

## The History and Political Economy of the Hatch-Waxman Amendments

*Erika Lietzan\**

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\* Associate Professor of Law, University of Missouri School of Law. This Article was supported by a Thomas Edison Innovation Fellowship from the Center for the Protection of Intellectual Property at Scalia Law School. I benefitted from the opportunity to speak with many people involved in the process leading to enactment of the Hatch-Waxman Amendments, including Peter Hutt (then primary outside counsel for the Pharmaceutical Manufacturers of America), Gerald Mossinghoff (then-Commissioner of Patents and Trademarks), William Corr (then-Counsel to the Subcommittee on Health and the Environment of the U.S. House of Representatives Committee on Energy and Commerce under Henry Waxman), William Schultz (then attorney at Public Citizen), Henry Grabowski (then professor of economics at Duke University), and a senior member of the Congressional Office of Technology Assessment (who wished to remain anonymous). I am grateful to the faculty of the Scalia Law School for inviting me to present this paper at a faculty workshop. I am thankful for comments from Jonathan Barnett, David Bernstein, Eric Claeys, James Cooper, Rebecca Eisenberg, Brook Gotberg, Dmitry Karshtedt, Kristina Acri, Adam MacLeod, Adam Mossoff, Michael Risch, Mark Schultz, Brenda Simon, and Todd Zywicki. Finally, I am grateful for the research support of Cynthia Shearrer, Associate Law Librarian at the University of Missouri School of Law, and the research assistance of Max Mauldin (class of 2018), Alex Weidner (class of 2019), and Alec Larsen (class of 2019).

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## I. INTRODUCTION

Reform of the Hatch-Waxman generic drug framework is in the air. Changes in how the U.S. Food and Drug Administration (FDA) implements the law, as well as changes to the law itself, are under serious consideration. These policymaking discussions are taking place against a backdrop of shared assumptions about the origins and nature of the original Hatch-Waxman legislation—assumptions that this Article claims are wrong.

The Hatch-Waxman statute, enacted more than thirty years ago and modestly revised fifteen years ago, authorized the FDA to approve generic drugs based on “abbreviated” marketing applications.<sup>1</sup> These applications

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<sup>1</sup> See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585; Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

do not contain safety and effectiveness data; instead they rely on data submitted by the companies whose drugs they copy.<sup>2</sup> Congress also created an exemption from patent infringement so that generic firms could make and test their drugs during the terms of patents covering the original drugs.<sup>3</sup> The scheme provided drug patent owners with an extension of their patents (one per drug)—also known as “patent term restoration”—to make up for time spent generating safety and effectiveness data before approval.<sup>4</sup> It also promised them a window of time before generic applications could be submitted (or approved, depending on the provision).<sup>5</sup> And it created a mechanism for generic firms and innovators to resolve patent infringement issues before generic drug launch.<sup>6</sup>

Many scholars urge reform on the ground that drug innovators “abuse” the scheme to enjoy more time on the market without generic competition. Professors Lemley, Dogan, and Carrier argue, for instance, that innovators introduce new versions of their products in a way that enables them to enjoy, inappropriately, a longer period before generic drug launch than they would otherwise enjoy.<sup>7</sup> Professors Carrier, Paradise, and Kesselheim argue that innovators improperly decline to share samples of their patented products with generic firms that seek to use the abbreviated pathway.<sup>8</sup> Professor Feldman argues that innovators take advantage of the Hatch-Waxman requirement that generic drugs have the same labeling as the drugs they copy, to prevent approval of generic drugs for longer than appropriate.<sup>9</sup> Some scholars, like Professor Shepherd, defend the status quo in the face of these arguments.<sup>10</sup> Others urge policy reform on the ground that the scheme provides inadequate incentives for innovation. Professor Goldman and colleagues suggest, for example, that Congress should amend the statute to

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<sup>2</sup> 21 U.S.C. § 355(j)(2)(A) (2018).

<sup>3</sup> 35 U.S.C. § 271(e)(1) (2018).

<sup>4</sup> 35 U.S.C. § 156.

<sup>5</sup> *E.g.*, § 355(j)(5)(F)(ii).

<sup>6</sup> §§ 355(b)(2)(j), 271(e)(2).

<sup>7</sup> Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167 (2016); Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685 (2009).

<sup>8</sup> Michael A. Carrier & Brenna Sooy, *Five Solutions to the REMS Patent Problem*, 97 B.U.L. REV. 1661 (2017); Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL’Y L. & ETHICS 293, 320–22 (2015); Jordan Paradise, *REMS as a Competitive Tactic: Is Big Pharma Hijacking Drug Access and Patient Safety?*, 15 HOUS. J. HEALTH L. & POL’Y 43 (2015).

<sup>9</sup> Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 506 (2016).

<sup>10</sup> Joanna Shepherd, *Deterring Innovation: NY v. Actavis and the Duty to Subsidize Competitors’ Market Entry*, 17 MINN. J.L. SCI. & TECH. 663, 664 (2016).

provide innovators with a longer respite before generic approval.<sup>11</sup> Professors Budish, Roin, and Williams suggest that the patent extension does not go far enough and that drug patent terms should begin with commercialization.<sup>12</sup>

Interest in reform is intensifying. In 2017, the Commissioner of Food and Drugs convened a public hearing and opened a docket for comment on the Hatch-Waxman scheme.<sup>13</sup> Most of the comments call for changes at the FDA, and many call for legislative change.<sup>14</sup> Also in 2017, the Federal Trade Commission (FTC) convened a workshop relating to generic drug competition and solicited responses to a series of questions, many of which related to legislative changes.<sup>15</sup> Congressional committees have held hearings in recent years,<sup>16</sup> and members have introduced bills to amend the scheme.<sup>17</sup> The innovating and generic drug industries have been vocal about change, along with third parties such as the American Medical Association (AMA).<sup>18</sup>

This policy discussion takes place within the context of a well-accepted narrative about the political history of the Hatch-Waxman Amendments and the nature of the resulting legislation. Conventional wisdom holds that the legislation represented a compromise between the competing interests of the generic drug companies and the innovating drug companies.<sup>19</sup> Some characterize the compromise as privately negotiated between the two

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<sup>11</sup> Dana P. Goldman et al., *The Benefits from Giving Makers of Conventional 'Small Molecule' Drugs Longer Exclusivity Over Clinical Trial Data*, 30 HEALTH AFF. 84, 84 (2011), <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2009.1056>.

<sup>12</sup> Eric Budish et al., *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials* (Nat'l Bureau of Econ. Research, Working Paper No. 19430, 2013), <http://www.nber.org/papers/w19430.pdf>.

<sup>13</sup> Administering the Hatch-Waxman Amendments, 82 Fed. Reg. 43767-01 (Sept. 19, 2017).

<sup>14</sup> See generally Comments to Docket No. FDA-2017-N-3615.

<sup>15</sup> *Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics*, FTC (Nov. 8, 2017), <https://www.ftc.gov/news-events/events-calendar/2017/11/understanding-competition-prescription-drug-markets-entry-supply>.

<sup>16</sup> See generally, e.g., *The Cost of Prescription Drugs: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions*, 115th Cong. (2017); *Antitrust Concerns and the FDA Approval Process: Hearing Before the Subcomm. on Regulatory Reform, Commercial, and Antitrust Law of the H. Comm. on the Judiciary*, 115th Cong. (2017).

<sup>17</sup> E.g., S. 124, 115th Cong. (2017); H.R. 2051, 115th Cong. (2017).

<sup>18</sup> See generally Comments to Docket No. FDA-2017-N-3615.

<sup>19</sup> Rebecca S. Eisenberg & Daniel A. Crane, *Patent Punting: How FDA and Antitrust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 MICH. TELECOMM. & TECH. L. REV. 197, 244 (2015) ("The Hatch-Waxman Act is a complex compromise between the interests of innovators and generics . . ."); Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 727 (2005) (describing the Hatch-Waxman Act as a "complex legislative compromise between the interests of research pharmaceutical firms and generic competitors").

industries.<sup>20</sup> Courts, too, accept this conventional wisdom. Many refer to a balance between competing policy goals, but they generally associate these goals with the interests of the respective industries, and some imply a private agreement.<sup>21</sup> Key to this narrative, though, is the notion that both sides won and both sides lost. The generic firms are said to have received a safe harbor from infringement liability for generic drug development as well as the right to rely on innovator testing data.<sup>22</sup> The innovating firms are said to have received additional protection in the market: a patent extension and data exclusivity.<sup>23</sup>

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<sup>20</sup> E.g., Dan L. Burk, *Means and Meaning in Patent Remedies*, 92 TEX. L. REV. SEE ALSO 13, 22 (2013) (“The Hatch-Waxman Act is a complicated series of legislative compromises between original pharmaceutical developers and generic manufacturers.”); Anna B. Laakmann, *The Hatch-Waxman Act’s Side Effects: Precautions for Biosimilars*, 47 LOY. L.A. L. REV. 917, 919 (2014) (writing that the scheme “structured a compromise between brand name and generic pharmaceutical manufacturers”); Rachel Sachs, *The New Model of Interest Group Representation in Patent Law*, 16 YALE J. L. & TECH. 344, 383 (2014) (writing that the statute was the “product of compromise” between “branded pharmaceutical firms and generic manufacturers”); Joanna M. Shepherd, *Biologic Drugs, Biosimilars, and Barriers to Entry*, 25 HEALTH MATRIX 139, 156 (2015) (describing the scheme as “a compromise on barriers to entry between original drug manufacturers and subsequent potential entrants”); Sarah R. Wasserman Rajec, *Evaluating Flexibility in International Patent Law*, 65 HASTINGS L.J. 153, 206 (2013) (“Thus, the Hatch-Waxman Act can be categorized as a complex legislative scheme, negotiated with all the relevant stakeholders, and administered by the Food and Drug Administration.”). Counsel for the generic industry association during the policymaking process described the scheme as a private agreement “hammered out” by representatives of both industries. See Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 J.L. & Tech. 389, 400 (1999), [http://www.ipmall.info/sites/default/files/hosted\\_resources/IDEA/11.Engelberg99.pdf](http://www.ipmall.info/sites/default/files/hosted_resources/IDEA/11.Engelberg99.pdf).

<sup>21</sup> Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1358 (Fed. Cir. 2003) (“The Hatch-Waxman Act was accordingly a compromise between two competing sets of interests: those of innovative drug manufacturers, who had seen their effective patent terms shortened by the testing and regulatory processes; and those of generic drug manufacturers, whose entry into the market upon expiration of the innovator’s patents had been delayed by similar regulatory requirements.”); Abbott Labs. v. Young, 276 F.3d 627, 991 (D.C. Cir. 1990) (“As the majority correctly notes, the Hatch-Waxman Amendments were the product of compromise.”); Tri-Bio Labs. Inc. v. United States, 836 F.2d 135, 139 (3d Cir. 1987) (stating that the Hatch-Waxman Amendments “reflect a statutory compromise of the competing concerns”); Allergan, Inc. v. Alcon Labs., Inc., 200 F. Supp. 2d 1219, 1226 (C.D. Cal. 2002), *aff’d*, 324 F.3d 1322 (Fed. Cir. 2003) (“After the subcommittee favorably reported the bill, Representative Henry Waxman of California conducted extensive negotiations with representatives of both generic and brand name pharmaceutical companies that generated a compromise that addressed the generic marketing and patent term aspects. This compromise was the basic language of the bill that became the Hatch-Waxman Act.”); Mylan Pharms. Inc. v. Henney, 94 F. Supp. 2d 36, 52 (D.D.C. 2000), *vacated sub nom.*, Pharmachemie B.V. v. Barr Lab., Inc., 276 F.3d 627 (D.C. Cir. 2002) (“As this Circuit observed nearly a decade ago, that Hatch-Waxman struck a compromise between pioneer and generic makers . . .”).

<sup>22</sup> E.g., Sachs, *supra* note 20, at 383–84.

<sup>23</sup> E.g., Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 53, 69 (2016); Lisa Larrimore Ouellette, Note, *How Many Patents Does It Take to Make a Drug? Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH.

Curiously, however, there have been few published histories of the Hatch-Waxman Amendments since the accounts written contemporaneously by participants in the policymaking process.<sup>24</sup> This Article steps into the gap by offering a contextualized history of the statute and describing its political economy. It takes a public choice approach, examining the role of participation and influence on policymaking.<sup>25</sup>

Beginning in the late 1970s, citing studies showing a decline in innovation, regulated patent owners sought restoration of the portions of their patent terms lost to premarket testing and federal agency review.<sup>26</sup> The final legislative proposal, which would have applied to many regulated industries, very nearly became law.<sup>27</sup> Understanding the political economy of the 1984 legislation requires understanding why these proposals had majority and bipartisan support in Congress through the fall of 1982, as well as how and why the tide turned.

Patent owners supported patent term restoration because it would lengthen the period of time they could commercialize their patented products and block competing copies. They had a strong incentive to organize and argue for policy change. Generally, they argued for restoration on the ground that it would restore (increase) incentives to innovate.<sup>28</sup> Academic economists bolstered this argument.<sup>29</sup> With respect to drug patents, the FDA

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L. REV. 299, 304 (2010); Sachs, *supra* note 20, at 383–84.

<sup>24</sup> The primary accounts by participants are: Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269 (1985); Alan D. Lourie, *Patent Term Restoration*, 66 J. PAT. OFF. SOC'Y 526, 529 (1984) [hereinafter Lourie, *Account*]; Alan D. Lourie, *Patent Term Restoration: History, Summary, and Appraisal*, 40 FOOD DRUG COSM. L.J. 351 (1985) [hereinafter Lourie, *History, Summary, and Appraisal*]; Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187 (1999). Brief accounts appear in later scholarly work. E.g., Ronald L. Desrosiers, Note, *The Drug Patent Term: Longtime Battleground in the Control of Health Care Costs*, 24 NEW ENG. L. REV. 115 (1989); Daniel I. Gorlin, *Staving off Death: A Case Study of the Pharmaceutical Industry's Strategies to Protect Blockbuster Franchises*, 63 FOOD & DRUG L.J. 823 (2008); Sachs, *supra* note 20.

<sup>25</sup> See generally Daniel A. Farber & Phillip P. Frickey, *The Jurisprudence of Public Choice*, 65 TEX. L. REV. 873 (1987) (explaining public choice theory and its use in public law scholarship). Few writers have considered the application of public choice theory to the legislation. Professor Sachs included the Hatch-Waxman legislation in an article on application of public choice theory to patent statutes; I address her analysis *infra* note 445. See also F. Scott Kieff, *Coordination, Property, and Intellectual Property: An Unconventional Approach to Anticompetitive Effects and Downstream Access*, 56 EMORY L.J. 327, 408 (2006) (commenting that “the Hatch-Waxman Act was very much a collective bargaining process that raised a host of public choice, administrative and market power problems”).

<sup>26</sup> See *infra* Section III.

<sup>27</sup> See *infra* Section III.A.4.

<sup>28</sup> See *infra* Section III.

<sup>29</sup> See *infra* Section III.

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supported restoration, perhaps to protect its premarket regulatory program, which was viewed as responsible for the truncation of patent terms. The Patent and Trademark Office (PTO) supported restoration on theoretical grounds, because it would compensate for time sacrificed to federal government requirements and ensure equal treatment of patent owners.

The competitors of these patent owners would have borne the cost of this legislation (a longer wait before launching competing products using the inventions), but they were not as well organized, perhaps because of the differing industries involved. With respect to drugs in particular, the public was also perceived to bear the costs through a delay in generic drug entry, which meant it would pay more for medicine for a longer period of time. Public Citizen, which had formed in 1971, made this pricing argument for the public, leading to a clash in views about where the public's interest lay. Opponents also focused on the empirical case for restoration, for instance questioning the supposed decline in innovation, questioning its causes, and questioning whether longer patents would lead to more innovation.

Until the fall of 1982, however, there was bipartisan support in Congress and widespread support from influential third parties including the national media. The final bill passed the Senate. In the House, however, it had been placed on the suspension calendar and fell five votes short of the supermajority needed for passage. A variety of explanations have been offered for its defeat, but overconfidence surely played a role.

In addition, however, the tide was already turning. The generic industry had coalesced around the issue of patent term restoration during the winter of 1981 to 1982, invoking the public's interest in lower drug prices. And by the spring of 1983, the generic companies had experienced a series of policymaking defeats in Congress, at the FDA, and in the courts, that propelled them to organize and push for legislation advancing their own interests. They sought legislation that would allow them to reach the market earlier and on the basis of applications omitting clinical data. They would rely on the data submitted by patent owners. The public would benefit, they argued, through earlier access to (their) less expensive medicines. They formed a new lobbying group, headed by a charismatic Washington insider, and they secured the support of Henry Waxman (D-CA), a relatively new but already influential member of the U.S. House who sought to make his name in health and environmental policymaking.

Representative Waxman introduced a placeholder bill in the summer of 1983. The broad contours of the legislation were then hammered out in private between July 1983 and January 1984. Waxman and his staff filled in the details during the spring, however, with provisions that surprised and disappointed patent owners. Only modest changes were made after this point. Some of the non-pharmaceutical patent owners split off, realizing

their own prospects for meaningful patent term restoration had dimmed with joinder to drug pricing issues. Although for the most part the language was presented to policymakers as a “done deal” in June, there was modest tinkering in the summer, and Senator Hatch and Representative Waxman put forward a series of final changes in August partly in response to concerns about the constitutionality of the legislation.

