term could never be restored (only the patent term lost after the IND was filed would be restored). Conversely, if the corresponding patent issued two years after an IND was filed, then the curve would be unchanged. For patents with twenty-year terms, the x-axis would range from zero to twenty years, but the shape of the curve would remain the same. Either way, as the analysis below explains, a five-year cap discourages investing in products with longer Regulatory Review Periods.

199. See supra Table 1.
There is, however, one major disadvantage to the five-year cap: it is prejudicial to products that take longer than the median to receive FDA approval, either because of a longer pre-clinical trials phase or a longer Regulatory Review Period.\(^{200}\) Compare two drugs, Drug A and Drug B. Drug A is a pain medication used to treat headaches; Drug B is used to slow the onset of Alzheimer’s and other neurodegenerative ailments.\(^{201}\) The safety of Drugs A and B can be tested through standard human clinical trials, and both are quickly proven. The efficacy of Drug A can also be quickly tested, as the headaches are either treated or they are not.

The efficacy of Drug B, however, will necessarily take many years to be proven. Its effect is meant to be marginal, as it prevents and slows the onset of Alzheimer’s but does not cure it. Early symptoms of Alzheimer’s can begin years before the symptoms are severe enough to warrant the Alzheimer’s diagnosis, and Alzheimer’s progresses over the course of a decade or longer.\(^{202}\) Proving the efficacy of such a drug can take a decade or more.

The ensuing lengthy clinical trials period (the Testing Phase) for Drug B is due to the nature of the treatment and the disease. It is not the fault of the brand name. Yet, under a five-year cap, the developer of Drug B receives significantly less patent protection, in the form of a shorter EPTWR, than the developer of Drug A. All other things being equal, this results in significantly less revenue for the developer of Drug B, which may result in less research and development for diseases such as Alzheimer’s. Extrapolating more generally, a five-year cap has the unintended consequence of disfavoring research into any treatment that takes longer to receive FDA approval.

A longer pre-clinical trials period or Regulatory Review Period can sometimes be determined ex ante, but even when it is not, brand names are constantly reassessing the value of bringing a product to market. As a result brand names consistently devalue products that take longer to receive FDA approval.\(^{203}\) Therefore, while a patent-term restoration system that contains only a five-year cap is effective at restoring most of the lost patent term for

\(^{200}\) See Grabowski & Vernon, supra note 2, at 108 (“[C]ertain types of drug therapies have significantly shorter expected development times than others (e.g., anti-infectives versus psychotherapeutics).”).

\(^{201}\) Credit goes to my Professor at the time, Hans Sauer, for suggesting this example.


\(^{203}\) Lourie, supra note 26, at 531.
most pharmaceutical products, it causes severe market distortions for treatments that require more extensive testing to receive FDA approval.

B. **THE FOURTEEN-YEAR LIMIT**

In addition to the five-year cap, pro-generic legislators extracted a further concession from pharmaceuticals: a fourteen-year period of maximum patent protection (EPTWR), known as the fourteen-year limit. Figure 13 presents a theoretical analysis of the fourteen-year limit in isolation so that its combination with the five-year cap can be better understood. Similar to the analysis of the five-year cap, this analysis assumes that the only limitation on patent-term restoration is the fourteen-year limit. That is, all of the patent term lost during the FDA approval period is restored, so long as the EPTWR does not exceed fourteen years.

*Figure 13. Theoretical Effective Patent Term With Restoration (EPTWR) Using a Fourteen-Year Limit*

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204. *Id.* at 534.
Without any caps limiting how much PTR can be granted, the fourteen-year limit effectively acts as a floor on EPTWR. Patents with less than fourteen years of EPT are granted the necessary PTR to ensure fourteen years of EPTWR. The result is the curve shown in Figure 13, where EPTWR declines from seventeen years to fourteen years and then holds. A fourteen-year limit in isolation would reflect congressional wisdom that, due to the importance of promoting pharmaceutical innovation, products requiring FDA approval should receive at least fourteen years of meaningful patent protection. A fourteen-year limit would thus provide tremendous stability, but grant little to no patent-term restoration for products that quickly receive FDA approval.

C. COMBINING THE FIVE-YEAR CAP AND THE FOURTEEN-YEAR LIMIT

Of course, Congress incorporated both the five-year cap and the fourteen-year limit into Hatch-Waxman. The result: both of their weaknesses, but neither of their strengths.

Figure 14. Theoretical Effective Patent Term With Restoration (EPTWR) Using Both a Five-Year Cap and a Fourteen-Year Limit

205. 35 U.S.C. § 156(c), (g) (2012).
As shown in Figure 14, when the five-year cap and the fourteen-year limit are both applied, EPTWR tracks the fourteen-year limit for the first eight years of lost patent term and follows the five-year cap for the remaining lost years of patent term. The fourteen-year limit operates as a ceiling and not a floor because the five-year cap prevents patents with long Regulatory Review Periods from receiving fourteen years of EPTWR. This means that products that quickly receive FDA approval get little to no patent-term restoration, while products that are slow to receive FDA approval receive less and less restoration. This outcome is clearly shown in Figure 15 and described below.

Figure 15 shows the theoretical effect of the five-year cap and the fourteen-year limit, separately and combined, on the percent of lost patent term that is restored. In isolation, the five-year cap restores 100% of the lost patent term for products that receive FDA approval within five years of patent issuance. The percent restored then gradually declines to ~30% if the entire seventeen-year patent term is lost. The median lost patent term for the dataset of 7.6 years corresponds to just under two-thirds of the lost patent term being restored. So as stated above, a five-year cap handily restores more than half of the lost patent term to most patents.
Looking at the effect of the fourteen-year limit, 0% of the lost patent term is restored for patents that lose three years of patent term or less while seeking FDA approval. For patents that lose more than three years of patent term, the fourteen-year limit acts as a floor. The result is an increasing percent of lost patent term restored, peaking at 82% for patents that lose the full seventeen-year term before receiving FDA approval.

Figure 15 also shows that the inclusion of both the five-year cap and the fourteen-year limit neither restores most of the patent term lost for most patents nor provides stability for products that take longer than average to receive FDA approval. The percent restored increases once three years of patent term have been lost, but then decreases once eight years of patent term have been lost. Indeed, only patents that lost between six years and ten years of their patent term receive more than half of the lost patent term back
through restoration.\textsuperscript{206} Effectively, the combination of the five-year cap and the fourteen-year limit grants little to no protection for products that take a relatively short or relatively long time to receive FDA approval.

Figure 15 thus shows how, when combined, the five-year cap and fourteen-year limit work against one another. From this basic contradiction flows Hatch-Waxman’s most glaring failures: (1) only an arbitrary subset of Hatch-Waxman patents have a substantial portion of the lost patent term restored; (2) by not restoring more than five years of lost patent term, products with longer pre-clinical or clinical trials are strongly disfavored; and (3) without a floor on EPTWR, the system is unpredictable.