This paper makes two claims about the final legislation.

*First*, the conventional wisdom about the Hatch-Waxman Amendments—that each side gained and each side lost—is wrong. The two industries sought directly conflicting policy outcomes. Considering each industry’s position before enactment and after enactment shows clearly that the generic industry emerged in a better position, while the patent owners emerged in a worse position. Understanding this requires understanding the state of the law and the position each industry was in before enactment. That the benefits accrued to one group while the costs were borne by the other group is not meant as a normative claim or a claim about the allocation of benefits and costs under the scheme as it operates today. Rather, it is a historical claim—that in September 1984, the generic industry clearly emerged in a better place, and the innovating industry emerged in a worse place.

*Second*, this outcome can be explained by a Baptists-and-bootleggers alliance between the generic industry and Public Citizen. The generic companies argued that their proposed policy changes would increase and accelerate the supply of less expensive drugs. They urged these policy changes because they would be selling the drugs in question and would profit from the legislation’s passage. But they managed to equate their own financial interests with the interests of the general public, and their policy proposal benefited from the strong support of Public Citizen and the entrepreneurship of Representative Waxman. Patent owners had very little leverage after losing the patent term restoration vote in September 1982, and once the alliance between Public Citizen and the generic industry association was cemented, the drug patent owners would have been lucky to hang onto the status quo.

Although it makes only historical claims, this Article could have normative implications. More than thirty years of scholarship, and policy reform proposals today, are grounded in the assumption that the Hatch-Waxman Amendments benefitted both industries. Indeed, some scholars assume that it benefitted the patent owners. Instead, it was a policymaking defeat for the innovators. Scholars, third-party opinion-shapers, and policymakers considering current policies and practices, as well as reform proposals, should understand this. And they should know that it resulted from an alliance between generic drug companies and Public Citizen, though



these are not, in fact, always fully aligned. This Article provides the basis for a clearer understanding of what happened in 1984 and perhaps normative work considering alternatives to the Hatch-Waxman framework or reassessment of the original patent term restoration proposals.

Section II of this Article describes the interaction between patent life and new drug approval that laid the groundwork for the restoration proposals. Section III tells the history of the Hatch-Waxman Amendments, beginning with the defeat of the Kastenmeier patent term restoration proposal in 1982 and then turning to the generic drug industry's policymaking defeats from 1979 to 1983, the introduction of generic drug legislation in the spring of 1983, and the development of the final legislation from July 1983 to September 1984. Section IV explains the political economy of the 1984 legislation, and the Conclusion offers brief thoughts on the implications of this Article's claims.

## II. BACKGROUND

### A. *Distorted Patent Terms*

#### 1. Early Filings

Since the founding of the Republic, and in accordance with express recognition in the U.S. Constitution, federal law has protected an inventor's rights in his or her invention.<sup>30</sup> In general, if a process, machine, manufacture, or composition of matter is useful and not obvious, and if the patent application satisfies certain additional requirements, the Patent Act will secure the inventor's exclusive right to the invention for a fixed time.<sup>31</sup> During this time, the inventor may exclude others from making, using, or selling the invention without permission.<sup>32</sup> As a practical matter, the right to exclude confers additional benefits, including the ability to provide that permission to others (to "license" the patent) and the ability to sell embodiments of the invention in a market that lacks copies and possibly close substitutes.

Various doctrines of patent law provide a strong incentive to file for a patent as soon as possible after invention. For instance, the PTO will generally deny a patent if the invention was described in a printed publication, or in public use, more than a year before the patent application was filed.<sup>33</sup> Today, the PTO awards the patent to the first to file a patent

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<sup>30</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>31</sup> 35 U.S.C. §§ 101–103, 112, 154 (2018).

<sup>32</sup> 35 U.S.C. § 271(a) (2018)

<sup>33</sup> The 1952 statute precluded a patent if the invention was in public use in the United States or described in a printed publication more than a year before the filing date. 35 U.S.C.

application, which also pushes inventors into filing as soon as possible so that another person does not secure the patent first.<sup>34</sup> In some cases, this early patenting occurs well before the invention takes the form of a product that will be commercially successful. As Professor Sichelman shows, transforming a prototype into a commercially viable product can require years of experimentation with product features as well as extensive market testing.<sup>35</sup> The nature and extent of the testing is a business judgment, as the inventor focuses on identifying features that will cost-effectively attract customers and minimize liability.<sup>36</sup>

Whether early patenting is beneficial remains disputed in the academic literature.<sup>37</sup> One concern, voiced by Professor Abramowicz, is germane to the history of the Hatch-Waxman Amendments. Abramowicz suggests that delays before commercialization increase the risk of patent “underdevelopment” (less investment in development of the invention than if the patent term had been longer) and “non-development” (abandonment of inventions that might have been developed if the patent term had been longer).<sup>38</sup> These risks intensify, he explains, if the post-patent cost of development and time to market are substantial. He gives the example of pharmaceuticals. Although he does not explore the point, pharmaceuticals differ from other products with lengthy commercialization delays *because* the commercialization delay derives from federal regulatory requirements.

## 2. Premarket Regulation

The essence of drug discovery is the uncovering or creation of a new active ingredient with useful physiological effects and thus therapeutic potential. Biological assays (for instance, using cells in the laboratory) and

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§ 102(b) (1952). Today, public use anywhere in the world and description in a printed publication defeat novelty, although there is an exception for disclosures by the inventor in the final year before the effective filing date (or by a third party during that same period after disclosure by the inventor). 35 U.S.C. § 102 (2018).

<sup>34</sup> 35 U.S.C. § 102.

<sup>35</sup> Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 347–53 (2010) (describing the process from invention to commercialization for a particular product, to show the “risky and costly efforts often involved”).

<sup>36</sup> *E.g., id.* at 350–51.

<sup>37</sup> Compare Yoram Barzel, *Optimal Timing of Innovations*, 50 REV. ECON. & STAT. 348, 352 n.11 (1968) (arguing that early patents prevent wasteful duplication of effort during what would otherwise be a longer pre-patent development phase), and Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 276–78 (1977) (arguing that early patenting may allow the patent owner to coordinate inventive activity with others, creating social value), with Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 88 (2009) (arguing that broad early patent filings necessitate more detailed applications later, burdening the patent system).

<sup>38</sup> Michael Abramowicz, *The Danger of Underdeveloped Patent Prospects*, 92 CORNELL L. REV. 1065, 1074 (2007).

animal tests substantiate the physiological effects and allow the inventor to describe the molecule's activity in a patent application.<sup>39</sup> Patent law allows one to establish utility on the basis of laboratory and animal testing data.<sup>40</sup>

But the federal government has required premarket applications for new drugs since 1938 and for biological medicines since 1902.<sup>41</sup> And the government does not approve active ingredients. Instead, it approves a finished product, meaning a particular formulation (a combination of active and inactive ingredients, such as excipients and buffers, tailored to have particular properties), as well as a particular presentation (route of administration, dosage form, and strength), and particular labeling for prescribers.<sup>42</sup> Moreover, the government will approve a medicine only if the applicant proves the product effective for a particular use (known as its "indication") described in the labeling.<sup>43</sup> Effectiveness for FDA purposes differs from utility for patent law purposes; it is a regulatory concept and a higher bar. The regulatory statute requires "substantial evidence" to support the indication.<sup>44</sup> This in turn requires statistically rigorous analysis of data from one or two "adequate and well-controlled" clinical trials testing a hypothesis about the use.<sup>45</sup>

Federal law requires the applicant to take a phased approach to development of these data.<sup>46</sup> A firm must first submit laboratory and animal testing results showing that it would be ethical to conduct trials in humans.<sup>47</sup> Once the FDA permits trials to begin, the firm must begin with small trials,

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<sup>39</sup> See generally JP Hughes et al., *Principles of Early Drug Discovery*, 162 BRIT. J. PHARMACOLOGY 1239 (2011).

<sup>40</sup> *Brenner v. Manson*, 383 U.S. 519, 534–35 (1966) (holding that invention must have "substantial utility" in the form of a "specific benefit" that is "currently available"); *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995) (noting that "proof of an alleged pharmaceutical property for a compound by statistically significant tests with standard experimental animals is sufficient to establish utility"); *Cross v. Iizuka*, 753 F.2d 1040, 1051 (Fed. Cir. 1985) (finding utility on basis of in vitro demonstration of claimed biological activity, preventing aggregation of platelets).

<sup>41</sup> Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 505, 52 Stat. 1040, 1052 (1938); Biologics Control Act of 1902, Pub. L. No. 57-244, 32 Stat. 728, 728-29 (1902).

<sup>42</sup> Erika Lietzan, *The Drug Innovation Paradox*, 83 MO. L. REV. 39, 71 (2018) [hereinafter Lietzan, *Innovation Paradox*].

<sup>43</sup> See 21 U.S.C. § 355(b)(1) (2018); 21 C.F.R. § 314.50(d)(5)(viii) (2018); Lietzan, *Innovation Paradox*, *supra* note 42. Cf. 42 U.S.C. § 262(a) (2018).

<sup>44</sup> 21 U.S.C. § 355(d) (requiring "substantial evidence" of effectiveness); see also *Procedures for Review of Safety, Effectiveness, and Labeling*, 37 Fed. Reg. 16,679 (Aug. 18, 1972) (explaining that the agency will apply a more flexible version of "substantial evidence" to biologics).

<sup>45</sup> 21 U.S.C. § 355(d) (defining "substantial evidence" as data from at least one "adequate and well-controlled [investigation]"); 21 C.F.R. § 314.126 (2018) (describing an "adequate and well-controlled [investigation]").

<sup>46</sup> See Lietzan, *Innovation Paradox*, *supra* note 42, at 52.

<sup>47</sup> See generally 21 C.F.R. § 312 (2018).

often in healthy volunteers.<sup>48</sup> These trials generate safety information and information about how the body processes the drug. The second phase of testing involves more subjects, often with the disease under investigation, and generates preliminary measurements of the drug's effects on the body as well as information about optimal dosing.<sup>49</sup> The process ends with trials designed to test whether use of a particular finished product (which the company plans to commercialize) achieves a particular clinical endpoint in a specific population.<sup>50</sup> The marketing application describes the product, how it is made, and the data generated during research and development.<sup>51</sup>

The patent owner has little control over the length of the premarket testing and approval process.<sup>52</sup> As a regulatory matter, the premarket requirements are more likely to turn on the drug's chemical class, the disease targeted, how well the disease is understood, the drug's mechanism of action, the clinical outcomes possible, and other available treatments.<sup>53</sup> Today the process from discovery to FDA approval averages ten to twelve years, but it can be much shorter or, indeed, much longer.<sup>54</sup> Recent empirical work shows that drugs for some types of use—such as drugs for diseases of the central nervous system—consistently take longer.<sup>55</sup>

The aspects of patent doctrine that counsel early filings nevertheless apply with equal force in the pharmaceutical setting. Use of an invention in a clinical trial may constitute disqualifying public use.<sup>56</sup> Scientific publications describing clinical research results may disqualify the invention for a patent.<sup>57</sup> Conventional wisdom holds that the patent for the active ingredient of a potential new drug should be filed before clinical testing

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<sup>48</sup> 21 C.F.R. § 312.21(a).

<sup>49</sup> 21 C.F.R. § 312.21(b).

<sup>50</sup> 21 C.F.R. § 312.21(c).

<sup>51</sup> 21 C.F.R. §§ 314.50, 601.2.

<sup>52</sup> Lietzan, *Innovation Paradox*, *supra* note 42, at 62–63.

<sup>53</sup> *Id.* at 110.

<sup>54</sup> Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016).

<sup>55</sup> Lietzan, *Innovation Paradox*, *supra* note 42, at 110–11.

<sup>56</sup> Christopher M. Holman, *Unpredictability in Patent Law and Its Effect on Pharmaceutical Innovation*, 76 MO. L. REV. 645, 659–60 (2011) (discussing whether clinical trials are patent-invalidating public use of the claimed invention); *see also* Dey, L.P. v. Sunovian Pharms., Inc., 715 F.3d 1351, 1358 (Fed. Cir. 2013) (reversing summary judgment on public use issue and listing cases in which courts have declined to find “public use” when investigators sign confidentiality agreements); *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369 (Fed. Cir. 2006) (finding that Lilly's trials of olanzapine were not public use, considering confidentiality of the study and experimental character of the tests).

<sup>57</sup> *See* Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs, Ltd., 476 F.3d 1321, 1324–25 (Fed. Cir. 2007) (explaining how prior publication forced Ortho-McNeil to narrow scope of patent); Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 523–24 (2009) (offering examples).

starts.<sup>58</sup> This appears to be common practice.<sup>59</sup>

### 3. Patent Term Distortion

Premarket regulation combines with early patent filings to create what the Supreme Court describes as “patent distortion.”<sup>60</sup> Today a patent lasts for twenty years, starting when the inventor files the patent application.<sup>61</sup> If the inventor spends a decade testing embodiments for regulatory purposes—animal testing to justify a clinical program, followed by three phases of clinical trials—only ten years of patent life remain when the FDA approves the finished product for the market. This is the product’s “effective patent life,” meaning the portion of the patent term during which the patent owner may lawfully sell embodiments of the invention while excluding others from doing so. Before 1995, when a patent lasted for seventeen years from issuance, the same thing happened. Ordinarily the patent issued during clinical trials, so a substantial period of the patent term lapsed before FDA approval. If the patent applicant filed a continuation or continuation-in-part application, the patent might issue later in time and thus expire later.<sup>62</sup> But so long as the patent issued during the premarket program, some portion of its term would be sacrificed. Under either patent scheme, the federal drug regulatory system leads to a shortened effective patent life.

The distortion affects more than just the initial active ingredient patent. The final product comprises not only a particular active ingredient, but a particular formulation, route of administration, dosage form, and strength, as well as labeling that describes the indication and provides instructions for use. These aspects of the product are typically worked out over the course of the premarket program. As the finished product’s features take shape through new discoveries, the company seeks additional patent coverage. Whether it can file a new original patent application or must instead file a continuation or continuation-in-part will depend on the new discovery and the scope of the original patent disclosure. But the distortion appears either way. A new original patent will generally expire later than the initial active ingredient patent. Before 1995, a continuation patent would have similarly

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<sup>58</sup> Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 348 (2007) (noting that applications for “composition of matter” patents are filed before clinical testing); Roin, *supra* note 57, at 539 (stating that pharmaceutical patents “are typically filed when drugs are in early preclinical research”).

<sup>59</sup> Lietzan, *Innovation Paradox*, *supra* note 42, at 86.

<sup>60</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990).

<sup>61</sup> 35 U.S.C. § 154 (2018).

<sup>62</sup> A continuation application relies on the disclosure in an earlier filed (“parent”) application, but the scope of its claims is different. A continuation-in-part application similarly refers to the parent application but can add subject matter. See U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE (MPEP) 201.07–201.08 (9th ed. 2018).

expired later, because the patent term lasted seventeen years from issuance. Today it will expire twenty years after the filing of its parent application. In each case, though, some portion of the term lapses before the FDA permits the inventor to sell a product that includes the invention. The regulatory system still distorts the patent.

#### 4. An Emergent Problem

Distortion of drug patent terms emerged as a problem in the third quarter of the 20th century when an explosion in medical innovation and pharmaceutical patenting coincided with growth of the administrative state.

The first modern medicines were launched in the early 1900s, with the discovery of insulin and the introduction of sulfa drugs, barbiturates, amphetamine, and heparin.<sup>63</sup> By the late 1940s, there were applications in effect for penicillin drugs, morphine, phenobarbital, epinephrine, niacin, codeine, testosterone, progesterone, conjugated estrogens, digitalis, benzocaine, and theophylline, many of which are still viewed as essential today.<sup>64</sup> But the big leap forward occurred when academic researchers began collaborating with the predecessors of today's research based companies.<sup>65</sup> Companies introduced an average of forty-three new chemical entities per year in the 1950s.<sup>66</sup> The FDA received applications for acetaminophen and new antibiotics, for example, as well as drugs to treat hypertension, anticoagulants, early cancer drugs, and the first oral contraceptive.<sup>67</sup> Some call the 1950s the decade of the "miracle drug."<sup>68</sup>

The inventors of these drugs sought patent protection. The medical and scientific establishments had opposed pharmaceutical patenting in the 19th century.<sup>69</sup> In the early decades of the 20th century, though, academic

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<sup>63</sup> Suzanne Junod, *FDA and Clinical Drug Trials: A Short History*, in A QUICK GUIDE TO CLINICAL TRIALS (Madhu Davies & Faiz Kermani eds., 2008).

<sup>64</sup> U.S. FOOD & DRUG ADMIN., EVER APPROVED DRUGS LIST [hereinafter EVER APPROVED DRUGS LIST] (obtained via Freedom of Information Act Request) (on file with author); see *WHO Essential Medicines: 20th List*, WORLD HEALTH ORG., <http://www.who.int/medicines/publications/essentialmedicines/en/> (last updated Aug. 2017)

<sup>65</sup> DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 118–22 (2010); Joseph M. Gabriel, *Pharmaceutical Patenting and the Transformation of American Medical Ethics*, 49 BRIT. J. HIST. SCI. 577, 587 (2016); Nicolas Rasmussen, *The Drug Industry and Clinical Research in Interwar America: Three Types of Physician Collaborator*, 79 BULL. HIST. MED. 50 (2005).

<sup>66</sup> SAM PELTZMAN, REGULATION OF PHARMACEUTICAL INNOVATION: THE 1962 AMENDMENTS 13 (1974).

<sup>67</sup> EVER APPROVED DRUGS LIST, *supra* note 64.

<sup>68</sup> E.g., HARRY M. MARKS, THE PROGRESS OF EXPERIMENT: SCIENCE AND THERAPEUTIC REFORM IN THE UNITED STATES, 1900-1990 149 (1997).

<sup>69</sup> Gabriel, *supra* note 65, at 585, 587. In the early 19th century, the orthodox medical community opposed patenting because it viewed commercialism as unseemly and because it equated patenting with secrecy, the province of quack medicines. *Id.* at 578–82. AMA

researchers began to patent their discoveries, often assigning these patents to their host institutions or other institutions with which they affiliated.<sup>70</sup> The domestic research-based companies also began to patent their discoveries.<sup>71</sup> The broader scientific and public health communities remained ambivalent about patenting medicines for several more decades. But when the academic medical community and research-based pharmaceutical companies began to collaborate in earnest in the 1950s and 1960s, with “impressive therapeutic dividends” as Professor Gabriel put it, pharmaceutical patenting became viewed as “ethically legitimate and even necessary, as a part of the incentive structure that underlay the development of powerful new drugs.”<sup>72</sup>

The administrative apparatus that truncates drug patent terms emerged at exactly the same time. Premarket review of new drugs dates to 1938, but early applications were based on safety data and modest in size and scope.<sup>73</sup> Regulators and academic scientists developed the randomized, controlled, blinded clinical trial for proof of therapeutic claims in the 1940s.<sup>74</sup> The FDA began routinely asking for outcomes data in the 1950s.<sup>75</sup> In 1962, Congress enacted a premarket-approval requirement and required companies to provide substantial evidence of effectiveness, and the FDA’s expectations about the content and scope of applications grew more rigorous over the following decades.<sup>76</sup> The average time from the first clinical trial to FDA approval increased threefold or fourfold, to around seven years, between 1950 and 1965.<sup>77</sup> The requirements for preclinical testing—which an

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prohibited holding patents and prescribing patented goods. *Id.* at 580. Early U.S. companies, such as Parke-Davis (now Pfizer) and E.R. Squibb (now Bristol-Myers Squibb), eschewed patents and trade secrets. *Id.*

<sup>70</sup> For example, the University of Toronto held the 1923 patent for insulin. U.S. Patent No. 1,469,994 (filed Oct. 9, 1923).

<sup>71</sup> Gabriel, *supra* note 65, at 587. For instance, Parke-Davis (now Pfizer) owned at least eight patents issued in the 1920s directed to chemicals for medicinal use or methods of medical treatment. *E.g.*, U.S. Patent No. 1,717,198 (filed June 11, 1929) (claiming “[a]n immunizing product comprising washings from disease-producing microorganisms, said washings containing antigens specific to said organisms and being substantially free from said organisms and from specific bacterial toxins and specific bacterial proteins of said organisms”).

<sup>72</sup> Gabriel, *supra* note 65, at 592–93.

<sup>73</sup> Lietzan, *Innovation Paradox*, *supra* note 42, at 49–52.

<sup>74</sup> Geoffrey Marshall et al., *Streptomycin Treatment of Pulmonary Tuberculosis: A Medical Research Council Investigation*, 2 BRIT. MED. J. 769 (1948) (report of first such trial); Lietzan, *Innovation Paradox*, *supra* note 42, at 50–51.

<sup>75</sup> 21 Fed. Reg. 5576, 5578 (July 25, 1956) (promulgating 21 C.F.R. § 130.4, describing contents of application).

<sup>76</sup> Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780; see Lietzan, *Innovation Paradox*, *supra* note 42, at 52–54.

<sup>77</sup> Harold Clymer, *The Changing Costs of Pharmaceutical Innovation* (1965), reprinted in *THE ECONOMICS OF DRUG INNOVATION* (Cooper ed., 1970). The Commissioner of Food and Drugs confirmed in early 1968 that new drugs averaged seven years from the beginning

inventor must complete before starting human trials—became more rigorous and time consuming in the same decades.<sup>78</sup>

These developments distorted patent terms. By the late 1960s, average effective patent life for new drugs had dropped to 13.9 years, and it dropped to 12.4 years by the early 1970s.<sup>79</sup> By 1979, the average dropped to 9.5 years.<sup>80</sup> One study found that a quarter of the erosion in patent life was attributable to an increase in the time between patent filings and the start of clinical trials, when the inventor conducts preclinical testing.<sup>81</sup> Half of the erosion was attributable to an increase in the time between the start of clinical trials and regulatory approval.<sup>82</sup>

### 5. Scope of the Problem

The new administrative state distorted patents in several fields of technology. Since 1958, for instance, federal law has required premarket approval of food additives.<sup>83</sup> A food additive petition must establish that the additive is safe and accomplishes its intended use.<sup>84</sup> Generating these data and securing FDA approval can take six years or longer.<sup>85</sup> Since 1960, color additives used in food, drugs, devices, and cosmetics have been subject to a similar preapproval requirement.<sup>86</sup> The petition must contain chemical, toxicological, and environmental data,<sup>87</sup> and the premarket timeline is comparable.<sup>88</sup> Since 1962, a new animal drug has required an approved application showing safety and effectiveness for its labeled use.<sup>89</sup> The

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of clinical trials until FDA approval. Harold A. Clymer, *The Changing Costs and Risks of Innovation in Drug Development*, 13 RES. MGMT. 375, 381 (1970) (quoting James Goddard).

<sup>78</sup> See *infra* note 227.

<sup>79</sup> DAVID SCHWARTZMAN, *INNOVATION IN THE PHARMACEUTICAL INDUSTRY* 173 (1976).

<sup>80</sup> Martin M. Eisman & William M. Wardell, *The Decline in Effective Patent Life of New Drugs*, 24 RES. MGMT. 18, 20 (1981); see also Peter Barton Hutt, *The Importance of Patent Term Restoration to Pharmaceutical Innovation*, 1 HEALTH AFFS. 6, 16–17 (1982) (discussing studies); Leonard G. Schifrin, *Lessons from the Drug Lag: A Retrospective Analysis of the 1962 Drug Regulations*, 5 HARV. J.L. & PUB. POL'Y 91 (1982) (discussing studies).

<sup>81</sup> Eisman & Wardell, *supra* note 80, at 20.

<sup>82</sup> *Id.* A final quarter was because the Patent Office issued patents faster. *Id.*

<sup>83</sup> Food Additive Amendments of 1958, Pub. L. 85-929, 72 Stat. 1784 (1958).

<sup>84</sup> 21 U.S.C. §§ 348(b)(2), (c) (2012).

<sup>85</sup> INST. OF MED., *ENHANCING THE REGULATORY DECISION-MAKING APPROVAL PROCESS FOR DIRECT FOOD INGREDIENT TECHNOLOGIES: WORKSHOP SUMMARY* 29, n.230 (1999).

<sup>86</sup> Color Additive Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 397 (1960).

<sup>87</sup> 21 U.S.C. § 379e (2018); Andrew J. Zajac & Julie N. Barrows, *FDA's Regulation of Color Additives*, FOOD SAFETY MAG., Oct./Nov. 2017, <https://www.foodsafetymagazine.com/magazine-archive1/octobernovember-2017/fdae28099-s-regulation-of-color-additives/>.

<sup>88</sup> Brief for Procter & Gamble Co. as Amicus Curiae Supporting Petitioner, *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990) (No. 89-243), 1989 WL 1127523, at \*2.

<sup>89</sup> 21 U.S.C. §§ 360b(a)(1), (b), (d) (2018).



research and development process averages 6.5 years for drugs intended for companion animals and 8.5 years for drugs intended for livestock.<sup>90</sup> Since 1976, higher-risk medical devices have required premarket approval from the FDA.<sup>91</sup> The application must provide a reasonable assurance of the device's safety and effectiveness, which generally requires data from clinical trials.<sup>92</sup> The premarket process averages three to seven years from concept to market.<sup>93</sup> Other regulators apply premarket testing and approval requirements to patented products. Veterinary biologics—vaccines, diagnostic kits, and other products of biologic origin intended for veterinary use—require a license under the Virus, Serum, Toxin Act of 1913 issued by the Animal and Plant Health Inspection Service (APHIS).<sup>94</sup> The applications contain safety and effectiveness data,<sup>95</sup> which take an average of 5.5 years to generate.<sup>96</sup> No one may market a pesticide without a license from the Environmental Protection Agency (EPA), issued under the Federal Insecticide, Fungicide, and Rodenticide Act.<sup>97</sup> Applications contain data on product performance (effectiveness and usefulness) and potential risks to human health and the environment (safety).<sup>98</sup> Testing, development, and registration of a new pesticide can take eight to ten years.<sup>99</sup> Some new chemicals require premarket review by EPA under the Toxic Substances Control Act (TSCA).<sup>100</sup>

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<sup>90</sup> *About Animal Medicines: Pharmaceuticals*, ANIMAL HEALTH INST., <https://www.ahi.org/about-animal-medicines/pharmaceuticals> (last visited July 22, 2018).

<sup>91</sup> Medical Device Amendments of 1976, Pub. L. 94-295, 90 Stat. 539 (1976); 21 U.S.C. § 360c(a)(1)(C) (defining class III devices), § 360e (requiring premarket approval of class III devices).

<sup>92</sup> 21 U.S.C. § 360e; 21 C.F.R. § 814.20 (2015).

<sup>93</sup> Kyle M. Fargen et al., *The FDA Approval Process for Medical Devices: An Inherently Flawed System or a Valuable Pathway for Innovation?*, 5 J. NEUROINTERVENTIONAL SURGERY 269, 270 (2013).

<sup>94</sup> Pub. L. 430, 72 Stat. 832 (codified at 21 U.S.C. §§ 151–158).

<sup>95</sup> 9 C.F.R. § 102.3 (2010); Veterinary Services Memorandum 800.50 (Feb. 9, 2011).

<sup>96</sup> This number reflects the five veterinary biologics for which patent owners have sought patent term restoration under 35 U.S.C. § 156 (2018). For each product, APHIS published the number of days in the “regulatory review period,” which began when it authorized preparation of an experimental veterinary biologic and ended when it issued a license. *See* 68 Fed. Reg. 17,335 (Apr. 9, 2003); 68 Fed. Reg. 24,705 (May 8, 2003); 72 Fed. Reg. 52,847 (Sept. 17, 2007); 74 Fed. Reg. 37,000 (July 29, 2009); 82 Fed. Reg. 16,337 (Apr. 4, 2017).

<sup>97</sup> 7 U.S.C. § 136a (2018).

<sup>98</sup> 40 C.F.R. § 152.50; 40 C.F.R. § 152.80; *see generally*, ENVTL. PROTECTION AGENCY, PESTICIDE REGISTRATION MANUAL (2017), <https://www.epa.gov/pesticideregistration/pesticide-registration-manual>.

<sup>99</sup> *The Pesticide Marketplace: Discovering and Developing New Products*, PURDUE UNIVERSITY: PURDUE EXTENSION 10 (2006), <https://www.extension.purdue.edu/extmedia/PPP/PPP-71.pdf>.

<sup>100</sup> 15 U.S.C. § 2604 (2018); David Markell, *An Overview of TSCA, Its History and Key Underlying Assumptions, and its Place in Environmental Regulation*, 32 WASH. U. J.L. & POL'Y 333, 353 (2010).

### B. Policy Proposals to Address Patent Term Distortion

The idea of restoring patents shortened by regulatory testing and premarket approval requirements emerged during the Carter Administration. When he took office in 1977, President Carter launched a “Domestic Policy Review of Industrial Innovation,” on the theory that increasing innovation would reduce inflation, create jobs, and improve the country’s trade position.<sup>101</sup> The Secretary of Commerce chaired a Cabinet-level committee that coordinated the policy review and solicited the views of an advisory committee of outside experts.<sup>102</sup> “More than 150 senior representatives from the industrial, public interest, labor, scientific, and academic communities” convened in subcommittees during the fall and winter of 1978 to consider the effect of the federal government on industrial innovation.<sup>103</sup> Although industry dominated Carter’s Domestic Policy Review, pharmaceutical companies were not heavily involved.<sup>104</sup>

After seven public symposia in January 1979, the subcommittees submitted final reports. Two subcommittees addressed patent life for regulated industries.<sup>105</sup> *First*, a subcommittee considering environmental, health, and safety regulations voiced concern that new drugs with short expected patent life “cannot be developed economically” and “are not developed.”<sup>106</sup> It proposed that drug patent terms start with drug approval.<sup>107</sup> A public interest subcommittee, staffed by executives from organizations such as the Consumer Protection Association, responded to the suggestion that regulations cause commercialization delays, but focused on EPA and Occupational Safety and Health Administration (OSHA) regulations, suggesting that companies deluged these agencies with documents and bore some responsibility for the delay.<sup>108</sup> *Second*, a subcommittee considering patent policy proposed patent extensions.<sup>109</sup> This group, which did not limit its inquiry to drug patents or even regulated patentees, sought to “remedy”

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<sup>101</sup> U.S. DEP’T OF COMMERCE, ADVISORY COMM. ON INDUS. INNOVATION FINAL REP. iii (1979) [hereinafter CARTER REPORT]; see also CLAUDE E. BARFIELD, SCIENCE POLICY FROM FORD TO REAGAN: CHANGE AND CONTINUITY 30 (1982) (noting that policymakers sought to “reindustrialize” the country to improve its economic performance).

<sup>102</sup> CARTER REPORT, *supra* note 101, at ii–iii.

<sup>103</sup> *Id.* at iii.

<sup>104</sup> Senior executives from the industry filled the twenty-three positions on the environment, health, and safety subcommittee, but only four came from large drug companies. *Id.* at 37–38. Only one of the fifteen members of the patent policy subcommittee came from the pharmaceutical industry. *Id.* at 118–19.

<sup>105</sup> *Id.* at 149, 157.

<sup>106</sup> *Id.* at 59.

<sup>107</sup> *Id.*

<sup>108</sup> CARTER REPORT, *supra* note 101, at 87.

<sup>109</sup> *Id.* at 157, 162.

the “inequity” of patent terms starting before commercialization.<sup>110</sup> It proposed “compensation” equivalent to the “period of delay,” and “measured from the time an inventor has adequate evidence of commercial embodiment of the invention.”<sup>111</sup> The public interest subcommittee responded by asking, somewhat rhetorically, whether the patent term should also be *shortened* when patent owners fail to commercialize.<sup>112</sup> It again suggested that regulated patentees “fight” regulations and “deliver truckloads of documentation”—presumably also a reference to companies regulated by the EPA and OSHA—and argued that commercialization delays might *increase* if patents expired later.<sup>113</sup>

Separately, after hearing from a broad array of stakeholders, including the FDA and academics, the National Research Council of the National Academies of Science (NAS) issued a report recommending that policymakers address truncated patent life.<sup>114</sup> “Patent incentives,” it wrote in 1979, “might be employed to offset the negative impact on R&D incentives in highly innovative sectors like drugs and medical devices, which are also likely to be subject to particularly stringent forms of regulation over the foreseeable future.”<sup>115</sup> The report suggested that patent life start “when regulatory approval is granted, thereby restoring the effective patent life to the nominal life of 17 years.”<sup>116</sup>

### III. HISTORY OF THE HATCH-WAXMAN AMENDMENTS

Patent term extension was not a new idea. More than 1000 patents had been extended over the course of U.S. history.<sup>117</sup> Under the Patent Act of 1836, for instance, a patent owner could obtain a seven-year extension of the fourteen-year patent term by showing that, without fault or negligence, he had failed to obtain “reasonable remuneration for the time, ingenuity, and expense” of developing the invention and “the introduction thereof into use.”<sup>118</sup> After Congress eliminated the statutory extension authority in 1861,

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<sup>110</sup> *Id.* at 162.

<sup>111</sup> *Id.*

<sup>112</sup> *Id.* at 198.

<sup>113</sup> *Id.* at 86–87, 198.

<sup>114</sup> HENRY G. GRABOWSKI & JOHN M. VERNON, NAT’L ACAD. OF SCIS., *THE IMPACT OF REGULATION ON INDUSTRIAL INNOVATION* vii–ix (1979).

<sup>115</sup> *Id.* at 55.

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

<sup>117</sup> Indeed, more than 1100 patents had been extended by 1874. A complete list of extensions from 1790 to 1873 appears in 2 SUBJECT-MATTER INDEX OF PATENTS FOR INVENTIONS ISSUED BY THE UNITED STATES PATENT OFFICE FROM 1790 TO 1873, at 1912–25 (Leggett, ed. 1874).