D. **RESTORING UP TO HALF OF THE TESTING PHASE**

It is somewhat unclear why only half of the Testing Phase is eligible for patent restoration.\textsuperscript{207} The failed Patent Term Restoration Act of 1982 would have restored only half of any regulatory review occurring after ten years from the corresponding patent application’s filing date.\textsuperscript{208} This reflected Congress’s view that a delay of longer than ten years was the brand names’ fault or intent, and so should be discouraged.\textsuperscript{209}

However, only allowing patent-term restoration for half of the Testing Phase does not logically follow from these concerns. As discussed above, a long Regulatory Review Period may be due to the nature of the disease or the treatment, not the innovator’s intransigence.\textsuperscript{210} And even without Hatch-Waxman, brand names have strong incentives to quickly gain FDA approval.\textsuperscript{211}

While the intended purpose may be foggy, the result of restoring at most half of the Testing Phase is clear: patents with longer Testing Phases receive less EPTWR. Thus, only restoring up to half the Testing Phase further discourages brand names from investing in products that require a longer Testing Phase. Furthermore, an unintended consequence of so strongly discouraging delay is the incentivization of cutting corners to receive FDA approval quickly.\textsuperscript{212} Instead of taking the time to conclusively prove safety

\textsuperscript{206} Of course, when provisions such as restoring at most half of the Testing Phase are added, the percent of lost patent term restored drops substantially. As shown in Table 1, the median value for the dataset is 33.9%.

\textsuperscript{207} 35 U.S.C. § 156(c)(2) (2012).

\textsuperscript{208} Lourie, supra note 26, at 530–31.

\textsuperscript{209} Id. at 530.

\textsuperscript{210} See supra Section IV.A.

\textsuperscript{211} See infra Section IV.E.

\textsuperscript{212} See, e.g., Gardiner Harris, In FDA Files, Claims of Rush to Approve Medical Devices, N.Y. TIMES (Jan. 12, 2009), http://www.nytimes.com/2009/01/13/health/policy/13fda.html;
and efficacy and fully understand how various subsets of the population respond to their product, brand names are in a race against time to gain FDA approval.

A recent example is zolpidem, the active ingredient in the widely-used sleeping medication Ambien. The FDA recently announced label changes to products containing zolpidem, as it has been discovered that the currently prescribed dosages are too high, often lingering in people’s bodies the next day and impairing motor skills, most notably driving abilities. The risk is particularly acute for women, who generally do not process the drug as quickly as men. In obtaining FDA approval, zolpidem had a longer Approval Phase (3.9 years) than Testing Phase (3.6 years), which is fairly rare. It is reasonable to assume that more thorough testing would have led to a more appropriate dosage for both men and women prior to FDA approval. It is also reasonable to assume that the owner of zolpidem wanted to obtain FDA approval as quickly as possible to maximize EPTWR. As this example demonstrates, Hatch-Waxman greatly exacerbates the tension between the health of the public and the financial incentives of brand names.

This dangerous incentive to obtain FDA approval as expeditiously as possible has also led to clearly illicit activities. Obtaining the required number of patients that meet the strict criteria for clinical trials is one of the primary reasons for delays during the Testing Phase. In at least one case, clinical researchers falsified patient data and exclusion criteria to obtain the necessary number of patients more quickly. Additionally, well-heeled brand names have been caught using political connections to pressure the FDA to approve their products, despite lingering concerns about safety and efficacy.


214. Gardner, supra note 212.


216. Milfred, supra note 212.
E. DUE DILIGENCE

The due diligence provision was inserted into Hatch-Waxman to ensure that brand names do not delay in seeking FDA approval for their products. It mandates that any period during which an applicant did not act with due diligence is not eligible for restoration. "Due diligence" is defined as "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period."  

Hatch-Waxman has detailed procedures for safeguarding against non-diligence. After a brand name submits an application for patent-term restoration to the USPTO, the USPTO alerts the FDA. The FDA then determines the Regulatory Review Period of the product claimed by the patent and publishes it in the Federal Register. Third parties who wish to challenge that a brand name acted with due diligence may file a petition within six months of the publication to either the Secretary of Health and Human Services or the Secretary of Agriculture, depending on the type of product. The challenging party must set forth facts from "which it may be reasonably determined that the applicant did not act with due diligence . . . ." The appropriate Secretary will then determine whether the applicant acted with due diligence, and adjust the Regulatory Review Period accordingly.

219. Id. § 156(d)(3).
220. See, e.g., id. § 156(c), (d).
221. Id. § 156(d).
222. Id. § 156(d)(2)(A).
223. Id. § 156(d)(2)(B)(i).
224. Id.
225. Id. § 156(d).
Since Hatch-Waxman’s enactment in 1984, three due-diligence petitions have been filed.226 Of these three petitions, two attempted to shoehorn other alleged deficiencies of the application into a due diligence challenge, rather than alleging actual non-diligence.227 In both cases, the Secretary declined to take the bait.228

The third petition truly alleged a lack of due diligence, and the applicant vigorously contested the allegations.229 Rather than resolve the dispute directly, the Secretary made a determination that even if the petition’s allegations were taken as true, the alleged period of non-diligence was not long enough that it would have an effect on the amount of patent-term restoration granted to the applicant.230 That is, the applicant hit the five-year cap on PTR regardless of whether they acted with due diligence during the disputed period.231 No determination on due diligence was made then.232 Indeed, no determination on due diligence has ever been made.

Interestingly, to date there has been one instance when a lack of due diligence impacted patent-term restoration.233 An applicant stated in their application for patent-term restoration that they had failed to act with due diligence for a period of 935 days.234 The USPTO accepted the applicant’s statement and deducted this period when calculating patent-term restoration.235 This resulted in a loss of 467 days of patent term that would otherwise have been restored.236 Thus, the only successful instance of a showing of a lack of due diligence has been through voluntary applicant admission.

The due diligence provisions of Hatch-Waxman were added to address the concern that innovators would drag their heels during the Regulatory Review Period in order to gain an advantage.237 Such fears are completely unfounded.

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227. *Id.* at 129–30, 134–35.

228. *Id.*

229. *Id.* at 130–34.

230. *See id.* at 134.

231. *Id.*

232. *Id.*


234. *See id.*

235. *See id.*

236. *See id.*

First, other provisions of Hatch-Waxman provide a strong incentive to act with diligence. Due to the basic structure of the law, there is no way to increase the EPTWR by prolonging the Regulatory Review Period. Due diligence only affects the portion of the Regulatory Review Period that occurs after the patent has issued, so the patent term clock is already ticking away. That is, every day of non-diligence results in a lost day of EPT. And since only half of the Testing Phase is eligible for restoration, every day of non-diligence during the Testing Phase results in the loss of half a day of EPTWR. Brand names cannot game Hatch-Waxman by prolonging the Testing Phase.

Even if the lack of diligence occurs during the Approval Phase, when all the days are eligible for restoration, the brand name still has nothing to gain; at best, the brand name gets the lost day of EPT back through patent-term restoration. And because the longer the Regulatory Review Period is, the more likely it is that the five-year cap will be reached, every additional day of non-diligence increases the likelihood that the lost day of EPT will not be compensated by an increase in PTR. Thus, a brand name can never increase their EPTWR through non-diligence.

Nor are there any strategic advantages to be had. Every day of non-diligence is a day that the product is not on the market. Most blockbuster drugs are profitable because they are first-in-kind or best-in-kind. The industry incentive is to get the product out quickly so that it can be the first or the best for as long as possible. Delay could mean increased competition or obsolescence.