<sup>118</sup> Act of July 4, 1836, 5 Stat. 124; *see also* Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent “Privilege” in Historical Context*, 92 CORNELL L. REV. 953 (2007) (discussing extensions under 1836 statute).

patent owners obtained extensions through private bills.<sup>119</sup> Many sought private extensions on the ground that they had not received sufficient profit during the statutory term.<sup>120</sup> The key House Committee decided in the 1870s that such an extension would be granted if the invention was valuable, the lack of adequate compensation stemmed from causes beyond the control of the inventor as well as a person of reasonable prudence and foresight, and the public would not be essentially injured.<sup>121</sup> In other cases, a 1978 congressional report explained that private relief was appropriate because the government had “a moral or ethical obligation toward the party.”<sup>122</sup>

Rather than this private patent extension history, however, the patent policy subcommittee cited the handling of secrecy orders under the Invention Secrecy Act of 1951.<sup>123</sup> Under this law, if disclosure of an invention might harm national security, the Commissioner of Patents must withhold the patent grant.<sup>124</sup> Prosecution of the patent continues until the patent could issue, but the patent does not issue.<sup>125</sup> Although an order lasts for one year, it can be renewed, and some last decades.<sup>126</sup> Meanwhile, the government may use the invention.<sup>127</sup> Once the government lifts the order and allows the patent to issue, the inventor receives the full patent term. The inventor may also receive compensation for the government’s use of the invention and for “damage” caused by the secrecy order.<sup>128</sup> Although the legislative history of

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<sup>119</sup> A private bill provides relief to a specific individual, corporation, or institution—typically an exemption from, or modification of, otherwise-applicable law. Congress also changed the patent term to seventeen years in 1861. Patent Act of 1861, Pub. L. No. 36-42, 12 Stat. 246.

<sup>120</sup> CHRISTINE P. BENAGH, CRS. HISTORY OF PRIV. PAT. LEGIS. H.R. 10 (1978), reprinted in *Private Patent Legislation: Hearing on H. R. 2882 before the Subcomm. on Courts, Civil Liberties, & the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 104–05 (1984) [hereinafter PRIVATE PATENT LEGISLATION].

<sup>121</sup> H.R. REP. NO. 45-177 (1879).

<sup>122</sup> PRIVATE PATENT LEGISLATION, *supra* note 120. The report cited extension of U.S. Patent No. 19,023 in December 1944 as a “classic example.” *Id.* This patent had been found invalid by a judge later convicted of taking payment for the verdict in question. *Id.* See generally Priv. L. No. 554, 58 Stat. 1095 (1944); *United States v. Manton*, 107 F.2d 834 (2d Cir. 1939).

<sup>123</sup> CARTER REPORT, *supra* note 101, at 157.

<sup>124</sup> 35 U.S.C. § 181 (2018).

<sup>125</sup> 35 U.S.C. § 181.

<sup>126</sup> 35 U.S.C. § 181; e.g., *Stein v. United States*, 135 F. Supp. 2d 265, 266 (D. Mass. 2001) (noting secrecy order from April 1973 to March, 2000.); *Am. Tel. & Tel. Co. v. United States*, 685 F.2d 1361, 1362 (Ct. Cl. 1982) (noting secrecy order from May 1949 to June 1975).

<sup>127</sup> 35 U.S.C. § 183 (2018).

<sup>128</sup> 35 U.S.C. § 183. Damage might include loss in market value because of the time shifting (for instance, because the technology became obsolete). Compensation is rare in practice. See Cynthia M. Ho, *Inoculation Inventions: The Interplay of Infringement and Immunity in the Development of Biodefense Vaccines*, 8 J. HEALTH CARE L. & POL’Y 111, 138 (2005).

the 1951 statute is thin,<sup>129</sup> courts generally characterize the goal as compensatory.<sup>130</sup> In theory, the statute restores the inventor to the position he would have occupied without the government's intervention.

The more analogous precedents might have been the statutes governing restoration of patents issued to soldiers. Under the World War I Patent Extension Act, any patent holder who served honorably in the military between April 6, 1917, and November 11, 1918, was eligible for a patent extension of three times his length of service.<sup>131</sup> The House Committee on Patents explained that the goal was to “extend the monopoly given to these men, if by reason of the fact that they were taken into service, they lost the income that they would otherwise have received, or if that income was reduced during the time spent in the military service.”<sup>132</sup> These men were “entitled” to an extension, and an extension of three times the length of service would be “equitable and just.”<sup>133</sup> Supporters of the legislation

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<sup>129</sup> The formal history comprises one published hearing with two witnesses, a brief House report, and a Senate report reprinting the House report. *Patent Disclosure: Hearings Before Subcomm. 3 on H.R. 4687, Comm. on the Judiciary*, 92d Cong. (1951); H.R. REP. NO. 82-1028 (1951); S. REP. NO. 82-1001 (1951). This legislation replaced predecessor legislation with similarly thin history. Under a 1917 statute, the government could impose a secrecy order that would last throughout World War I. Act of Oct. 6, 1917, ch. 95, 40 Stat. 394. During World War II but before the United States entered the war, Congress amended the statute to authorize secrecy orders lasting as long as national interest required, but the statute itself would expire in two years. Act of July 1, 1940, ch. 501, 54 Stat. 710. After the United States entered the war, Congress changed the language back, so that secrecy orders would last through the war. Act of June 16, 1942, Pub. L. No. 77-415, 56 Stat. 370. Congress passed a permanent law in 1951 because earlier orders remained in place, the government had imposed additional orders, and the Korean War had started. Pub. L. No. 82-256, 66 Stat. 3 (1952); see generally H.R. REP. NO. 96-1540, at 33–62 (1980) (recounting history of invention secrecy).

<sup>130</sup> *E.g.*, *Linick v. United States*, 104 Fed. Cl. 319, 320 (2012), *aff'd*, 515 F. App'x 892 (Fed. Cir. 2013) (mem.) (stating that Section 183 grants “a patent owner the right to seek ‘just compensation’ for damage caused by a secrecy order”); *Constant v. United States*, 223 Ct. Cl. 148, 155 (1980) (stating that overall purpose of Section 183 “seems to be to provide a comprehensive scheme for compensation to patent owners proving damages due to the issuance of a secrecy order”).

<sup>131</sup> Act of May 31, 1928, ch. 992, § 1, 45 Stat. 1012 (1928).

<sup>132</sup> H.R. REP. NO. 70-1314, at 2 (1928) (“When war was declared in April, 1917, and the conscription act was passed, all able-bodied men were called to the colors, including men who were the holders of patents; and it has developed that a few of them, at least had started to build organizations for the development of the invention on which a patent had issued, but the call to war caused a necessary abandonment of such organization, and the invention and development were left at a standstill while the men were in service.”).

<sup>133</sup> *Id.*; S. REP. NO. 70-1339, at 1 (1928) (containing identical language); see also *Extension of Time Limitations On Certain Patents: Hearing on S. 4927 Before the S. Comm. on Patents*, 69th Cong. 21 (1927) (hearing on an earlier version of the legislation) (“[T]he sovereign has the duty to perform those things which will inspire in the breasts of citizens the patriotism which it wants there and it has, in order to inspire that patriotism, always, from the first beginning of the history of states, the sovereign has rewarded service rendered and has always taken steps to see that the service rendered would not work an injustice to those who rendered the service.”) (statement of Senator Stewart); *id.* (“[T]he Government, as a sovereign

sometimes spoke of honoring a “contract” between the government and patent owners, but the thrust was that the government had chosen a different social goal and would make things right for the patent owners.<sup>134</sup>

The World War II Patent Extension Act was similarly meant “to provide for an extension of the life of patents issued to veterans of World War II, on the theory that their service would have in many cases precluded them an opportunity to exploit their patents during that period.”<sup>135</sup> Removal from their occupations “effectively deprived them off their freedom to exploit their patent rights.”<sup>136</sup> The extension for the second World War was limited to twice the veteran’s length of service.<sup>137</sup>

#### A. Patent Term Restoration

In April 1979, Representative Steven Symms (R-ID) introduced a two-page bill adopting the approach proposed by President Carter’s health and safety subcommittee.<sup>138</sup> The term of any patent issued for a new drug or animal drug would begin on the date of patent issuance but end on the earlier of either (a) seventeen years after drug approval or (b) twenty-seven years after patent issuance.<sup>139</sup> As a practical matter, the twenty-seven-year rule would cabin the patent term only if the patent issued more than ten years before drug approval. Otherwise, the seventeen-year rule would be the operative limit, and drug patent owners would enjoy the full seventeen years. The proposal can be analogized somewhat to the secrecy order framework. Like regulatory premarket requirements, a secrecy order precludes

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power, with all its ancient rights and justice and mercy will not permit an injury to be done”).

<sup>134</sup> E.g., *Extension of Time Limitations On Certain Patents: Hearing on S. 4927 Before the S. Comm. on Patents*, 69th Cong. 2 (1927) (statement of Arthur Rathjen, witness) (“[T]his legislation . . . is for the purpose of curing an inequity resulting from the fact that the United States Government violated a contractual relation with a certain class of citizens; that is, men who were drafted into the service of the United States”); *id.* (“We have not treated you just right. We made a contract with you. We did not keep it. We had something more important to do. We put you to doing something which we thought was of a great deal more importance. You could not develop your patent. And besides, your income was affected by it. We put you in the Army and you could not do it. But, we will keep our faith with you. We will keep our part of the contract.”).

<sup>135</sup> H.R. REP. NO. 81-1214, at 33 (1949); *see* Act of June 30, 1950, Pub. L. No. 81-598, 64 Stat. 316.

<sup>136</sup> § 1, 64 Stat. 316.

<sup>137</sup> *Id.*

<sup>138</sup> H.R. 3589, 96th Cong. (1979). Rep. Harold Sawyer (R-MI) had introduced similar language during a markup of legislation that became the Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980). He withdrew the amendment “with the understanding that the matter would be taken up in the 97th Congress after an opportunity for thorough education and study.” COMM. ON THE JUDICIARY, PATENT TERM RESTORATION ACT OF 1982, H.R. REP. NO. 97-696, at 6 (1982).

<sup>139</sup> This bill was referred to the House Committee on the Judiciary, and Congress took no further action.

commercialization of an invention.<sup>140</sup> After the PTO lifts the secrecy order, the patent lasts for a normal term. Giving regulated products seventeen years of effective patent life has the same effect. In both cases the patent is time-shifted but enjoyed in full.

The Symms bill launched a five-and-a-half-year-legislative process considering patent term restoration for regulated patent owners. It was, however, the only bill to specify a fixed term that would, by default, apply equally to all drug patents, as well as the only one that overtly aimed for a seventeen-year effective patent life. The Kastenmeier proposals, introduced in 1980 and 1981, instead took the approach urged by the patent policy subcommittee of tailoring the restoration to the time lost by each patentee, as the veteran statutes had done.<sup>141</sup>

### 1. The Kastenmeier Proposals

The Kastenmeier proposals applied to *any* product subjected to federal premarket regulatory review, including new drugs, new animal drugs, food additives, color additives, human and veterinary biological products, pesticides, and chemicals regulated under TSCA. Any patent covering such a product or a method of using such a product would be extended by an amount of time equal to the product's "regulatory review period."<sup>142</sup> The patent owner could recover only the portion of the regulatory review period after patent issuance, which meant that effective patent life could not exceed the statutory seventeen-year term.<sup>143</sup> These bills also limited the number of days the patent owner could recover; no extension could exceed seven years.<sup>144</sup> The drafters based this on the length of the average clinical testing program and application review period for new drugs.<sup>145</sup> The seven-year cap meant that if a particular product's premarket program took longer than the average program for new drugs, the patent owner would lose those patent

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<sup>140</sup> 35 U.S.C. § 186 (2018) (Disclosure of the invention—including through commercial sales—is a federal crime).

<sup>141</sup> Sen. Birch Bayh (D-IN) and Rep. Robert Kastenmeier (D-WI) introduced these bills in 1980. Patent Term Restoration Act of 1980, S. 2892, 96th Cong. (1980); Patent Term Restoration Act of 1980, H.R. 7952, 96th Cong. (1980). The bills were referred to the Senate Judiciary Committee and the House Committee on the Judiciary, respectively, and Congress took no further action. Sen. Charles Mathias (R-MD) and Rep. Kastenmeier re-introduced the bills in 1981. S. 255, 97th Cong. (1981); H.R. 1937, 97th Cong. (1981).

<sup>142</sup> A new drug "regulatory review period" lasted from the date the company asked permission to start clinical trials until the date the FDA permitted commercial sales. *E.g.*, S. 2892, 96th Cong. § 155(c)(4) (1980).

<sup>143</sup> *E.g.*, S. 2892, 96th Cong. §§ 155(c)(4), 155(a) (1980).

<sup>144</sup> *E.g.*, S. 255, 97th Cong. § 155(a)(2) (1981).

<sup>145</sup> Lourie, *Account*, *supra* note 24, at 528. Both the industry and FDA had shown that the time from the start of clinical trials to FDA approval averaged seven years in the late 1960s. *See supra* note 77. The legislative history does not explain why Kastenmeier capped restoration at the average experience.

years. Regardless of the cap, however, if a patent issued in the final seven years before the product received marketing approval, the inventor would enjoy seventeen years of patent life.

The Kastenmeier proposals borrowed more from the veteran statutes than from the secrecy order framework. The veteran statutes added years to the end of an already-issued patent, because the patentee had been unable to commercialize the patent due to participation in the war effort.<sup>146</sup> Patent-term restoration for regulated products would similarly add years to an already-issued patent and similarly because the patent owner could not commercialize the patent because of a federally-imposed obligation to perform tasks advancing different national priorities.

There are, however, distinctions. *First*, no federal law precluded the veteran from commercializing the patent during his service, which means that some may have enjoyed passive revenue during the war and still benefited from restoration. Although a regulated patent owner might receive royalties on its patent during the premarket period, this income would be modest because any licensee would be similarly unable to commercialize the invention. *Second*, veterans received two or three times the number of days lost to service in the war.<sup>147</sup> The legislative history does not explain the decision to multiply the days, but it may reflect the value placed on military service and the moral standing of veterans at the time. Or it may reflect an assumption that veterans lost more momentum in development of their inventions than just days of actual service. But it meant that a veteran's ultimate effective patent life—even excluding passive life during the war—could be more than the effective life enjoyed by others.

## 2. Bipartisan Support and Passage in the Senate

Throughout the policy-making process, supporters of patent-term restoration identified two rationales for acting. *First*, patent-term restoration would repair the incentive to innovate in regulated sectors of the economy.<sup>148</sup> *Second*, restoration would compensate the patent owner for the portion of the patent right sacrificed because of public policy objectives embedded in a

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<sup>146</sup> Some patent owners participated voluntarily; others did not. EXTENSION OF PATENTS HELD BY VETERANS OF WORLD WAR II, H.R. REP. NO. 81-124, at 34 (1949).

<sup>147</sup> The drafters of the World War I statute had proposed that all veterans receive seven years, but the bill evolved to tie each veteran's restoration to his days of service. *E.g.*, *Patents of World War Soldiers: Hearings Held Before the Comm. on Patents of the H.R.*, 90th Cong. 44 (1928).

<sup>148</sup> *E.g.*, *Health and the Env't Misc.—Part 2: Hearings Before the Subcomm. on Health and the Env't of the Comm. on Energy and Commerce*, 97th Cong., 305 (1981) (statement of Lewis Engman, President, Pharmaceutical Manufacturers Association) (discussing “substantial consumer benefits from the innovations which will be encouraged by patent term restoration”).



statute administered by another part of the government.<sup>149</sup> Some cast this in terms of preventing discrimination or inequity; regulated inventors should not be disadvantaged with shorter effective patent life than other inventors.<sup>150</sup>

Drug patent owners bolstered the case for restoration with empirical studies finding a decline in the rate of new drug introductions over the years when the effective patent life had grown shorter.<sup>151</sup> The most influential study was Professor Peltzman's 1974 paper connecting the decline to the 1962 amendments to the Federal Food, Drug, and Cosmetic Act (FDCA), which had introduced the formal requirement to provide substantial evidence of effectiveness.<sup>152</sup> Peltzman found that the number of new chemical entities dropped from an average of forty-three each year in the decade before the 1962 amendments to an average of sixteen after the amendments.<sup>153</sup> Working from different data sources, Professor Grabowski reported in 1976 that the average annual rate of new chemical entity introductions had dropped from fifty-six (between 1950 and 1961) to around seventeen after the 1962 law.<sup>154</sup> FDA leadership at first questioned the reports but soon confirmed a "declining number of new single entity drugs approved" in the United States.<sup>155</sup> By the late 1970s and early 1980s, when policymakers

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<sup>149</sup> COMM. ON THE JUDICIARY, THE PATENT TERM RESTORATION ACT OF 1981, S. REP. NO. 97-138, at 1 (1981) ("S. 255 would remedy this unintended and inequitable side effect by restoring to the term of the patent the time lost in complying with the government's premarket testing and review requirements"); *The Patent Term Restoration Act of 1983: Hearings Before the Subcomm. on Patents, Copyrights and Trademarks of the Comm. on the Judiciary*, 98th Cong. 15 (1983) (statement of Sen. Dennis DeConcini (D-Ariz.) ("I am a cosponsor of S. 1306, . . . because it . . . will restore the intent of the patent law to protect, for a set period of time, the rights of a creator [in] the fruits of his labor. . . . Instead of having 17 years in which to recover its investment, like firms in virtually all other industries, patent life is cut substantially, almost in half.")).

<sup>150</sup> *E.g.*, *The Patent Term Restoration Act of 1981—S. 255: Hearing Before the Comm. on the Judiciary*, 97th Cong. 61 (1981) (statement of Arthur Smith, General Counsel for the Office of Sponsored Programs at MIT) ("[T]here has evolved a pattern which, in practice, discriminates against one class of patentholders by insuring that they will not receive the benefits of the full 17-year patent life which is available to other patentholders"); S. REP. NO. 97-138, at 28 (statement of Gerald Mossinghoff, Acting Deputy Secretary of Commerce) ("The inequity to certain sectors of our industry, whose inventions are denied a full patent term due to Federal premarketing approval requirements, has been widely recognized.").

<sup>151</sup> *E.g.*, *Health and the Env't Misc.—Part 2: Hearings Before the Subcomm. on Health and the Env't of the Comm. on Energy and Commerce*, 97th Cong. 353–67 (1981) (statement of Lewis Engman).

<sup>152</sup> PELTZMAN, *supra* note 66, at 13–16.

<sup>153</sup> *Id.* at 13. Peltzman focused on the rate of new chemical entity introductions rather than the rate of application submissions. This is common in empirical accounts of innovation. The FDA approves most new chemical entity applications; attrition typically occurs before a company submits its marketing application, for instance because of failure in phase 2 or phase 3 trials. Lietzan, *Innovation Paradox*, *supra* note 42, at 78–79.

<sup>154</sup> HENRY GRABOWSKI, DRUG REGULATION AND INNOVATION: EMPIRICAL EVIDENCE AND POLICY OPTIONS 17–18 (1976).

<sup>155</sup> Compare Henry Grabowski, John Vernon, & Lacy Thomas, *Estimating the Effects of*

were considering the effective patent life problem, a substantial body of empirical literature verified the decline.<sup>156</sup>

Professor Peltzman's analysis showed that the new regulatory regime had reduced the annual flow of new drugs by about sixty percent.<sup>157</sup> The Commissioner of Food and Drugs suggested in 1978 that this reflected rejection of ineffective drugs that would have reached the market under the pre-1962 law.<sup>158</sup> Efficacy had always been a part of premarket review, however, even when it was not a formal statutory requirement.<sup>159</sup> And Peltzman found that the 1962 amendments had little impact on the incidence of ineffective drugs in the market.<sup>160</sup> He concluded that the marketplace before 1962 had imposed adequate penalties on sellers of ineffective drugs.<sup>161</sup> Professor Wiggins brought the data forward in 1981, finding that regulation had reduced new drug introduction rates in the 1970s by roughly sixty percent.<sup>162</sup>

Some economists criticized Peltzman's work—for instance, because he failed to account for a downward trend in innovation in the late 1950s,<sup>163</sup> or because his model did not include supply-side factors relating to the

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*Regulation on Innovation: An International Comparative Analysis of the Pharmaceutical Industry*, 21 J.L. & ECON. 133, 137 (1978) (quoting 1974 speech of Commissioner Schmidt that “[t]he rate of development and marketing of truly important, significant, and unique therapeutic entities in this country has remained relatively stable for the past 22 years”), with *Examination of the Pharmaceutical Industry, 1973-74, Part 1: Hearings on S. 3441 and S. 966 Before the Subcomm. on Health of the Comm. on Labor and Public Welfare, 93rd Cong., 272 (1973-74)* [hereinafter *Examination of Industry*] (statement of Comm’r Schmidt) (noting “declining number of new single entity drugs approved in the U.S.” and other countries).

<sup>156</sup> E.g., Leonard G. Schifrin & Jack R. Tayan, *The Drug Lag: An Interpretive Review of the Literature*, 7 INT’L J. HEALTH SERVS. 359, 371 (1977) (reviewing evidence, finding “a considerable possibility that a drug lag exists,” and noting that “both economic and medical analyses indicate that by delaying, occasionally for long periods, the availability of most new drugs, we have also denied their benefits to patients”).

<sup>157</sup> PELTZMAN, *supra* note 66, at 19.

<sup>158</sup> Donald Kennedy, *A Calm Look at the “Drug Lag,”* 239 J. AM. MED. ASS’N 423, 425 (1978) (noting that better understanding of pharmacokinetics, analytical toxicology, and the need to test for carcinogenic, mutagenic, and teratogenic effects leads to more extensive and longer-term safety testing before market approval, which results in a longer premarket program and some drug rejections).

<sup>159</sup> Lietzan, *Innovation Paradox*, *supra* note 42, at 49–50.

<sup>160</sup> PELTZMAN, *supra* note 66, at 45, 48.

<sup>161</sup> *Id.* at 48. In his view, the primary benefit of the 1962 law derived from the fact that mandatory premarket testing revealed a drug’s toxic effects before market entry. *Id.* at 31. Previously drug companies had borne a small proportion of the consumer cost for unusually harmful drugs, leading to over-production of those drugs. *Id.* at 52.

<sup>162</sup> Steven N. Wiggins, *Product Quality Regulation and New Drug Introductions: Some Evidence from the 1970s*, 63 REV. ECON. & STAT. 615, 617, 619 (1981). A literature review in the early 1980s reached the same conclusion. JOHN W. EGAN ET AL., *ECONOMICS OF THE PHARMACEUTICAL INDUSTRY* 133 (1982).

<sup>163</sup> E.g., Schifrin, *supra* note 80, at 94.

depletion of scientific knowledge.<sup>164</sup> For instance, the FDA contended that researchers had already identified many important therapeutic agents; the “gaps” in knowledge had thus decreased and further “opportunities” had declined.<sup>165</sup> In the late 1970s Professor Grabowski investigated the role of research depletion empirically, comparing new drug innovation in the United States with new drug innovation in the United Kingdom. This study confirmed that depletion of opportunities played a role but also found that U.S. regulatory requirements played a significant role.<sup>166</sup>

Supporters of patent term restoration attributed the decline in innovation to the increased time and cost to market that resulted from evolution in the premarket paradigm. In other words, the additional testing requirements increased the cost of bringing an invention to market and delayed commercialization, *and* the delay shortened the effective patent life during which the inventor could recover the now-increased investment. A Merck executive explained this in April 1981. The patent is the “predominant incentive” for pharmaceutical research and development.”<sup>167</sup> Indeed, “[t]he research budget authorized by Merck’s Board of Directors is directly related to the rewards dependent upon our patent system.”<sup>168</sup> The company was “becoming much more sensitive to the years likely to remain on the patent when a candidate for development is finally ready to be marketed.”<sup>169</sup> Thus, if all other considerations were equal, “a development candidate which may take an inordinate amount of development time, with a resultant loss of effective patent life, is going to be less attractive than one with a shorter projected development period.”<sup>170</sup> At Merck, “[a] patent term that is reduced by seven or more years is not a sufficiently strong investment

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<sup>164</sup> *E.g.*, GRABOWSKI, DRUG REGULATION, *supra* note 154, at 28.

<sup>165</sup> *Examination of Industry*, *supra* note 155, at 272; *see also* Kennedy, *supra* note 158, at 424 (arguing that the “wave of miracle drugs” in the 1940s and 1950s was not followed by a second wave “comprising drugs that can treat with the same degree of effectiveness” conditions such as cancer, arthritis, and cardiovascular disease, perhaps because of an “apparent exhaustion of certain basic knowledge in which the industry’s earlier breakthroughs were based”).

<sup>166</sup> Grabowski, Vernon, & Thomas, *supra* note 155. The authors found a significant decline in the number of new chemical entities discovered and introduced (per effective research and development dollar) in both countries after 1962, suggesting at least some decline in the United States stemmed from factors other than U.S. regulatory requirements. But it also found a six-fold productivity decline in the United States, compared to a three-fold decline in the United Kingdom, between 1960 to 1961, and 1966 to 1970. A regression analysis showed that U.S. regulatory requirements had a statistically significant and quantitatively important effect.

<sup>167</sup> *Health and the Env’t Misc.—Part 2: Hearings Before the Subcomm. on Health and the Env’t of the Comm. on Energy and Commerce*, 97th Cong. 321 (1981) (statement of Dr. Lewis H. Sarett).

<sup>168</sup> *Id.* at 322.

<sup>169</sup> *Id.*

<sup>170</sup> *Id.* at 322–23.

incentive for a management concerned about the increasing costs of R&D.”<sup>171</sup> In response to a question from Representative Thomas J. Bliley (R-VA), the witness identified research programs Merck had dropped because of shortened effective patent life: treatments for cystic fibrosis, myasthenia gravis, and emphysema.<sup>172</sup>

The push for patent term restoration drew support from the new Reagan Administration and research universities. The Reagan transition team’s Health Policy Advisory Group endorsed patent term restoration for new drugs in November 1980.<sup>173</sup> After Reagan took office in January 1981, his Secretary of Commerce established an intellectual property committee, chaired by the new Commissioner of Patents and Trademarks, Gerald Mossinghoff, which similarly urged patent term restoration.<sup>174</sup> The General Accounting Office (GAO) took a similar position, reporting in 1981 that the average effective patent life for new drugs was roughly ten years, and that these drugs needed twelve to nineteen years to break even and earn a competitive return on capital.<sup>175</sup> Research and development expenditures in the pharmaceutical industry are sensitive to expected returns and cash flow, it added, and patent term restoration would have “positive impacts on both.”<sup>176</sup> At hearings, university witnesses added that patent term restoration would benefit university patent holders, who need to attract industrial licensees to transfer technology invented on campuses.<sup>177</sup> Throughout the legislative process, supporters also had a powerful ally in the FDA.<sup>178</sup> As far

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<sup>171</sup> *Id.* at 323.

<sup>172</sup> *Id.* at 340; *see also* Lewis H. Sarett, *FDA Regulations and Their Influence on Future R&D*, 17 RES. MGMT. 18 (1974).

<sup>173</sup> Memorandum to William J. Casey et al., *Report of the Chairman of the Health Policy Advisory Group to President-elect Ronald Reagan* (Nov. 14, 1980), William J. Casey Papers, Box 299, Folder 11, Hoover Institution Archives, at 17 (“It is apparent that under existing legislation and regulation new drug research has diminished drastically within our own country. Legislation is needed . . . to . . . [e]xtend the patent life of pharmaceuticals to match the time lost in delays involved in obtaining FDA marketing approval.”); *see also* Marilou Sturges, *Cut! Chop! Energize!*, 1 PHARMACEUTICAL EXECUTIVE 21 (1981); Morton Mintz, *Laxalt, Reagan Advisers Differ on Drug Cost Plan*, WASH. POST. (Dec. 1, 1980), [https://www.washingtonpost.com/archive/politics/1980/12/01/laxalt-reagan-advisers-differ-on-drug-cost-plan/203bc473-8a68-4db3-865c-838be1f0b285/?noredirect=on&utm\\_term=.ad7e9eb111e1](https://www.washingtonpost.com/archive/politics/1980/12/01/laxalt-reagan-advisers-differ-on-drug-cost-plan/203bc473-8a68-4db3-865c-838be1f0b285/?noredirect=on&utm_term=.ad7e9eb111e1)

<sup>174</sup> Mossinghoff, *supra* note 24, at 188.

<sup>175</sup> GEN. ACCT. OFF., REPORT TO SENATOR MATHIAS (1981), *as reprinted in* COMM. ON THE JUDICIARY, THE PATENT TERM RESTORATION ACT OF 1981, S. REP. NO. 97-138, at 11 (1981).

<sup>176</sup> *Id.*

<sup>177</sup> *The Patent Term Restoration Act of 1981—S. 255: Hearing Before the Comm. on the Judiciary*, 97th Cong. 61–67 (1981) (statements of Arthur Smith, MIT, and Edwin Yates, Johns Hopkins University).

<sup>178</sup> *Health and the Env’t Misc.—Part 2: Hearings Before the Subcomm. on Health and the Env’t of the Comm. on Energy and Commerce*, 97th Cong. 343 (1981) (statement of

as the agency was concerned, “innovators typically lose years of patent exclusivity because of testing requirements and regulatory review.”<sup>179</sup> Concerned about “the paradox that the careful and time-consuming scientific review needed to confirm safety and effectiveness may be reducing incentives to develop drugs that come to [the] FDA for review,”<sup>180</sup> the agency supported patent term restoration “as a means of encouraging research.”<sup>181</sup>

Following an April 1981 hearing at which supporters made the case for restoration, the Senate Judiciary Committee favorably reported the Kastenmeier bill. “The patent has traditionally served as a major incentive for innovation,” it stated in its report.<sup>182</sup> The patent “provides an incentive for the costly and lengthy work of developing an invention by giving the inventor a sufficient opportunity to market a new product exclusively.”<sup>183</sup> Congress had “selected 17 years as the period which best fulfilled this objective.”<sup>184</sup> The “substantial erosion of the patent term for products subject to extensive Federal premarketing testing, notification, and review requirements,” however, “raises the serious question of whether the patent term continues to play its traditional role of encouraging innovation for these products.”<sup>185</sup> Firms “cannot commit funds to initiate long-term research projects unless they have reasonable assurances that money will continue to be available to pay for those projects in later years.”<sup>186</sup> Restoration would benefit downstream competitors; “successful measures to stimulate greater development and marketing of valuable new drugs will ultimately rebound to the benefit of companies who bring low-cost generic versions to the public by enlarging the stream of innovation they exploit.”<sup>187</sup>

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Richard Crout, Director, Bureau of Drugs) (agreeing that there had been “an erosion of the patent life” for regulatory reasons, and he would “favor” a “solution to the problem,” because “drugs are valuable commodities” and society needs “the right economic incentives for research on them”); *see also The Patent Term Restoration Act of 1981—S. 255: Hearing Before the Comm. on the Judiciary, 97th Cong. 2 (1981)* (noting that Secretary Schweiker had endorsed the objectives of the patent term restoration bill).

<sup>179</sup> *Drug Price Competition and Patent Term Restoration Act of 1984: Hearing on S.2748 Before the Comm. on Labor & Human Res., 98th Cong. 18 (1984)* (statement of Mark Novitch, Acting Comm’r of Food & Drugs).

<sup>180</sup> *Id.*

<sup>181</sup> *Id.* at 19.

<sup>182</sup> S. REP. NO. 97-138, at 6 (1981).

<sup>183</sup> *Id.*

<sup>184</sup> *Id.*

<sup>185</sup> *Id.*

<sup>186</sup> *Id.* at 7.

<sup>187</sup> *Id.* at 9.

Although incentive arguments dominated the policy discussion, arguments about the “fairness” of providing compensation and the need to ensure equal outcomes for all inventors also gave the Kastenmeier proposal momentum. The Assistant Commissioner of Patents argued that there was “absolutely no reason” why pharmaceutical companies and other companies subject to premarket requirements “should receive patents with a shorter effective patent life than is available to other industries.”<sup>188</sup> These sentiments informed legislative support at this stage as well. Representative Waxman commented, for instance, that “seventeen years is . . . the amount of time we say it is fair to have exclusive rights as the result of research and development not only in drugs but in all other areas.”<sup>189</sup> The Senate Judiciary Committee report commented that “[t]here is no valid reason for a better mousetrap to receive 17 years of patent protection and a lifesaving drug less than ten years.”<sup>190</sup> Patent term restoration would “remedy” a “simple but serious inequity in the patent system.”<sup>191</sup>

Support for the Kastenmeier proposals on both grounds was bipartisan in Congress, and the major newspapers endorsed restoration, citing both rationales.<sup>192</sup> Even the American Association of Retired Persons (AARP) agreed.<sup>193</sup> The Senate passed the Kastenmeier bill in July 1981 and referred the proposal to the House Committee on the Judiciary, which was already reviewing the companion bill in the House. A subcommittee of the House

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<sup>188</sup> *The Patent Term Restoration Act of 1981—S. 255: Hearing Before the Comm. on the Judiciary*, 97th Cong. 37 (1981) (statement of Rene D. Tegtmeyer, Acting Comm’r of Patents and Trademarks).

<sup>189</sup> *Health and the Env’t Misc.—Part 2: Hearings Before the Subcomm. on Health and the Env’t of the Comm. on Energy and Commerce*, 97th Cong. 368 (1981).

<sup>190</sup> COMM. ON THE JUDICIARY, THE PATENT TERM RESTORATION ACT OF 1981, S. REP. NO. 97-138, at 2 (1981).

<sup>191</sup> *Id.* at 1.