Finally, the attorney filing the application for patent-term restoration must certify that everything in the application is accurate. Therefore,

238. 35 U.S.C. § 156(c) (2012); see Gaudry, supra note 226, at 135–36 (describing how the provisions of 35 U.S.C. § 156 provide applicants with “an incentive to proceed diligently through [FDA approval] to conserve [their] patent’s term”).
240. Id.
241. Id.
244. Gaudry, supra note 226, at 135–36 (“Because the FDA must approve a drug before it can be marketed, a slow regulatory review merely further delays the applicant’s opportunity to begin earning revenue from the product.”).
245. See Morris, supra note 2, at 258–59.
246. See id.
247. See id.
lawyers have an ethical obligation to self-report non-diligence. The self-certified case of non-diligence was likely motivated by lawyers taking these duties seriously. Therefore, even if the five-year cap and loss of half the Testing Phase provisions of Hatch-Waxman are removed, as this Article argues for, there is simply no known incentive to act with non-diligence, but plenty of good reasons to act quickly. The fact that there has not been a single finding of non-diligence through a petition in the nearly thirty-year existence of Hatch-Waxman speaks volumes.

The drafters of Hatch-Waxman were clearly concerned with gaming of the patent-term restoration system through intentional delay. In fact, earlier drafts of the legislation required mandatory due diligence reviews to be conducted by the FDA if either the Testing Phase or the Approval Phase was above-average in length. Now that both theory and practice have shown that intentional delays by brand names is not a serious concern, all mentions of due diligence in Hatch-Waxman should be removed. The existing provisions are a solution without a problem.

Furthermore, the due diligence procedures are not harmless. The six-month waiting period after the FDA publishes its determination of the Regulatory Review Period, during which third parties can allege a lack of due diligence, increases the time until a Certificate of Extension is issued by the USPTO. This adds to the uncertainty and unpredictability of the system, increasing costs and decreasing innovation. As shown in Table 3, the average time from when the FDA publishes its determination until the USPTO issues a Certificate of Extension is 2.9 years.

There is also the risk of abuse of the due diligence proceedings. Since the FDA has never made a determination of diligence, it is unclear what showing by a third party is necessary to trigger review of the Regulatory Review Period, and what level of “diligence” is required to avoid losing PTR. This opens the door to an increase in due-diligence petitions as a collateral attack

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249. Lourie, supra note 26, at 527 (“All patent applicants are subject to a duty of candor to the Office and any patent or extension procured by truly wrongful conduct would be subject to the same penalties as other such wrongful conduct in the course of patent procurement, including patent unenforceability, attorneys’ fees, even potential disbarment.”).

250. See Gaudry, supra note 226, at 135.

251. See Lourie, supra note 26, at 535–36.

252. Id.

253. 35 U.S.C. § 156(d)(2)(B)(i); see Table 3.

254. Gaudry, supra note 226, at 124–29 (discussing the various sources of guidance on when a due diligence review should be conducted and what showing is required).
on patents that have received Hatch-Waxman restoration.\footnote{Id. at 138 ("Due-diligence petitions seem to represent a relatively unrecognized and low-cost mechanism to limit pharmaceutical monopolies.").} This is demonstrated by the fact that two of the three due-diligence petitions were not actually about diligence.\footnote{Id. at 129–35 (discussing the three petitions alleging non-diligence by an applicant for patent term extension).}

For these reasons, all of the due diligence provisions except for self-certification should be removed from Hatch-Waxman.

\section*{F. The Untapped Fortune}

This Section examines a loophole that existed before the enactment of GATT through which brand names could have obtained a full patent term for every single one of their products. It would have taken Congress decades to fully address the loophole, and the judicial branch could have at best limited the loophole. As unlikely as it may seem, the dataset and case law supports the conclusion that this loophole was never fully discovered, and certainly not widely exploited.

GATT is the unlikely hero that, over nearly twenty years, appears to have sealed the loophole shut. Even so, the framework for viewing the Hatch-Waxman provisions that led to the discovery of the loophole continues to provide insight into maximizing EPTWR. This Section therefore argues for a fundamental shift in the prevailing view of the interplay between patent filing and IND filing.

\subsection*{1. The “Delay Loophole”}

The patent system was very different in 1984 than it is today. Patent terms were seventeen years from the date of patent issuance, the USPTO did not publish patent applications, and the USPTO’s allowance of unlimited continuations meant that patents could theoretically live forever and issue whenever.\footnote{Lemley & Moore, supra note 134, at 64, 84.} Today, patent term is twenty years from the filing date, the USPTO publishes patent applications eighteen months after submission, and, though the USPTO still allows unlimited continuations, the twenty-years from filing date patent term effectively limits the life of a patent.\footnote{Id. at 84–89.} The loophole discussed herein existed under the older, pre-GATT rules.

Let us suppose that it is 1984, just after Congress enacted Hatch-Waxman, and a patent applicant was trying to game the system. The applicant recently invented a new drug, filed a patent application, and clinical
testing was about to begin. Knowing that the seventeen-year patent term begins when a patent issues and that the applicant can control when issuance occurs, at what point in the Figure 1 timeline should the applicant have the patent issue to maximize EPTWR?

Clearly, the applicant would wait to have the patent issue until after FDA approval for the product has been granted.259 By waiting until the FDA granted approval, there is no loss of EPT. The entire seventeen-year patent term occurs after the product has approval for marketing. As simple as this seems, and even though the concept of submarine patents is well documented,260 there is no evidence that this strategy (“the delay loophole”) was ever employed by brand names.

The implications of the delay loophole are tremendous: Hatch-Waxman patent-term restoration was completely unnecessary because brand names could already attain a full patent term by delaying issuance until after FDA approval. Indeed, the delay loophole predates Hatch-Waxman. It was possible to have a full patent term ever since the FDCA passed in 1938, causing the first losses in EPT due to regulation.261 Given how long the delay loophole existed for and the size of the industry, the amount of revenue that brand names left on the table is easily in the trillions of dollars.

The earliest legislative drafts of Hatch-Waxman included limits on the total patent term based on the patent filing date.262 For example, the failed Patent Term Restoration Act of 1982 prevented patents from having a total patent life of more than twenty-seven years from the first filing anywhere in the world.263 Similar provisions endured throughout the negotiations,264 but no such provision made it into the final draft.265 The drafters were more concerned with evergreening and delays at the FDA than with delays at the USPTO.266 As the evergreening provisions were trimmed back through lobbying by the pharmaceutical industry, Congress removed the cap on total

259. It may be most beneficial to have the patent issue after the period of data exclusivity has ended. Innovators also might wait until the generic applies for FDA approval, or even until the generic enters the market, at which point they can issue a patent with carefully worded claims to maximize the likelihood of infringement and damages. Because there is no publication requirement, generics might not even realize there is a patent for the drug. Indeed, generics might not enter the market for fear of being sued based on a patent they have no information on.

260. Lemley & Moore, supra note 134, at 79.
261. See Grabowski & Vernon, supra note 2, at 103.
262. Lourie, supra note 26, at 530.
263. Id.
264. Id. at 530, 545.
266. See Lourie, supra note 26, at 537–45.
patent life. Furthermore, even if Congress incorporated such a provision into Hatch-Waxman, it would only have limited the delay loophole. Brand names could still have delayed patent issuance to capture the maximum amount of exclusivity allowable.

Post-GATT, patent term is based on the filing date, so delaying patent issuance does not alter the patent term. Thus, the delay loophole no longer exists for patent applications filed on or after June 8, 1995, when GATT took effect. Even if the delay loophole had been recognized by Congress, there does not appear to be a practical way to eliminate it other than by tying the patent term to the filing date. As the decades-long transition to GATT’s twenty-years from filing date patent term has demonstrated, this solution takes a long time to implement. Indeed, some GATT transition patents are still pending.