<sup>192</sup> *Extending Patents on New Drugs*, CHI. TRIB., Sept. 15, 1982 (“[A]rguments by consumer groups fail to take into account a number of important points . . . Consumers—and taxpayers who now pay such a big portion of medical bills—will benefit enormously from the development of new medications. Extending the life of patents will encourage drug companies to invest more in research and make more effective new medications possible.”); *Long Life to Patents*, WALL ST. J., May 28, 1981 (“There is a simple way to help restore R&D incentive to the drug industry: guarantee the full 17-year protection by starting the patent clock ticking *after* FDA approval, not before.”); *Patently Fair*, WASH. POST., May 20, 1981 (“But there are strong[] arguments in favor of patent life assurance. One is simple fairness. If 17 years is the right period for protecting the exclusive rights of inventors, there is no reason why those subject to federal regulation should be denied it solely by reason of that regulation.”); *The Half-Life Patents*, N.Y. TIMES, May 23, 1981 (“The system discriminates unfairly against some of the most important research-based industries.”).

<sup>193</sup> *E.g., The Patent Term Restoration Act of 1981—S. 255: Hearing Before the Comm. on the Judiciary*, 97th Cong. 291–92 (1981) (statement of the National Retired Teachers Association and the American Association of Retired Persons) (“We therefore can support S. 255’s restoration of the patent grant for the period of time—not to exceed seven years—that nonpatent regulatory requirements prevent the marketing of a potential product.”).

Judiciary Committee considered both bills through the fall and early winter of 1981.

### 3. Emergence of Opposition in the Winter of 1981-1982

Opposition to patent term restoration grew over the winter of 1981, fueled by the generic drug industry's new lobbying group, the Generic Pharmaceutical Industry Association (GPIA) and supported by its allies in the private and public sectors.<sup>194</sup> In the legislature, the generic companies had strong support from Representatives Waxman and Gore (D-TN), as well as Senator Metzenbaum (D-OH), among others. Chief among the private sector allies was Public Citizen, with supporting roles played by labor and groups representing senior citizens. Ralph Nader had founded Public Citizen in 1971 with the mission of protecting health, safety, and democracy. Sidney Wolfe had joined Public Citizen the same year and directed the Health Research Group, devoted to pressing for health-related legal reforms. Public Citizen, and Sidney Wolfe in particular, were deeply engaged in the battle against patent term restoration from the earliest days.

Opponents of patent term restoration made a variety of arguments at this stage, most of which they continued to make until enactment of the Hatch-Waxman Amendments in the fall of 1984. William Schultz, speaking on behalf of Public Citizen, argued from the very beginning that effective patent life should be *shorter*, rather than longer.<sup>195</sup> Others were more temperate, conceding the incentive role of the patent but questioning the economic justification put forward for restoration.<sup>196</sup> The AARP commented in 1981 that the "equity argument" was "reasonable" and "warrants consideration," but it was not "as convinced by the arguments based on economic disincentives."<sup>197</sup> The generic industry, in particular, questioned the empirical support for the proposals. William Haddad, then a member of the board of the newly formed Generic Pharmaceutical Industry Association, told Congress "we favor patent protection, but the case has yet to be made

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<sup>194</sup> Judee Shuler, *Bill Haddad*, 6 PHARMACEUTICAL EXECUTIVE 24, 27 (1986) ("The fight solidified GPIA.")

<sup>195</sup> *The Patent Term Restoration Act of 1981—S. 255: Hearing Before the Comm. on the Judiciary*, 97th Cong. 402–05 (1981) (statements of William B. Schultz, Attorney, Public Citizens Litigation Group, Accompanied by Benjamin Gordon, Staff Economist; and Fred Wegner, Pharmaceutical Specialist, American Association of Retired Persons and National Retired Teachers Association).

<sup>196</sup> *E.g.*, COMM. ON THE JUDICIARY, THE PATENT TERM RESTORATION ACT OF 1981, S. REP. NO. 97-138, at 63 (1981) (statement of William Haddad, President, GPIA) ("Research has not declined; innovation has not declined; patent life has not been cut in half.")

<sup>197</sup> *The Patent Term Restoration Act of 1981—S. 255: Hearing Before the Comm. on the Judiciary*, 97th Cong. 418 (1981) (statement of Fred Wegner, Pharmaceutical Specialist, Specialist, American Association of Retired Persons and National Retired Teachers Association).

that the industry is not getting this protection.”<sup>198</sup> If the innovators “make their case that delay requires additional patent life, [then] they should have additional life, but to date they have not made their case.”<sup>199</sup> The association’s outside counsel questioned the relevance of declining effective patent life, arguing that it did not correspond with declining exclusivity in the market.<sup>200</sup> The association argued that “actual average exclusive market life” for the 100 most widely used drugs ranged from sixteen to 18.5 years, largely because of patents on the product and method of use.<sup>201</sup>

This is an important point, but it needs historical context. Once the compound patent expired, a generic firm *could* market the compound. Nothing *required* it to pursue the same route of administration, dosage form, strength, or use.<sup>202</sup> And nothing required it to use the same manufacturing process. While many newer drugs may have enjoyed sixteen to eighteen and a half years on the market before another company introduced the same active ingredient in a competing product, this generally reflected business decisions made by individual generic companies. In part, this may have been because the applications were expensive to prepare. At the time, generic companies had to file the same kind of application as innovators filed.<sup>203</sup> That is, generic companies filed full new drug applications (“NDAs”), with the results of their own clinical trials, which cost millions of dollars to prepare. At least 100 newer drugs were off patent and lacked generic competition simply because generic companies would not invest in full clinical programs.<sup>204</sup>

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<sup>198</sup> *The Patent Term Restoration Act of 1981—S. 255: Hearing Before the Comm. on the Judiciary*, 97th Cong. 434 (1981) (statement of William Haddad).

<sup>199</sup> *Id.* See also *Drug Legislation: Hearings on H.R. 1554, H.R. 3605, H.R. 1055 and H.R. 1097 Before the Subcomm. on Health & the Env’t of the Comm. on Energy and Commerce*, 98th Cong. 51 (1983) (statement of Haddad) (“[I]f patent life has been retarded by Government regulations, it should be restored,” but the patent owners have not provided information to “prove” that case).

<sup>200</sup> Alfred Engelberg, *Patent Term Extension: An Overreaching Solution to a Nonexistent Problem*, 1 HEALTH AFFS. 34, 41 (1982).

<sup>201</sup> *Drug Legislation: Hearings on H.R. 1554, H.R. 3605, H.R. 1055 and H.R. 1097 Before the Subcomm. on Health & the Env’t of the Comm. on Energy and Commerce*, 98th Cong. 49 (1983) (statement of Kenneth Larsen, chair, GPIA); see also *Innovation and Patent Law Reform: Hearings on H.R. 3285, H.R. 3286 and H.R. 3605 Before the Subcomm. on Courts, Civil Liberties, & the Admin. of Justice of the Comm. on the Judiciary*, 98th Cong. 413, 420 (1984) [hereinafter *Innovation and Patent Law Reform*].

<sup>202</sup> It might prefer to introduce an identical copy, however, to take advantage of the new automatic substitution laws. These had not been enacted in every state. Henry Grabowski & John Vernon, *Substitution Laws and Innovation in the Pharmaceutical Industry*, 43 LAW & CONTEMP. PROBS. 43 (1979).

<sup>203</sup> See *infra* Section III.B.

<sup>204</sup> Mossinghoff, *supra* note 24, at 187.



Opponents of patent term restoration also questioned the connection between federal regulation and declining effective patent life, suggesting that drug firms would perform the research anyway. For instance, Senators Theodore Kennedy (D-MA) and Metzenbaum commented in 1981 that manufacturers “by their own admission engage in substantial testing of safety and efficacy to protect themselves against product liability and consumer fraud suits.”<sup>205</sup> Alfred Engelberg, who represented the generic industry association in the legislative process, added in an article that

the true length of government-caused delay is, in fact, no greater than the difference between the date on which a reasonably prudent businessman, subject to product liability claims, would commercially release a product and the date on which the government commercially releases the product by approval of a new drug application.<sup>206</sup>

These arguments would be made throughout the legislative debate. Senator Metzenbaum commented in 1983, for instance, that “[a]ny responsible firm would do tests to make sure that its products are safe and effective.”<sup>207</sup>

Professor Peltzman’s study had shown, however, that the research required by the FDA was more than the companies would do on their own.<sup>208</sup> The PTO, which consistently supported patent term restoration, responded directly to this criticism in 1983. Every year, the Commissioner of Patents reported that patent owners sought private relief from the legislature because they could not bring their invention to the market for one reason or another.<sup>209</sup> He explained that the Administration generally opposed relief for commercialization delays.<sup>210</sup> “[T]he patent system is kind of a fail-safe system itself,” he commented, and “the people who enter it take the chance that, for one reason or another, they may not be able to achieve the full seventeen years.”<sup>211</sup> The drug and agricultural chemical industries, however,

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<sup>205</sup> COMM. ON THE JUDICIARY, THE PATENT TERM RESTORATION ACT OF 1981, S. REP. NO. 97-138, at 22 (1981) (additional views of Sens. Kennedy & Metzenbaum).

<sup>206</sup> Engelberg, *supra* note 200, at 35.

<sup>207</sup> *The Patent Term Restoration Act of 1983: Hearings Before the Subcomm. on Patents, Copyrights and Trademarks of the Comm. on the Judiciary*, 98th Cong. 13 (1983); *see id.* at 44; *see also* COMM. ON THE JUDICIARY, PATENT TERM RESTORATION ACT OF 1982, H.R. REP. NO. 97-696, at 22 (1982) (dissenting views of Rep. Frank) (“Surely it is not equitable to expect the elderly and ill, who are often already in severe financial straits, to pay the price for patent extension, especially where the extension is not even necessary in order to promote the development of new drugs.”).

<sup>208</sup> *See supra* Section III.A.2.

<sup>209</sup> *The Patent Term Restoration Act of 1983: Hearings Before the Subcomm. on Patents, Copyrights and Trademarks of the Comm. on the Judiciary*, 98th Cong. 27 (1983) (statement of Gerald Mossinghoff).

<sup>210</sup> *Id.*

<sup>211</sup> *Id.*

were “a classic exception to that.”<sup>212</sup> While any inventor might perform modest testing, most of the premarket research and development program was required instead by federal regulations.<sup>213</sup>

Opponents made a related argument that restoring patents might not prompt more innovation.<sup>214</sup> In 1981, the Congressional Office of Technology Assessment (OTA), responding to an inquiry from Representative Waxman, wrote that restoration would “enhance” innovation incentives,<sup>215</sup> but the Office could not guarantee that innovation would increase.<sup>216</sup> Restoration might just “compensate” patent owners for research they would have done anyway.<sup>217</sup> Representative Gore complained in 1982 that patent term restoration would increase prescription drug prices “without any assurances whatever that any of the extra revenue derived would be reinvested in pharmaceutical R&D.”<sup>218</sup> When this argument was raised in 1983, the Commissioner of Patents similarly could not “guarantee” that restoration would lead to breakthroughs. There was, however, a “demonstrable period of time” during which marketing of drugs was “delayed beyond what most other inventions are.”<sup>219</sup> Moreover, “throughout the many years of its existence, our patent system has encouraged innovation through the incentives it provides.”<sup>220</sup> And “[a]s these incentives are diminished, so is the encouragement which the patent system might otherwise have provided.”<sup>221</sup>

Opponents also made two significant arguments about drug patenting practices, which—despite credible responses from supporters of restoration—had enough traction to prompt changes to the Kastenmeier drafts.

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<sup>212</sup> *Id.*

<sup>213</sup> *Id.* at 25.

<sup>214</sup> *Health and the Env't Misc.—Part 2: Hearings Before the Subcomm. on Health and the Env't of the Comm. on Energy and Commerce*, 97th Cong. 340 (1981) (“[W]hat evidence do we have that restoring or lengthening the patent term would reduce the decline in innovation?”); *id.* at 333 (“If we have patent term restoration legislation enacted, would Merck increase its research and development budget . . . by investing additional revenues in research and development?”).

<sup>215</sup> U.S. CONG. OFFICE OF TECH. ASSESSMENT, PATENT-TERM EXTENSION AND THE PHARMACEUTICAL INDUSTRY 45 (1981) [hereinafter OTA Report].

<sup>216</sup> *Id.* at 4.

<sup>217</sup> *Id.* at 65.

<sup>218</sup> Al Gore, Jr., *Patent Term Extension: An Expensive and Unnecessary Giveaway*, 1 HEALTH AFFS. 25, 32 (1982).

<sup>219</sup> *The Patent Term Restoration Act of 1983: Hearings Before the Subcomm. on Patents, Copyrights and Trademarks of the Comm. on the Judiciary*, 98th Cong. 17 (1983); *id.* at 22.

<sup>220</sup> *Innovation and Patent Law Reform*, *supra* note 201, at 47.

<sup>221</sup> *Id.*

*First*, they argued that drug inventors filed patents earlier than necessary, so that the shortened effective patent life was the inventors' own fault.<sup>222</sup> For instance, Representative Gore described a strong negative relationship between effective patent life and the period between patent filing and clinical trials.<sup>223</sup> He inferred that companies delayed clinical testing, which, he argued, should "end the debate over patent term extension."<sup>224</sup>

The relationship between the preclinical period and shortened effective patent life was well known. Eisman and Wardell had confirmed that one-quarter of the erosion of patent life was attributable to an increase in the time between patent filing and start of clinical trials.<sup>225</sup> Proponents of restoration simply disagreed about the significance of this finding.<sup>226</sup> The regulatory framework requires a company to perform preclinical testing sufficient to support an application to conduct human trials. This testing differs from, and is more extensive than, the testing needed to establish utility of a compound for patenting purposes. Patent owners viewed the lengthening gap between patent filings and clinical trials as a function of preclinical regulatory requirements becoming more complex and time consuming in the 1960s and 1970s.<sup>227</sup>

*Second*, opponents argued that drug inventors filed continuation applications to delay issuance, and thus patent expiry, which meant that the effective patent life was not so short after all.<sup>228</sup> Patent owners responded

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<sup>222</sup> *E.g.*, OTA Report, *supra* note 215, at 66.

<sup>223</sup> Gore, *supra* note 218, at 30.

<sup>224</sup> *Id.*

<sup>225</sup> Eisman & Wardell, *supra* note 80, at 20.

<sup>226</sup> *E.g.*, *Drug Legislation: Hearings on H.R. 1554, H.R. 3605, H.R. 1055 and H.R. 1097 Before the Subcomm. on Health & the Env't of the Comm. on Energy and Commerce*, 98th Cong. 129 (1983) (statement of Pharmaceutical Manufacturers Association (PMA) that the increase in regulatory requirements included preclinical research which can consume as many as four years).

<sup>227</sup> Before the 1960s, for instance, the FDA did not require nonclinical toxicology testing before human trials. 21 C.F.R. § 130.3 (1956). After 1963, the agency required the results of pharmacology and toxicology studies sufficient in kind, duration, and scope to show that it was reasonably safe to conduct a first-in-humans test and that the described trials would assure the safety and rights of the trial subjects. New Drugs, 28 Fed. Reg. 179 (Jan. 8, 1963) (to be codified at 21 C.F.R. pt. 130) (requiring investigational new applications to contain results of preclinical testing); Robert Temple, *Development of Drug Law, Regulations, and Guidance in the United States*, in GOVERNMENT REGULATION OF DRUGS 1645 (1994) (noting that in the 1960s the FDA settled on the animal toxicity studies needed to justify human testing); Nonclinical Laboratory Studies, 43 Fed. Reg. 59,986 (Dec. 22, 1978) (to be codified at 21 C.F.R. pt. 58) (adding good laboratory practice regulations to ensure scientific integrity and validity of laboratory data). And in the 1970s, the FDA published its first laboratory practices regulations, imposing substantial new requirements on all aspects of the planning, conduct, and reporting of preclinical studies, as well as inspection and disqualification of testing facilities. *Id.* at 59,986, 59,990, 60,013–25.

<sup>228</sup> *E.g.*, Engelberg, *supra* note 200, at 39.

that this misunderstood how drug discovery and approval work. Sometimes an initial discovery leads to a broad genus claim, following which the firm studies the entire family to identify new compounds within the family that are more likely to result in a finished product that can be brought through the regulatory process. The firm then prosecutes the individual compounds in continuing applications. In the summer of 1984, when opponents continued to make these arguments, an executive testifying for American Home Products offered an example.<sup>229</sup> The Squibb Corporation had patented the genus of 9-halosteroids and then developed two topical steroid products from the genus: Kenalog (triamcinolone acetonide) and Halog (halcinonide).<sup>230</sup> Prohibiting restoration of the patent claiming the novel active ingredient of the distinct drug product Kenalog—that is, requiring the firm to restore the earlier genus patent instead—would be inconsistent with the basic point of restoring patents compromised by regulatory requirements.<sup>231</sup> Even though it had discovered the steroid class, the firm could not commercialize the invention of triamcinolone acetonide until it developed a finished product (formulation of *triamcinolone acetonide* and appropriate inactive ingredients, route of administration, dosage form, and strength), ran *that* product through the premarket regulatory paradigm, and substantiated specific claims about *that* product for the regulatory labeling.<sup>232</sup> While the patents might be linked, the *regulatory* requirements for a triamcinolone acetonide product would not be different or less burdensome simply because the firm had earlier discovered the genus.