2. The Equitable Doctrine of Prosecution Laches

The only other way that the delay loophole could have been mitigated is through the courts, under the equitable doctrine of laches. Laches is the legal doctrine that a legal right or claim will not be enforced if a long delay in asserting the right has prejudiced an adverse party. Courts have established the defense of prosecution laches in the context of delays during patent prosecution. A potential infringer can assert the defense of prosecution laches against a charge of infringement, alleging that the patent “issued only after an unreasonable and unexplained delayed in prosecution that constitutes an egregious misuse of the statutory patent system under the totality of the circumstances.” If prosecution laches is successfully asserted, then the patent is rendered unenforceable. However, as demonstrated in Cancer Research Technologies Ltd. v. Barr Laboratories, Inc., the Federal Circuit has

268. See PATENT-TERM EXTENSION AND THE PHARMACEUTICAL INDUSTRY, supra note 39, at 66 (discussing how a maximum patent life “could act as a disincentive for delaying proceedings in the Patent Office”).
269. Lemley & Moore, supra note 134, at 84.
270. Id. at 84–85.
271. See id. at 83–92 (discussing the lack of effectiveness of legislative and judicial action in eliminating submarine patents).
272. Id. at 83–84.
273. Id.
274. See, e.g., BLACK’S LAW DICTIONARY 431 (4th pocket ed. 2011).
276. Id. at 728.
277. Id. (internal quotations omitted).
not been particularly receptive to the defense of prosecution laches for pharmaceutical patents subject to the Hatch-Waxman framework. 278

In Cancer Research, the Federal Circuit reviewed the District of Delaware’s finding that U.S. Patent No. 5,260,291 (“the ’291 patent”) was unenforceable due to prosecution laches. 279 The ’291 patent had an 11.2-year Patent Prosecution Phase, during which there were “11 patent applications, 10 abandonments, and no substantive prosecution for a decade.” 280 Essentially, the patent application was put on ice after one of the compounds of the claimed invention was deemed “not a favorable candidate” to bring to market. 281 However, when additional clinical trials revealed that a different claimed compound had significant antitumor effects against certain types of lymphoma, Cancer Research Labs licensed the patent application to a pharmaceutical company for product development. 282 Thus, patent prosecution was intentionally delayed until economic opportunity materialized.

What happened next, however, demonstrates that the delay loophole was never comprehended. The licensee of the patent application did not then wait to issue the patent until FDA approval, but instead waited to file an IND until after the patent had issued. 283 Indeed, the IND was filed one month after the ’291 patent issued. 284 If the licensee had understood the delay loophole, it would have waited until well after the IND had been filed before issuing the patent, as this would decrease the amount of patent term that was lost before the granting of FDA approval. The licensee did the exact opposite.

On appeal, a Federal Circuit panel reversed the district court’s finding of prosecution laches and made future findings of prosecution laches unlikely by holding that it requires a showing by the alleged infringer that they (or others) “invested in, worked on, or used the claimed technology during the period of delay.” 285 The alleged infringer, a generic, could not meet this standard because they did not file an ANDA until thirteen years after the ’291 patent had issued. 286 Indeed, it is unlikely that any generic could meet this standard. By definition, generics copy products that have received FDA approval. They

278. See id. at 729–32.
279. Id. at 732.
281. Id. at 568.
282. Id. at 568–69.
283. Cancer Research, 625 F.3d at 731.
284. Id.
285. Id. at 729 (emphasis added).
286. Id. at 731.
do not engage in competitive research before a patent has even issued. Rather than recognizing how intentional delay could undermine Hatch-Waxman, the court practically sanctioned the delay, adding that “the public has benefited here by the fact that [the plaintiff] did develop and market [the product], induced by the protection of its patent.”

Thus, Cancer Research effectively foreclosed the defense of prosecution laches for generics.

Taken as a whole, Cancer Research suggests that brand names did not realize the full potential of delaying patent issuance and that the Federal Circuit may have been unwilling to declare pharmaceutical patents unenforceable for intentional delay during patent prosecution.

3. Evidence of the Delay Loophole

Overall, there is scant evidence of brand names delaying patent issuance for pre-GATT patents until right before FDA approval, suggesting that the delay loophole was never discovered. While any patent for which issuance was delayed until right before FDA approval would obviously not need Hatch-Waxman patent-term restoration and so would not appear in this Article’s dataset, word of such a massive loophole would undoubtedly have spread quickly and led to the declining use of the Hatch-Waxman framework. Yet the number of patents receiving Hatch-Waxman patent-term restoration has been stable over the years, and the defense of prosecution laches in the context of a Hatch-Waxman patent did not reach the Federal Circuit until Cancer Research, a 2010 decision.

There is also little evidence of more modest uses of the delay loophole, such as more modest delays in patent issuance. Indeed, widespread delay of patent issuance until right before FDA approval may have been unlikely given the risk of drawing the attention of the courts or of Congress. Knowledge of the loophole might have surfaced more subtly, such as through an increased Patent Prosecution Phase. But as shown in Figure 16, the Patent Prosecution Phase never increased in a way that would suggest that brand names were intentionally delaying patent issuance.

287. Id. at 732.
289. See Kelly, supra note 33, at 428–29 (noting that “pioneer companies frequently listed ‘improvement’ patents in the Orange Book,” thereby taking advantage of the original evergreening loophole).
290. See supra Figure 2 (the number of products comprising each data bar, which is displayed above each data bar (“N=XX”), is relatively constant).
Factors such as the staffing levels and the backlog at the USPTO necessarily inject a certain amount of ebb and flow into the Patent Prosecution Phase. This inherent variation does not appear to be exceeded. The sharpest change in Figure 16 is a drop in the average Patent Prosecution Phase from the 1965 to 1975 period to the 1976 to 1980 period of 1.2 years. Furthermore, the longest average Patent Prosecution Phase occurred from 1965 to 1975. There is practically no change in Patent Prosecution Phase between patents filed right before Hatch-Waxman (1981–1985) and patents filed soon after Hatch-Waxman (1986–1990).

Given how slow patent prosecution can be—patentees often wait multiple years before a first office action, have up to six months to

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291. See Lemley & Moore, supra note 135, at 66 n.7.
292. Hatch-Waxman was enacted on September 24, 1984. Lourie, supra note 26, at 549.
293. See Lemley & Moore, supra note 135, at 66 n.7.
respond to an office action, and can prolong prosecution by filing continuations—brand names could easily justify adding two to three years to the average Patent Prosecution Phase without raising prosecution laches concerns. Yet Figure 16 does not show any increase of more than a few months from the 4.1 year average for the entire dataset. This suggests that neither Hatch-Waxman, GATT, nor the delay loophole had any significant effect on patent prosecution attorneys’ behavior.

Examining the dataset at a more micro level further confirms that the delay loophole was not widely recognized. Nineteen patents in the dataset had a Patent Prosecution Phase of ten years or more, with the longest Patent Prosecution Phase weighing in at a whopping eighteen years. Yet for these eighteen patents, the defense of prosecution laches was only asserted once during any ensuing litigation. This case was the previously discussed Cancer Research. As it stands, the weight of the evidence strongly suggests that the delay loophole was not recognized during its existence.

4. Delaying the Filing of an IND for Post-GATT Patents

Experienced pharmaceutical patent practitioners may protest that there are many competing incentives, and that delaying patent issuance was not a realistic option. After all, brand names need to be confident in their patent rights before investing in the prolonged and costly clinical trials necessary to receive FDA approval, and sometimes need to enforce those rights before FDA approval is granted. This may all be true. But even so, knowledge of the delay loophole dictates that the benefits of a quick issuance be counterbalanced against the benefits of delay. The circumstances

294. MANUAL OF PATENT EXAMINING PROCEDURE § 710.01 (2014) (“The maximum statutory period for reply to an Office action is 6 months.” (citing 35 U.S.C. § 133 (2012))).
295. Lemley & Moore, supra note 135, at 66–69 (describing how the patent prosecution process works).
296. See id. at 70–71 fig.1 (showing the bell curve for patent prosecution times, with litigated patents having a curve that peaks at over a year longer than non-litigated patents).
298. The defense was nearly asserted in another lawsuit. The alleged infringer of U.S. Patent No. 6,306,141 (the patent in the dataset with a Patent Prosecution Phase of eighteen years) moved to amend their Answer to assert prosecution laches. But the motion was denied because, ironically, it was filed too late. See Medtronic, Inc. v. AGA Med. Corp., No. C-07-567 MMC, 2008 WL 5245896, at *2–3 (N.D. Cal. Dec. 17, 2008).
surrounding some products cannot be extrapolated as a general rule. Not when so much money is at stake.

The events underlying *Cancer Research* once again serve as an excellent example. In *Cancer Research*, obtaining a patent was crucial to getting a brand name on board to pursue the development of the product. 301 This is why the FDA approval process did not begin until a month after the patent was granted. 302 The decision to wait until patent issuance before filing an IND did not ultimately matter, as the '291 patent still received fourteen years of EPTWR. 303 But such risk-aversion by brand names is not always justified. And this principle applies to post-GATT patents as well as pre-GATT patents.

Filing an IND earlier has the same effect on EPTWR as delaying patent issuance. That is, it increases how far into the Regulatory Review Period a patent will issue. Since the Pre-Patent Issuance Phase is subtracted from the Testing Phase when calculating the Patent Term Eligible for Restoration, a later patent issuance means that less of the Testing Phase is eligible for restoration. Thus, waiting for patent issuance before filing an IND can lead to a lower EPTWR. Conversely, filing an IND before patent issuance, particularly for products with an above-average Regulatory Review Period, can lead to a higher EPTWR.

Consider the following example: a brand name is deciding whether to begin clinical trials for a new $1 Billion Product. A patent covering the product has just been filed at the USPTO and there is a 50% chance that it will be granted. Assuming that the product will have a Regulatory Review Period of eight years (a seven-year Testing Phase and a one-year Approval Phase) and that a final patentability determination will be made in four years, it is a no-brainer for the brand name to file an IND as soon as possible rather than wait until the patent has issued. This is because filing an IND now will yield one-and-a-half additional years of EPTWR compared to waiting, which translates to an additional $750 million in revenue. Thus, the expected return (probability of patent being granted multiplied with the expected additional revenues from a longer EPTWR) of filing an IND immediately is $375 million more than the expected return of waiting until the patent has issued. This increase in expected return is almost certainly more than the costs of clinical trials during the first four years.

301. *Id.*
302. *See id.* at 570.
303. *See Cancer Research*, 625 F.3d at 731–32. Filing the IND before patent issuance would also have resulted in a fourteen-year EPTWR.
This conservative example demonstrates the risk-reward trade-off involved in waiting for a patent to issue. In practice, this analysis is dynamic. Even before a patentee files their patent application, they can assess the odds of receiving a patent with some degree of certainty. After the applicant receives a first Office Action from the USPTO, a patentee can assess patentability with even greater accuracy. The applicant can weigh the strength of the Examiner’s arguments, and any previously undiscovered prior art would most likely have come to light. Brand name applicants can also weigh preliminary clinical trial results against the increasingly accurate odds of patentability.

Not only are the odds of an eventual payout quite high, but there is also a ceiling on any potential losses. Assuming that the product eventually receives FDA approval, which is a risk that is borne regardless of whether a patent issues or not, the brand name would be the only seller of its product for five years under Hatch-Waxman’s data exclusivity provisions. Thus, even now that GATT has closed the delay loophole, an applicant should examine whether to wait until a patent has issued before investing in clinical trials on a case-by-case basis. The Leahy-Smith America Invents Act of 2011 (“AIA”), which changed the United States’ patent system from granting priority based on first-to-invent to first-to-file, has not altered this analysis.

It is never possible to foresee all the problems and unintended consequences that will result from new laws. It is equally impossible to gauge what the effects would have been had the delay loophole been widely known. All things considered, it is probably for the best that it was never discovered.

G. PRE–PATENT ISSUANCE PHASE

Returning to an analysis of the elements of Hatch-Waxman, this Section focuses on the Pre–Patent Issuance Phase provision (“PPIP provision”). Like the due diligence provisions, the PPIP provision seeks to solve a problem the never existed.

As discussed in Part II of this Article, the Pre–Patent Issuance Phase is the portion of the Regulatory Review Period that occurs before the date of patent issuance. The Pre–Patent Issuance Phase is generally a portion of the Testing Phase, though it also consists of part of the Approval Phase for a handful of patents in the dataset. If the patent issues prior to the start of the Regulatory Review Period, then the Pre–Patent Issuance Phase is zero

304. NCEs are given five years of data exclusivity regardless of any patent protection. Small Business Assistance, supra note 167.
days. Under the PPIP provision, these days are ineligible for being restored.

The PPIP provision has its roots in the failed 1982 Patent Term Restoration Act, which provided up to seven years of patent-term restoration and did not contain a fourteen-year limit on EPTWR. The purpose of the PPIP provision in the 1982 legislation was to prevent brand names from receiving more patent-term restoration than had been lost during FDA approval. For example, a product could have an eight-year Regulatory Review Period, only three years of which occurred after patent issuance. Under the 1982 legislation framework, but without the PPIP provision, the patent would receive seven years of PTR, which, when added to a fourteen-year EPT (17 years – 3 years) results in a twenty-one year EPTWR. With the PPIP provision, only the three years of the Regulatory Review Period that occurred after patent issuance would be restored, resulting in a seventeen-year EPTWR. The PPIP provision was thus a vital part of the failed 1982 legislation.

When new drafts of the legislation were negotiated, the PPIP provision was retained. But with the addition of the fourteen-year limit, which explicitly limits EPTWR to fourteen years, it became impossible for brand names to receive more EPTWR than the statutory maximum. Thus, the problem that led to the PPIP provision does not exist under the Hatch-Waxman framework.

Lack of purpose should not be confused with lack of effect. The PPIP provision still prevents brand names from receiving PTR for the portion of the Regulatory Review Period that occurs before patent issuance. So, all else being equal, an earlier patent issuance leads to an increased PTR. This has different effects on EPTWR for pre-GATT (seventeen-year patent term from issuance) and post-GATT (twenty-year patent term from filing) patents.

For pre-GATT patents, as explained when discussing the delay loophole, every day of delay in patent issuance results in an additional day of EPT.

307. See id.
308. See id.
309. See Lourie, supra note 26, at 528–21, 533–34.
310. See id. at 529 (“No regulatory review period could be considered to have begun prior to issuance of a patent, thereby ensuring that no extension would result in more than a 17 years effective patent life . . . .”).
312. See id.
313. Id.
314. See id.
315. See supra Section IV.F.
This creates a powerful incentive for brand names to delay patent issuance that the PPIP provision merely lessens, as the increase in EPT from delay always equals or exceeds any decrease in PTR from a smaller Pre–Patent Issuance Phase. For example, delaying patent issuance an additional year into the Testing Phase will increase EPT by one year, but potentially decrease PTR by a half-year. For pre-GATT patents, therefore, the PPIP provision has no effect on incentives. It does lower PTR, and sometimes EPTWR, for certain pre-GATT patents.