Objections to continuations must also be placed in historical context. Before Congress changed the patent term in 1995, continuation patents could mitigate the truncation of patent life from testing requirements. That is, a continuation slowed issuance of the patent, and if the patent issued later, it expired later. Even under the restoration proposals, however, a continuation patent could never have an effective patent life exceeding the nominal statutory term of 17 years. Although the restoration days would be added to a later expiry date, less of the patent term would have been lost to testing, so the company would receive fewer days in restoration.<sup>233</sup> In 1981, OTA

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<sup>229</sup> *Innovation and Patent Law Reform*, *supra* note 201, at 438–39 (statement of John R. Stafford).

<sup>230</sup> *Id.*

<sup>231</sup> *Id.*

<sup>232</sup> *See supra* Section II.A.

<sup>233</sup> For instance, suppose clinical trials for a new drug began in 1986, and suppose the FDA approved the drug in 1996. Consider a patent that issued on the day that trials started, in 1986. Before restoration this patent would expire in 2003. If the PTO restored all of the patent life consumed by testing, it would restore ten years, and the patent would expire in 2013. The new drug would therefore have a seventeen-year effective patent life, from 1996 to 2013. Now consider a patent that issued two years before FDA approval, thus in 1994. Before restoration this patent would expire in 2011. If the PTO restored all of the patent life

recommended a cap on restoration measured from the date of filing the first patent application, in order to eliminate the benefit from filing continuation patents, or “extensions of long duration.”<sup>234</sup> But as a mathematical matter, the effective patent life could never exceed seventeen years.<sup>235</sup> So by “extensions of long duration,” OTA necessarily meant simply “extensions that lead to 17 years of effective patent life.” The objection to use of continuations thus reflected a rejection of a basic goal of the proponents of patent term restoration: ensuring comparable patent terms for regulated patent owners.

#### 4. House Vote on the Proposal

In May 1982, Representative Kastenmeier introduced revised language.<sup>236</sup> As before, the proposal would restore up to seven years of patent life lost to testing and agency review.<sup>237</sup> At the urging of generic companies and Public Citizen, however, the bill included provisions to penalize patent owners for long intervals between patent filings and clinical trials and to discourage continuation applications.<sup>238</sup>

*First*, a patent owner would receive all of the regulatory review period after patent issuance until ten years after the earliest relevant patent application, but only half of the regulatory review period from years ten to twenty after the patent application.<sup>239</sup> *Second*, the extended patent term could not expire more than twenty-seven years after the earliest patent application.<sup>240</sup> Judge Lourie—then at SmithKline and chairing the patent policy committee of the innovative industry’s trade association, Pharmaceutical Manufacturers Associations (PMA)—explained the number shortly after enactment.<sup>241</sup> The PTO took an average of three years to process a patent application, Judge Lourie wrote, and the remaining premarket

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consumed by testing, it would restore two years, and the patent would expire in 2013. The new drug would again have a seventeen-year effective patent life, from 1996 to 2013. It could *never* have a longer effective patent life.

<sup>234</sup> OTA Report, *supra* note 215, at 66.

<sup>235</sup> See *supra* note 233.

<sup>236</sup> The subcommittee considering the bill held a markup in March and forwarded the revised language to the full committee in May in the form of a clean bill with a new number. H.R. 6444, 97th Cong. (2d Sess. 1982).

<sup>237</sup> *Id.* at 3 (proposing 35 U.S.C. § 155(a)(2)(B)).

<sup>238</sup> See COMM. ON THE JUDICIARY, PATENT TERM RESTORATION ACT OF 1982, H.R. REP. NO. 97-696, at 8 (1982) (“This amendment was designed to encourage companies to file and process U.S. patent applications expeditiously and to complete regulatory related testing as rapidly as possible.”); *id.* at 7 (explaining that these changes responded to criticisms from the generic industry and Public Citizen).

<sup>239</sup> H.R. 6444, *supra* note 236, at 2 (proposing that 35 U.S.C. § 155(a)(1) be amended to make the regulatory review period last from the start of clinical trials until FDA approval).

<sup>240</sup> *Id.* at 3 (proposing 35 U.S.C. § 155(a)(2)(B)).

<sup>241</sup> Lourie, *Account*, *supra* note 24, at 530.

process averaged seven more years.<sup>242</sup> The twenty-seven-year limit would allow the average experience to result in seventeen years of effective patent life.<sup>243</sup>

But the new approach meant that some companies would be unable to secure seventeen years of effective patent life for their drugs. If regulatory requirements led to a lengthy preclinical or clinical program, and the FDA approved the product more than ten years after the inventor filed his patent application, the company could no longer use a later-expiring continuation patent to secure seventeen years of effective patent life.<sup>244</sup> Under earlier proposals and the Senate's language, a continuation patent that issued in the final seven years before this drug's approval could enjoy a seventeen-year term after its lost years were restored.<sup>245</sup> This was no longer possible. This bill also limited a company to one patent per regulatory review period, meaning, effectively, one patent per product.<sup>246</sup> PTO did not object to capping the restoration of continuation patents, but it objected strenuously to limiting the patents eligible for restoration.<sup>247</sup>

The House considered the bill through the summer of 1982.<sup>248</sup> Public support was strong and included physician organizations (such as the American Academy of Dermatology, the American College of Cardiology, and the AMA), volunteer organizations devoted to improving health (such as the American Heart Association), academic institutions (such as Johns Hopkins University), medical schools and treatment centers (such as the University of Cincinnati Medical Center and the University of Wisconsin Medical School), government agencies (for instance, the EPA and FDA), and pharmacies (the National Association of Chain Drug Store), and wholesalers (the National Wholesale Druggists Association).<sup>249</sup> Supporters of the bill placed the bill on the suspension calendar.<sup>250</sup> In this scenario, a series of noncontroversial bills are bundled together for vote, and the time for debate

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<sup>242</sup> *Id.*

<sup>243</sup> *Id.*

<sup>244</sup> Again, the bill would have required the patent to expire twenty-seven years after the earliest application. If the FDA approved the product ten years after the patent application, the company would have seventeen years of effective patent life (as twenty-seven minus ten). If the approval process took longer, the company would have fewer years.

<sup>245</sup> These bills did not impose a twenty-seven year limit. They did impose a seven-year cap. *E.g.*, S. 255, 97th Cong. § 155(a)(2) (1981). If a patent issued in the final seven years before approval, the patent owner would receive back all of the years lost to the preapproval process. It would, therefore, enjoy its full 17-year statutory term.

<sup>246</sup> H.R. 6444, *supra* note 236 (proposed 35 U.S.C. § 155(a)(2)(C)).

<sup>247</sup> *See Innovation and Patent Law Reform, supra* note 201, at 388–89.

<sup>248</sup> *See* H.R. 6444, 97th Cong. (reported with amendments Aug. 4, 1982).

<sup>249</sup> COMM. ON THE JUDICIARY, PATENT TERM RESTORATION ACT OF 1982, H.R. REP. NO. 97-696, at 8–9 (1982).

<sup>250</sup> Mossinghoff, *supra* note 24, at 188; Interview with Bill Corr (Mar. 29, 2018).

of each bill is limited.<sup>251</sup> A two-thirds majority must vote to suspend the rules and pass the bill by voice vote.<sup>252</sup> If a bill fails to receive two-thirds support, it returns to the House Rules Committee and is put through the regular committee process.<sup>253</sup> Placement on the suspension calendar presumably reflected the fact that the Kastenmeier bill had strong bipartisan support and belief that the main objections from the prior winter had been addressed.

On September 15, a majority of the House voted for passage. But the bill fell five votes short of the supermajority needed.<sup>254</sup> Explanations vary. One account reports heavy fog at airports in the East and Midwest that delayed several members who would have supported the bill.<sup>255</sup> Another explains that Representatives Gore and Waxman worked the floor extensively on the day of the vote in order to defeat passage.<sup>256</sup> Both explanations could be true.

#### B. *Generic Industry Policymaking Defeats*

During these same years, the generic companies experienced a series of policymaking defeats that propelled them to organize and push for legislation advancing their own interests. These companies had marketed generic drugs since the 1930s. Many marketed generic drugs based on full applications containing clinical research, but, until the early 1980s, there were also two possibilities for market entry *without* research. Developments at the FDA and in the courts in the 1970s through the early 1980s foreclosed these possibilities. In the summer of 1983, Representative Waxman introduced legislation that would allow generic companies to reach the market earlier and on the basis of applications omitting clinical data. While patent term restoration legislation would have lengthened effective patent life, this legislation would *shorten* exclusivity in the marketplace for patented drugs. The arguments *against* patent term restoration became

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<sup>251</sup> Christopher M. Davis, *How Measures Are Brought to the House Floor: A Brief Introduction*, CONG. RES. SERV. (Sept. 16, 2005), <https://fas.org/sgp/crs/misc/RS20067.pdf>.

<sup>252</sup> Mossinghoff, *supra* note 24, at 188.

<sup>253</sup> *Id.*

<sup>254</sup> Lourie, *Account*, *supra* note 24, at 532.

<sup>255</sup> Although it proved challenging to verify the fog or flight delays, the fifty members of the House who did not vote included one of the bill's five sponsors, Jack Brooks (D-TX), as well as a half dozen Republicans from states on the East Coast and in the Midwest. *See* 128 CONG. REC. 23656-57 (Sept. 15, 1982) (*e.g.*, Lyle Williams, Elwood Hillis, Thomas Hartnett, Ed Bethune, and Skip Bafalis). At the same time, as Bill Schultz has pointed out to me, had the bill failed only because five supporting votes were delayed by weather, supporters could have brought the bill up for a new vote a few days later. Email from William B. Schultz to Erika Lietzan (May 12, 2018).

<sup>256</sup> Interview with Bill Corr (Mar. 29, 2018); *Representative Henry Waxman, Author of the Hatch-Waxman Act*, CLAUSE 8 21:44–23:18 (Oct. 11, 2018), <https://www.clause8.tv/>.

arguments *for* the generic drug pathway. From this moment forward, the generic companies and their allies dominated the policymaking process, and the Kastenmeier proposal never had another meaningful chance of passage.

### 1. Potential Pathways for Generic Drugs

Understanding why the generic companies mobilized suddenly on their own behalf in 1983 requires a description of the policymaking defeats in the 1970s and early 1980s, which in turn requires understanding the two possible pathways to market without safety and effectiveness data that evaporated in the early 1980s.

#### i. Two Pathways for Copies of Pre-1962 Drugs

The FDCA requires NDAs only for “new drugs.”<sup>257</sup> From 1938 to 1962, generic drugs reached the market without applications, on the theory that they were not new drugs in the first place. Thus, after one company brought a new drug to market under an NDA, other companies launched copies without submitting applications. Some concluded that the underlying drug was “generally recognized as safe” (thus, not a “new drug”) because of the NDA.<sup>258</sup> Others relied on written opinions from the FDA, known as “old drug opinions.”<sup>259</sup> After Congress amended the FDCA in 1962 to add an effectiveness requirement, the FDA withdrew these opinions.<sup>260</sup> But the statute still excluded not-new drugs from the NDA requirement. So the FDA decided to use rulemaking to determine which drugs were exempt.<sup>261</sup> The agency never finalized the proposal, however, because it was concerned about losing regulatory control over drugs that it exempted.<sup>262</sup>

Instead, it used rulemaking to develop an “abbreviated new drug application” (ANDA) pathway.<sup>263</sup> An ANDA would contain information

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<sup>257</sup> 21 U.S.C. § 355(a) (1938). From 1938 to 1962, “new drug” meant any drug not “generally recognized . . . as safe” under the conditions described in its labeling. 21 U.S.C. § 321(p) (1938). Since 1962 it has meant a drug that is not generally recognized as safe *and effective* under these conditions. 21 U.S.C. § 321(p) (1962). It also means a drug that *is* generally recognized as safe and effective but that has not been marketed to a material extent and for a material time under the conditions in its labeling. *Id.*

<sup>258</sup> PETER BARTON HUTT ET AL., *FOOD AND DRUG LA: CASES AND MATERIALS* 775–76 (4th ed. 2014).

<sup>259</sup> *Id.*

<sup>260</sup> New Drugs, 33 Fed. Reg. 7758 (May 28, 1968) (to be codified at 21 C.F.R. pt. 130).

<sup>261</sup> Drugs in Finished Dosage Form, 33 Fed. Reg. 7762 (May 28, 1968) (to be codified at 21 C.F.R. pt. 130).

<sup>262</sup> Condition for Marketing Human Prescription Drugs, 40 Fed. Reg. 26,142, 26,144 (June 20, 1975) (to be codified at 21 C.F.R. pt. 130).

<sup>263</sup> Food Additives, 34 Fed. Reg. 2672, 2673 (proposed Feb. 27, 1969) (to be codified at 21 C.F.R. pt. 121); New Drugs, 35 Fed. Reg. 6574 (Apr. 24, 1970) (to be codified at 21 C.F.R. pt. 130).



about the generic drug and its manufacturing process, and it would include bioavailability information and any preclinical or clinical data developed by the applicant relating to adverse effects.<sup>264</sup> The application would also confirm that the drug complied with specifications in an official compendium or that specifications and testing ensured the drug's identity, strength, quality, and purity.<sup>265</sup> But unlike an NDA, it would not contain clinical safety or effectiveness data.

A generic company could file an ANDA to copy a "new drug" that had been the subject of an NDA before the 1962 amendments, but only *after* the FDA reviewed the first drug and confirmed its effectiveness, which the agency did as part of its implementation of the 1962 amendments.<sup>266</sup> The FDA also expected companies already marketing copies to file ANDAs.<sup>267</sup>

#### ii. Copying Post-1962 Drugs

By 1975, the FDA had received over 6000 ANDAs for copies of pre-1962 innovator drugs.<sup>268</sup> Also, in the 1970s, patents on post-1962 drugs began to expire. Generic firms that wanted to market copies could not file ANDAs, however, because these were reserved for copies of pre-1962 drugs.

The FDA sought to fill the gap with a "paper NDA" pathway, which permitted generic companies to submit published literature as proof that their copies were safe and effective.<sup>269</sup> But as soon as the agency approved the first paper NDA, it faced litigation: suits from the innovative industry arguing, among other things, that the policy was inconsistent with the statute and, separately, that it required notice and comment rulemaking, as well as suits from generic companies seeking to compel approval of their paper NDAs after the agency stayed its policy.<sup>270</sup> Ultimately, the agency was permitted to proceed, but there was rarely enough information in the

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<sup>264</sup> New Drugs, 35 Fed. Reg. 6574, 6575 (Apr. 24, 1970) (to be codified at 21 C.F.R. pt. 130).

<sup>265</sup> New Drugs, 35 Fed. Reg. at 6575.

<sup>266</sup> Food Additives, 34 Fed. Reg. 2672, 2673 (proposed Feb. 27, 1969) (to be codified at 21 C.F.R. pt. 121).

<sup>267</sup> U.S. FOOD & DRUG ADMIN., GUIDANCE FOR FDA STAFF AND INDUSTRY: MARKETED UNAPPROVED DRUGS—COMPLIANCE POLICY GUIDE 10 (Sept. 19, 2011), <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm070290.pdf>.

<sup>268</sup> Condition for Marketing Human Prescription Drugs, 40 Fed. Reg. 26,142, 26,145 (June 20, 1975) (to be codified at 21 C.F.R. pt. 130).

<sup>269</sup> Response to Petition Seeking Withdrawal, 45 Fed. Reg. 82,052 (Dec. 12, 1980) (announcing and defending policy, and responding to petition asking it to withdraw policy); Response to Petition Seeking Withdrawal, 45 Fed. Reg. at 82,058 ("paper NDAs are based on published literature").

<sup>270</sup> Memorandum from Mary Francis Lowe to Mark Novitch (Jan. 23, 1981), *reprinted in Competition in the Drug Industry: Hearing Before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce, 97th Cong. 63–65 (1981)*.

published literature for a paper NDA strategy to work. This left two possibilities for generic firms: old drug status or expansion of the ANDA regulation. Innovators opposed both, on the ground that these policies would allow generic firms to “free ride” on their original research.<sup>271</sup> This, they argued, would be unprecedented.<sup>272</sup> The FDA had treated the safety and effectiveness data in NDAs as trade secret for decades, refusing to release the data or allow competitors to rely on them.<sup>273</sup>

The FDA seriously considered the old drug theory.<sup>274</sup> In the agency’s view, a quartet of Supreme Court rulings in 1973 broadly sustained its primary jurisdiction to determine the status of drugs.<sup>275</sup> In 1974, therefore, an agency official explained the plan.<sup>276</sup> The FDA would publish a monograph (regulation) specifying the conditions under which a particular drug could be marketed without premarket approval. The agency would begin with copies of pre-1962 drugs, but post-1962 drugs would eventually be covered.<sup>277</sup> In June 1975, the FDA promised that the proposal was imminent.<sup>278</sup> The next month, a federal court commented that the FDA “certainly” had the power to promulgate these regulations.<sup>279</sup> Concerned about the legal arguments raised by innovators, however, the agency never

<sup>271</sup> William W. Vodra, *The Drug Regulation Reform Act of 1978: Putting Some Economic Issues Into Different Contexts*, 1 *MANAGERIAL & DECISION ECON.* 184, 189 (1980).