For post-GATT patents, however, every day of delay in patent issuance potentially results in a lost day of EPTWR. As earlier discussed, a brand name cannot increase EPTWR by delaying patent issuance when the patent term is measured from the filing date instead of the issuance date. But the PPIP provision still decreases PTR when patent issuance is delayed. Because the Pre–Patent Issuance Phase nearly always occurs during the Testing Phase, during which only half of each day is eligible for restoration, each day of delay in patent issuance usually translates into a half-day less of PTR. This decrease in PTR then translates into a decrease in EPTWR. In this way, the PPIP provision creates a strong incentive for brand names to hasten patent issuance for post-GATT patents.

Thus, the PPIP provision went from being a crucial part of the failed 1982 legislation, to a pointless part of Hatch-Waxman that made delaying patent issuance a somewhat less beneficial strategy, to a pointless part of Hatch-Waxman that greatly decreases EPTWR for late-issuing patents. The retention of the PPIP provision into Hatch-Waxman is therefore an unsung and perhaps unrealized victory for pro-generic forces.

Furthermore, GATT has rendered the PPIP provision arbitrary. That is, since patent term is tied to patent filing rather than patent issuance for post-GATT patents, the PPIP’s reliance on the patent issuance date is nonsensical.

Consider the following example: a post-GATT patent is filed two years prior to an IND for the corresponding product. The product receives FDA approval after eight years, with a seven-year Testing Phase and a one-year Approval Phase. If the patentee obtains a patent after three years of patent

316. PTR will decrease by half a year if the five-year and fourteen-year caps are not hit, as one-half of the lost year of the Testing Phase would have been restored without the delay.
318. Id.
319. See Gaudry, supra note 226, at 135–36 (describing how prolonging clinical trials tends to result in less than fully compensatory patent term extension because delay would most likely occur during the Testing Phase).
320. The decrease in PTR translates into a decrease in EPTWR unless the five-year cap or fourteen-year limit makes any decrease irrelevant.
prosecution, then the patent will have fourteen years of EPTWR (ten years of EPT and four years of PTR). But if the patentee obtains a patent after five years of patent prosecution, then the patent will have only thirteen years of EPTWR (ten years of EPT, three years of PTR). There is simply no principled reason for the outcome of these scenarios being different. The length of patent prosecution should not affect the PTR for post-GATT patents.

To avoid the Kafkaesque PPIP provision, brand names should request expedited prosecution of any pharmaceutical patent application that may not issue before the start of the Regulatory Review Period or that is filed after the start of the Regulatory Review Period (e.g., improvement patents). The cost of expedited prosecution is easily justified by the resulting increase in EPTWR. Post-GATT patents have an average Pre–Patent Issuance Phase of 2.3 years. Assuming that half of this time would have been restored if not for the PPIP provision, then the average post-GATT $1 Billion Product has lost $562 million in revenue due to this tailbone-like rule.

The PPIP provision used to incentivize delay in order to gain additional EPTWR, but fortunately, this effect was largely ignored. The PPIP provision now incentivizes quick patent prosecution in order to avoid losing EPTWR. Brand names would be wise not to ignore it any longer. Congress would be wise to remove the PPIP provision.

V. PROPOSED IMPROVEMENTS TO HATCH-WAXMAN

A. LESSONS FROM HATCH-WAXMAN, 1984–2013

Looking at the history and structure of Hatch-Waxman, one would be hard-pressed to conclude that its purpose was to compensate brand names for the patent term lost while seeking FDA approval. The failed Patent Term Restoration Act of 1982 was designed to solve this problem, but following its defeat, the legislation became plagued with contradictory and extraneous provisions that resulted in an unpredictable, biased, and innovation-suppressing patent-term restoration system.

As demonstrated by the empirical and economic analyses, patent-term restoration is unpredictable. EPTWR fluctuates from product to product, over time, and based on the type of treatment and illness. There are arbitrary and unnecessary delays throughout the process, resulting in a fifteen-year waiting period before brand names know how much EPTWR a product will

receive. Even then, one in six of these calculations are incorrect. That it can take decades before the expiration date of a given patent is known with certainty is shocking and unprecedented.

Patent-term restoration is also unstable. The length of pre-clinical trials continues to increase and the Regulatory Review Period has large fluctuations from product to product and over time. Moreover, the implementation of GATT has revealed that the basic mechanics of the law can be considerably altered by subsequent changes in the patent laws. GATT radically altered any “balance” that Hatch-Waxman may have created. Its change in patent term increased and then decreased EPTWR and altered brand names’ incentives through the PPIP provision. Indeed, as the increasing reliance on improvement patents demonstrates, the legacy of GATT is still being written.322

Worst of all, patent-term restoration has failed to align the incentives of the pharmaceutical industry with the health of the public. The unpredictability and instability of the system results in widespread underinvestment in new treatments and is used to justify the industry’s above-average profit margins.323 The five-year cap on PTR ensures a lack of uniformity as products that lose a substantial amount of EPT seeking FDA approval are not placed on equal footing with products that quickly receive FDA approval. Indeed, the combination of the five-year cap on PTR, the PPIP provision, the restoration of at most half of the Testing Phase, and the implementation of GATT actually punishes products with a long FDA approval period more than the system prior to Hatch-Waxman.324 This strongly discourages research into illnesses requiring longer pre-clinical or clinical trials. It also systematically discourages fields of technology that take longer to show safety and efficacy, such as medical devices.

Brand names have responded to these incentives by increasingly relying on improvement patents. This represents an inefficient run-around, as improvement patents are generally weaker, making litigation more likely and

322. Brand names appear to be increasingly applying patent term restoration to improvement patents as a result of GATT. Whether this trend continues remains to be seen.
323. See Morris, supra note 2, at 259 (discussing pharmaceutical profit margins and the increasing reliance on blockbuster products).
324. See id. at 268–69 (describing how, prior to Hatch-Waxman, generics had to conduct their own safety and efficacy studies, which granted brand names a de facto 3–4 year extension on patent term). Assuming that the time required to prove safety and efficacy for a generic correlated with the regulatory review period for the brand name, then this de facto patent term extension prior to Hatch-Waxman was longer for products with longer FDA approval periods.
product development more costly.\textsuperscript{325} Weaker patents also encourage numbers-game litigation by generics,\textsuperscript{326} incentivizing licensing agreements by brand names that protect improvement patents but raise antitrust concerns, leading to yet more litigation.\textsuperscript{327} Furthermore, the increased reliance on improvement patents may itself be an inefficiency, as it means that brand names invest in incremental improvements rather than “leapfrog” products.\textsuperscript{328}

B. THE SIMPLEST SOLUTION: THE X-YEAR FLOOR ON EPTWR

The simplest method of addressing the aforementioned litany of problems would be to remove all of the Hatch-Waxman limits on patent-term restoration except for the fourteen-year limit. That is, any patent term lost while seeking FDA approval is restored as long as EPTWR does not exceed fourteen years. Without the five-year cap or any of the other provisions limiting PTR, the fourteen-year limit would function as a floor (as shown in Figure 13), guaranteeing at least fourteen years of exclusivity to new products. This would provide the needed stability and predictability to effectively promote pharmaceutical research. Brand names could focus on competing against one another instead of against their patent-term clocks, eliminating the inefficiencies discussed above. It would also provide a simple and uniform foundation on which supplemental cost-control measures for pharmaceutical products could be implemented.

Retaining only the fourteen-year limit provision would be a huge boon for brand names relative to the status quo. The proposed fourteen-year floor should therefore be replaced with an X-year floor, where X represents the optimal patent term for pharmaceutical products. X should be chosen to balance innovation, which leads to future benefits in the form of game-changing drugs, against access, which benefits those in need of treatment today. This Article takes no position on where that line should be drawn.

\textsuperscript{325} Id. at 274–75 (“Sequential patents do tend to be ‘weaker,’ however, and are therefore more likely to draw Paragraph IV challenges.”).

\textsuperscript{326} Id. at 274 (describing generic Paragraph IV challenges as “a sort of Russian roulette”).

\textsuperscript{327} Id. at 274–76 (describing the increased judicial scrutiny of “reverse-payment settlements”).

\textsuperscript{328} See id. at 274–75 (describing the circularity and inefficiency of Hatch-Waxman increasing the number of improvement patents, which led to increased litigation over these weaker patents).
C. FDA AS THE GATEKEEPER: MARKET EXCLUSIVITY

A better solution would be to replace patent-term restoration with pre-defined periods of market exclusivity, granted and enforced by the FDA. Market exclusivity would ensure that a generic could not enter the market until a certain number of years after the brand-name product has received FDA approval. A system of market exclusivity, effectively an enhanced version of the FDA’s existing data exclusivity provisions, would provide the benefits of a floor on EPTWR with none of the drawbacks of the patent system. It would also have the flexibility to align the research incentives of brand names so as to best promote the public health.

Data exclusivity, which is very similar to the proposed market exclusivity, already exists under Hatch-Waxman. Hatch-Waxman currently grants five years of data exclusivity for new chemical entities (“NCEs”) and three years of data exclusivity for significant changes in already-approved drug products that required new clinical investigations. Examples of “significant changes” include a change in active ingredients, strength, dosage form, method of administration, or conditions of use. Essentially, Hatch-Waxman grants three years of data exclusivity to “improvement” products. The proposed market exclusivity system would also grant exclusivity for new and improvement products, applying the same standards the FDA currently requires for data exclusivity, but with one important difference in enforcement.

During the period of data exclusivity, a generic can neither file an ANDA nor rely on publicly available publications to establish safety and efficacy. A generic can still receive FDA approval during a period of data exclusivity by conducting its own clinical trials. The costs of clinical trials are generally prohibitively expensive, making data exclusivity de facto market exclusivity. However, the time and expense of clinical trials is significantly lower for

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329. Small Business Assistance, supra note 163 (“Exclusivity provides the holder of an approved new drug application limited protection from new competition in the marketplace for the innovation represented by its approved drug product.”).
330. See id.
331. Id. Only four years if the generic asserts that the patent is invalid or not infringed.
332. Id.
333. Id. (“[Exclusivity] precludes approval of certain 505(b)(2) applications or certain abbreviated new drug applications (ANDAs) for prescribed periods of time.”).
334. Shulman et al., supra note 49, at 64 (“[T]he cost to generic firms of generating their own safety and efficacy data poses a considerable barrier to market entry . . . .”); see Grabowski & Vernon, supra note 2, at 99, 110 fig.6 (equating FDA exclusivity period with patent protection).
some products, making duplicative clinical trials a realistic option.335 This is particularly true if the period of data exclusivity is lengthened, such as it has been for biologics under the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”).336 To eliminate this inefficiency, as conducting duplicate clinical trials is inherently wasteful and potentially unethical,337 this Article advocates for closing this pathway to generic entry during the period of exclusivity. Thus, the proposed market exclusivity is a complete bar to FDA approval of a generic product during the period of exclusivity.

A major advantage of market exclusivity compared to patents is its ease of enforcement. Unlike determinations of patent infringement, which rely on a case-by-case analysis of invalidity, claim construction, and infringement, on which different district courts and even different panels of the Federal Circuit can reasonably disagree,338 the FDA has a refreshingly uniform and simple procedure for enforcing exclusivity. If the requirements for receiving exclusivity are met, no generic is approved until the statutory time period of exclusivity has expired.339

Also, FDA exclusivity is superior to patent enforcement because it is automatic and costless.340 Upon receiving FDA approval, there is nothing a brand name needs to do to enforce its accompanying exclusivity.341 The FDA will not approve a generic, and will remove unapproved products and target firms marketing unapproved products.342 By contrast, patents must be vigilantly enforced at great cost. Patent litigation costs at least $1 million per

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335. See supra Table 2. The minimum Testing Phase, Approval Phase, and Regulatory Review Period are quite short for some of the products in the dataset.


337. Accord Kelly, supra note 33, at 421 (describing House Report on proposed ANDA process, which declared that requiring generics to retest already-approved drugs and submit NDAs was “unnecessary and wasteful” and “unethical”).


339. Small Business Assistance, supra note 163.


341. Id.

Settlement provides no protection from additional lawsuits by additional generics, and brand names may face litigation over the settlement itself. These extensive enforcement costs, which divert resources from pharmaceutical research, do not exist in a system of market exclusivity.

Another advantage of exclusivity is that it reduces the opportunity for gaming of the rules. Under Hatch-Waxman, brand names can keep generics off the market for up to thirty months by attesting that the generic version of their product infringes a patent they own. This allows brand names to game the system by asserting infringement and delaying generic entry, even if the patent is invalid or if there is no infringement. Conversely, generics sometimes reap windfalls by challenging patents that protect legitimate innovation, but are ultimately found invalid or not infringed due to an error or oversight during patent prosecution or litigation. Some generics play a numbers game by challenging pharmaceutical product patents in the hope that one will fall and the generic can reap the ensuing profits of being the first generic on the market.

And because of the costs and uncertainty involved in patent litigation, and the enormous amount of money at stake (as indicated by the conservative $1 Billion Product used as an example in this Article), the pharmaceutical industry is susceptible to nuisance lawsuits. Faced with the threat of losing their multi-billion-dollar patents, brand names often enter into settlement agreements with generics, transferring large portions of their

343. Roth, supra note 340, at 283 (“A lawsuit to invalidate a patent typically costs a million dollars or more.”).
344. Morris, supra note 2, at 274–76 (describing the increased judicial scrutiny of “reverse-payment settlements”).
345. Maxwell R. Morgan, Regulation of Innovation Under Follow-On Biologics Legislation: FDA Exclusivity as an Efficient Incentive Mechanism, 11 Colum. Sci. & Tech. L. Rev. 93, 104 (2010) (“The prospect of having to either pursue these lawsuits and risk patent invalidation or enter into costly reverse-payment settlements with generic challengers almost certainly reduces ex ante incentives to innovate.”).
346. Nussbaum & Radice, supra note 35, at 235–36 (describing the Hatch-Waxman Paragraph IV certification process, which leads to up to a thirty-month stay of FDA approval of the generic while infringement litigation is pending).
347. Id. (describing how, despite the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), the thirty-month stay still incentivizes brand-names asserting multiple counts of patent infringement, irrespective of the merits of the allegations, to keep a generic off the market for as long as possible).
348. Morris, supra note 2, at 269–70 (noting that “even the best pharmaceutical patent is not iron-clad”).
349. Id. at 269–71 (describing generic Paragraph IV challenges as “a sort of Russian roulette”).
profits to the litigious generic through reverse-payment settlements. The result is that brand names and generics share in the enormous profits, while the public receives little to no benefit. The most anti-competitive of these agreements have been limited by a recent Supreme Court decision, but the threat of antitrust litigation remains. These inefficient activities may be avoided altogether by having exclusivity hinge on an FDA determination rather than a patent determination by the USPTO or judiciary.

Furthermore, FDA exclusivity protects products that are unpatentable. It may seem unnecessary to protect products that are not patentable, but there are several reasons why unpatentable products are still deserving of a period of exclusivity. For example, incidental prior disclosure may anticipate certain products and scientific advances may make products seem obvious in hindsight. Additionally, certain products may not meet the statutory requirements for patentable subject matter. As a result, many pharmaceutical products, which require enormous investment expenditures, are wholly reliant on the FDA’s current data exclusivity. This is a shortcoming of the patent system that exclusivity can easily correct.

Finally, having the FDA serve as the gatekeeper offers flexibility in correcting market failures that the patent system cannot address. As mentioned above, Hatch-Waxman currently grants NCEs five years of data exclusivity, but only grants improvement products three years of data exclusivity. This reflects the view that new chemicals are generally more innovative and hence more beneficial to the public health than improvements to already-existing products, and are therefore entitled to more protection. Thus, data exclusivity under Hatch-Waxman properly incentivizes major breakthroughs over incremental improvements.

351. Id. at 240 (describing reverse-payments as a win-win-lose situation, where the resulting supra-competitive prices means that brand-names and generics win by while drug purchasers lose).
353. See Abbott Labs. v. Geneva Pharm., Inc., 182 F.3d 1315, 1318 (Fed. Cir. 1999) (holding that a prior sale of a chemical compound was an invalidating sale under 35 U.S.C. § 102(b) even though the precise nature of the subject matter being sold was not known at the time of the sale).
354. See In re Dillon, 919 F.2d 688, 693–94 (Fed. Cir. 1990); see also Morgan, supra note 345, at 105 (discussing why promising products may fail patentability requirements).
356. Small Business Assistance, supra note 163. Only four years if the generic asserts that the patent is invalid or not infringed.
This framework is undercut by Hatch-Waxman patent-term restoration. The empirical data suggests that brand names are increasingly selecting improvement patents as the recipients of patent-term restoration. This means that improvement patents are actually receiving more patent term than new product patents, which in turn incentivizes more research into improvement patents. Hatch-Waxman patent-term restoration thus achieves the exact opposite of what the data exclusivity provisions were intended to do.

Currently, the Hatch-Waxman framework also provides enhanced data exclusivity for orphan drugs and pediatric drugs. Under the Orphan Drug Act of 1983, orphan drugs are defined as drugs that treat illnesses affecting less than 200,000 people. In order to incentivize research for these illnesses, which brand names might not otherwise undertake because of the limited market, orphan drugs are granted seven years of data exclusivity. Similarly, brand names that conduct pediatric clinical trials at the request of the FDA are granted an additional six months of exclusivity. This provision, first passed as part of the Food and Drug Administration Modernization Act of 1997, is intended to encourage brand names to conduct the specialized testing needed to ensure the safety, efficacy, and dosage of drugs administered to children.

The proposed, improved system would thus build on and expand the current laws that provide different amounts of data exclusivity for different categories of products in order to promote the research needed to best improve the public health. For example, X years of data exclusivity could be granted for new products, while improvement products could receive Y years of data exclusivity, where Y is less than X. Additionally, orphan drugs could receive O years of data exclusivity, where O is greater than X, and brand names could receive an additional P years of data exclusivity for conducting requested pediatric studies for a product. Such a system would provide clear incentives to brand names.

Since such a system of market exclusivity would take primacy over the patent system, an additional change could be made to ensure that market exclusivity is not overly generous. A major tradeoff of the patent system is that, in exchange for a grant of exclusivity over the claimed subject matter,

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357. 21 U.S.C. § 355a (2012); id. § 360cc.
358. Id. § 360bb.
359. Id. § 360cc.
360. Id. § 355a.
the patentee must disclose to the public how the invention works.\textsuperscript{362} FDA market exclusivity should allow a similar tradeoff by requiring disclosure of all clinical trials data. This would allow the public to independently assess safety and efficacy, providing a further check on the FDA’s approval mechanisms. The push for the public availability of complete clinical trials data has been a long time in coming.\textsuperscript{363} Rather than relying solely on the FDA, various public-health interest groups could provide recommendations on the safety and efficacy of brand-name products, as well as cost-effectiveness and other analyses, which are currently all but non-existent.\textsuperscript{364}

Ideally, Hatch-Waxman patent-term restoration should end. Instead, the FDA should simply refuse to approve a generic version of new products until after the brand name’s market exclusivity ends. This does not mean that pharmaceutical patents will become irrelevant. Once the FDA exclusivity has expired, if there is still any patent term remaining, the brand name may assert it in courts through normal patent infringement proceedings. Because there is an assumption that the period of data exclusivity is optimal, there would be no need to prevent generic entry—as currently exists under Hatch-Waxman. Rather, generics may enter, and as in other businesses, be required to pay a reasonable royalty, and possibly treble damages,\textsuperscript{365} if they are found to infringe.

Critics might argue that emphasizing FDA exclusivity promotes a “shadow” or “dual” patent system. The truth is that a dual system currently exists for pharmaceutical products. By requiring FDA approval before marketing or sale, the FDA is already the gatekeeper.\textsuperscript{366} Replacing patent-term restoration with FDA market exclusivity merely recognizes this reality. Thus, rather than stretching the patent system and asking the courts to constantly accommodate the incongruities of pharmaceutical products, the FDA and the courts can stick to their areas of expertise. The FDA continues to look after the best interests of the public by approving generics when it is beneficial to the public health and the courts continue to enforce valid patents against infringers under well-established principles.


\textsuperscript{365} See 35 U.S.C. § 284 (2012) (“[T]he court may increase the damages up to three times the amount found or assessed.”).

\textsuperscript{366} See Kelly, supra note 33, at 419 (“Under the [FDCA of 1938], FDA now performed a gatekeeping role . . . .”).
VI. CONCLUSION

On the thirtieth anniversary of Hatch-Waxman, both the shortfalls of the current system and the importance of the pharmaceutical industry have become increasingly apparent. The increasing costs of cutting-edge medical treatments have resulted in significant resistance to the pharmaceutical industry’s tactics from consumers, insurers, hospitals, and even physicians. Yet overreaction to the perceived greed of the pharmaceutical industry risks real harm to future innovation.

The United States’ role as the leader in promoting intellectual property protections must also be taken into account. Following the enactment of Hatch-Waxman, many countries affiliated with the Organization for Economic Co-operation and Development, including Japan and the European Union countries, adopted similar patent-term restoration provisions. Virtually all of these countries’ patent-term restoration laws include a version of the five-year cap, and many include a version of the fourteen-year limit as well. They therefore contain the same basic flaws as Hatch-Waxman. And if recent reports are to be believed, the United States is seeking to export at least some Hatch-Waxman provisions through the upcoming Trans-Pacific Partnership Agreement.

This makes it all the more crucial that the flaws of Hatch-Waxman are addressed now. Incremental, modest changes will not do; large-scale, comprehensive changes need to be made. Only by fixing the foundation can the future incentivization of pharmaceutical innovation be assured.

367. Hall, supra note 364.
369. Id.