<sup>272</sup> *Drug Legislation: Hearings on H.R. 1554, H.R. 3605, H.R. 1055 and H.R. 1097 Before the Subcomm. on Health & the Env’t of the Comm. on Energy and Commerce*, 98th Cong. 126 (1983) (statement of PMA).

<sup>273</sup> *E.g.*, Food and Drug Administration, 39 Fed. Reg. 44,602, 44,612 (Dec. 24, 1974) (“The Food and Drug Administration has on numerous occasions testified before Congress that current statutory prohibitions prevent disclosure of useful information contained in the agency’s files, and, particularly, data relating to the safety and effectiveness of drugs.”); Food and Drug Administration, 39 Fed. Reg. at 44,634 (“The Commissioner advises that, since 1938, it has been the consistent administrative interpretation that [section 301(j), which refers to trade secrets] can encompass animal and human data[.]”); *id.* at 44,635 (“[T]he Commissioner concludes that the provisions of 18 U.S.C. § 1905 and the trade secrets exemption to the Freedom of Information Act are clearly applicable to such data.”).

<sup>274</sup> Condition for Marketing Human Prescription Drugs, 40 Fed. Reg. 26,142, 26,146 (June 20, 1975) (to be codified at 21 C.F.R. pt. 130).

<sup>275</sup> *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973), *Ciba Corp. v. Weinberger*, 412 U.S. 640 (1973), *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645 (1973), *USV Pharm. Corp. v. Weinberger*, 412 U.S. 655 (1973); Condition for Marketing Human Prescription Drugs, 40 Fed. Reg. 26,142, 26,146 (June 20, 1975) (to be codified at 21 C.F.R. pt. 130) (explaining the FDA’s interpretation of the rulings).

<sup>276</sup> Mary A. McEniry, *Drug Monographs*, 29 *FOOD DRUG COSM L.J.* 166 (1974).

<sup>277</sup> *Id.* at 168–70.

<sup>278</sup> *See* Condition for Marketing Human Prescription Drugs, 40 Fed. Reg. 26,142, 26,146 (June 20, 1975) (to be codified at 21 C.F.R. pt. 130) (noting that the FDA decided “to proceed with the development of an old drug monograph system for regulating human prescription drugs” and stating that the FDA “anticipates that these regulations will be published as a proposal in the near future”).

<sup>279</sup> *Hoffmann-LaRoche, Inc. v. Weinberger*, 425 F. Supp. 890, 894 (D.D.C. 1975).

published the proposal. Instead it proposed *legislation* authorizing the creation of drug monographs, which would effectively exempt generic drugs from the NDA requirement.<sup>280</sup>

The FDA also considered permitting ANDAs for copies of post-1962 drugs. Indeed, in 1978, it announced it would draft regulations permitting these ANDAs.<sup>281</sup> Draft regulations were leaked to the press in early 1982.<sup>282</sup> Under this proposal, applications could be submitted, once the FDA issued a finding that a particular innovative drug product was “suitable” for ANDAs.<sup>283</sup> These ANDAs would contain the same information as ANDAs proposing copies of pre-1962 drugs.<sup>284</sup> The Bureau of Drugs proposed a fifteen-year waiting period, to ensure sufficient incentives for innovation, and it assumed a generic firm would need another two years to perform testing and secure approval.<sup>285</sup> Facing opposition from both sides, the FDA abandoned the effort.<sup>286</sup> Innovators objected to the fact that ANDAs would

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<sup>280</sup> See Vodra, *supra* note 271, at 194 (noting that the FDA proposed the legislation). Under the Drug Regulation Reform Act, a company could petition the FDA to issue a monograph describing drug products authorized for licensure under the monograph and specifying the labeling required. For the first five years after monograph publication, consent of the original NDA holder would have been required for market entry. S. 2755, 95th Cong. (introduced Mar. 16, 1978); H.R. 11611, 95th Cong. (introduced Mar. 16, 1978). Sen. Kennedy and Rep. Waxman reintroduced the bill in 1979. S. 1075, 96th Cong. (introduced Oct. 2, 1979); H.R. 4258, 96th Cong. (introduced May 30, 1979). The Senate passed the bill in October 1979 (with the five-year window changed to seven years. *Drug Legislation: Hearings on H.R. 1554, H.R. 3605, H.R. 1055 and H.R. 1097 Before the Subcomm. on Health & the Env't of the Comm. on Energy and Commerce*, 98th Cong. 113 (1983)). But the House took no action after committee referral.

<sup>281</sup> Abbreviated New Drug Applications, 43 Fed. Reg. 39,126, 39,128 (Sept. 1, 1978) (to be codified at 21 C.F.R. pt. 310 and 21 C.F.R. pt. 314) (announcing plan to “extend the ANDA concept at a later time to post-1962 drug products by publishing criteria for making such a determination about these drugs”); see also Abbreviated New Drug Applications for New Drugs Approved After October 10, 1962, 47 Fed. Reg. 1765, 1767 (Jan. 13, 1982) (to be codified at 21 C.F.R. pt. 314) (stating that the FDA would publish a notice of proposed rulemaking in March 1982 for ANDAs copying drugs approved after October 10, 1962).

<sup>282</sup> See *Post-1962 ANDA Reg Proposal in the Works Would Build In 15-Year Gap Between Pioneer Approval Date and Generic Eligibility for ANDA*, PINK SHEET, Mar. 8, 1982.

<sup>283</sup> Draft Proposed Rule, New Drugs Approved After October 10, 1962, for Human Use: Proposal to Accept Abbreviated New Drug Applications (Feb. 8, 1982) at 23, 27 (on file with author).

<sup>284</sup> *Id.* at 30.

<sup>285</sup> *Id.* at 24. Because “a 17-year period coincides with the statutory patent period,” the Bureau believed “it would provide an adequate period to maintain drug research and incentives.” *Drug Legislation: Hearings on H.R. 1554, H.R. 3605, H.R. 1055 and H.R. 1097 Before the Subcomm. on Health & the Env't of the Comm. on Energy and Commerce*, 98th Cong. 118 (1983) (statement of PMA, quoting FDA documents); see also *id.* at 19 (comments of Rep. Waxman); *id.* at 32.

<sup>286</sup> *Drug Legislation: Hearings on H.R. 1554, H.R. 3605, H.R. 1055 and H.R. 1097 Before the Subcomm. on Health & the Env't of the Comm. on Energy and Commerce*, 98th Cong. 116–25 (1983) (statement of PMA, quoting FDA documents). Although the FDA abandoned the effort to extend its ANDA regulation to post-1962 new drugs, the ANDA regulation for

rely on the data in their applications. Generic firms objected to the waiting period.<sup>287</sup> The Bureau of Drugs submitted the proposed regulations to the Secretary but the draft went no further.<sup>288</sup>

## 2. Developments in 1982 and 1983

The lack of an abbreviated pathway did not mean a lack of generic competition. Some generic companies filed full applications for copies of post-1962 drugs. The number of new generic prescriptions filled in 1980 was 6.8% more than it had been in 1979 and 275% more than it had been in 1966.<sup>289</sup> Generic drugs comprised 14.7% of all prescriptions filled by 1980, compared to 6.4% in 1966.<sup>290</sup> Various federal agencies worked with the states to facilitate the cost savings that these generic drugs promised. Between 1976 and 1979, nearly 80% of the states enacted automatic substitution laws, which would allow—or in some cases direct—pharmacists to substitute a less expensive drug product that was therapeutically equivalent to the prescribed product.<sup>291</sup> The FTC and the Department of Health, Education, and Welfare issued a model law in January 1979 to help the states develop legislation for drug product selection.<sup>292</sup> The FDA then began publishing an annual list of approved drug products and therapeutic equivalence determinations.<sup>293</sup>

Generic companies nevertheless continued to argue that once the FDA approved an NDA, the underlying active ingredient became a not-new drug that could be marketed by others without premarket approval. By the end of 1981, the courts of appeals were divided on the issue.<sup>294</sup> In March 1982, the Supreme Court granted the government's petition for *certiorari* in the Fifth Circuit *Generix* case, raising the possibility that it would confirm the FDA's view that generic drugs require applications.<sup>295</sup> During the same month, the FDA abandoned the idea of expanding its ANDA regulation to permit copies

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pre-1962 drugs remained on the books.

<sup>287</sup> *Id.* at 119 (statement of PMA, quoting FDA documents)

<sup>288</sup> *Id.*

<sup>289</sup> *Top 200 Drugs of 1980*, PHARMACY TIMES, April 1981.

<sup>290</sup> *Id.*

<sup>291</sup> Grabowski & Vernon, *supra* note 202, at 43.

<sup>292</sup> *See* Therapeutically Equivalent Drugs, 45 Fed. Reg. 72,582, 72,593 (Oct. 31, 1980) (to be codified at 21 C.F.R. pt. 20) (describing Model Act).

<sup>293</sup> U.S. FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) (1st ed. 1980).

<sup>294</sup> *United States v. Generix Drug Corp.*, 654 F.2d 1114 (5th Cir. 1981) (agreeing with generic industry that “new drug” refers to the active ingredient alone); *Premo Pharm. Lab. Inc. v. United States*, 629 F.2d 795 (2d Cir. 1980) (holding that “new drug” definition applies to finished products not just active ingredients).

<sup>295</sup> *United States v. Generix Drug Corp.*, 455 U.S. 988 (1982).

of post-1962 drugs.<sup>296</sup> Applications would need full safety and effectiveness research.

Two additional developments impelled the generic companies to seek legislative relief. *First*, in July 1982, a federal court in California ruled that manufacturing and testing generic doxycycline during the innovator's patent term, to obtain FDA approval to market after the patent term, infringed the patent.<sup>297</sup> The court had already found that International Rectifier Corporation (IRC) infringed Pfizer's patent on doxycycline by making, using, and selling generic doxycycline in the United States.<sup>298</sup> After the court issued an injunction, IRC used its infringing doxycycline to make substantial quantities of infringing products, which it tested for bioequivalence to Pfizer's product in order to seek FDA approval.<sup>299</sup> When Pfizer asked the court to hold IRC in contempt, IRC argued that its activities fell within the common law experimental use privilege.<sup>300</sup> In July 1982, the court rejected the argument.<sup>301</sup> Use of infringing doxycycline to manufacture and test infringing products and submit the resulting data to the FDA was designed to determine marketability, gain a commercial advantage, and indirectly promote product sales, so the experimental use privilege did not apply.<sup>302</sup>

*Second*, in March 1983 the Supreme Court ruled in *Generix*, agreeing with the FDA that generic drugs are new drugs that require approved applications.<sup>303</sup> The statutory inquiry whether a drug is "generally recognized as safe and effective" (and thus not-new) focuses on the finished drug product rather than the active ingredient.<sup>304</sup> A proposed generic drug product would therefore be a "new drug" even if the FDA had previously approved the active ingredient.<sup>305</sup> This decision ended the argument that generic companies could bring copies to market simply by citing approved products. A group of generic companies sued the FDA in June 1983, seeking to compel the agency to resume the ANDA rulemaking that it had abandoned and asking the FDA to approve copies of post-1962 drugs based on ANDAs.<sup>306</sup> Had the agency complied, however, it would have faced suit

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<sup>296</sup> See *supra* Section III.C.1.

<sup>297</sup> *Pfizer, Inc. v. Int'l Rectifier Corp.*, No. 73-58, 1982 WL 51039 (C.D. Cal. July 20, 1982).

<sup>298</sup> *Id.* at \*1.

<sup>299</sup> *Id.*

<sup>300</sup> *Id.*

<sup>301</sup> *Id.* at \*8.

<sup>302</sup> *Id.* at \*7.

<sup>303</sup> *United States v. Generix Drug Corp.*, 460 U.S. 453 (1983).

<sup>304</sup> *Id.* at 459.

<sup>305</sup> *Id.* at 460.

<sup>306</sup> *Complaint, Nat'l Ass'n of Pharm. Mfrs., Inc. v. Heckler*, No. 88-4817 (S.D.N.Y. June 24, 1983). The parties eventually agreed that the Hatch-Waxman Amendments mooted the case. *Stipulation and Order of Dismissal Without Prejudice, Nat'l Ass'n of Pharm. Mfrs.*,

from innovators.

### C. *Development and Passage of the Generic Drug Bill*

The vote on the Kastenmeier bill occurred in the fall of 1982, between the ruling in *International Rectifier* (July 1982) and the ruling in *Generix* (March 1983). The generic industry's chances of reaching the market without performing clinical trials after patent expiry were thus already waning. Bill Haddad, by now the president and chief executive officer of the new generic industry association, began to shift the group's focus to the impact of patents and exclusivity on drug prices.<sup>307</sup> Haddad was a veteran on the Hill, having worked for Senator Kefauver during the drug pricing hearings that preceded the 1962 amendments to the FDCA.<sup>308</sup> By early August, he had persuaded the major papers to reverse their positions and oppose patent term restoration.<sup>309</sup>

The more aggressive focus on pricing aligned with arguments that consumer groups—particularly Public Citizen—had been making all along. In 1981, for instance, Schultz had recommended compulsory licensing of drug patents three to five years after new drug approval, arguing that “the monopoly period is too long, not too short.”<sup>310</sup> With the encouragement of GPIA and Public Citizen, sympathetic members of Congress now focused on the high profit margin of the pharmaceutical industry.<sup>311</sup> This, then, could

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Inc. v. Heckler, No. 88-4817 (S.D.N.Y. Jan 7, 1985).

<sup>307</sup> CHRISTOPHER SCOTT HARRISON, *THE POLITICS OF INTERNATIONAL PRICING OF PRESCRIPTION DRUGS* 57–58 (2004) (noting that Haddad's strategy was to add the price dimension, which divided the support for patent term restoration).

<sup>308</sup> *Id.* at 57.

<sup>309</sup> *E.g.*, *An Unwarranted Patent Stretch*, N.Y. TIMES: ARCHIVES (Aug. 7, 1982), <https://www.nytimes.com/1982/08/07/opinion/an-unwarranted-patent-stretch.html> (“Congress has let itself be persuaded, after a hasty review, that the extension is fair and will foster innovation. But the drug industry's case is dubious. Its chief premise is that extension will restore the time unfairly lose from patent life by having to prove to the Government that new drugs are safe and effective. But the testing of drugs in animal and clinical trials is something that any responsible company would wish to do anyway.”); *Patents and Medicine*, WASH. POST, Aug. 5, 1982 (“In fact, there isn't much evidence that drug research has been stifled, and there should be no concern over the industry's profitability. Drug research is important, but so is encouraging competition and lower prices for consumers.”).

<sup>310</sup> *Health and the Env't Misc.—Part 2: Hearings Before the Subcomm. on Health and the Env't of the Comm. on Energy and Commerce*, 97th Cong. 406 (1981) (testimony of Sidney Wolfe and William Schultz).

<sup>311</sup> *E.g.*, Gore, *supra* note 218, at 30; *Competition in the Drug Industry: Hearing Before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 97th Cong. 8 (1981) (statement of Sidney Wolfe) (“I would estimate that most of these drugs by the time they come off patent will have yielded their manufacturers hundreds of millions of dollars, if not, in the case of several of them, billions of dollars in sales by the time they come off patent. That raises questions to me as to how much more protection of investments is needed.”); COMM. ON THE JUDICIARY, *THE PATENT TERM RESTORATION ACT OF 1981*, S. REP. NO. 97-138, at 21 (1981) (additional views of Sen. Kennedy and Sen. Metzenbaum) (noting

be another explanation for the failure of the Kastenmeier bill—the generic industry’s increased sense of urgency about a pathway to market and Haddad’s aggressive focus on drug prices, which aligned with arguments Public Citizen had been making. Indeed, Public Citizen now claims credit for defeat of the Kastenmeier bill, noting on its website that its “lobbying efforts halt[ed] plans to extend drug manufacturers’ monopolies on their products by up to seven years.”<sup>312</sup>

The vote on the Kastenmeier bill in September 1982 was nevertheless close. The Commissioner of Patents later called the vote “a wake-up call” for the generic companies.<sup>313</sup> They intensified their opposition to patent term restoration, and subsequent efforts to revive the Kastenmeier approach failed.<sup>314</sup> After the *Generix* decision in March, they turned to Representative Waxman for help with a statutory pathway for generic drugs.

Waxman had joined the House in 1975, making it clear that his priorities were health and environmental issues.<sup>315</sup> He had introduced the FDA’s Drug Regulation Reform Act in 1979 to create a monograph old-drug system for generic drugs, and he was quick to start the statutory process for abbreviated NDAs in July 1983.<sup>316</sup> His placeholder bill would have added one sentence to the new drug provision of the FDCA, exempting companies from the obligation to submit full applications for copies of drugs approved in the past, provided their abbreviated applications satisfy “appropriate standards of identity, strength, quality, purity, stability, bioavailability, and bioequivalence” in relation to the approved drug.<sup>317</sup> Over the summer, he convened a series of hearings in the House that mostly featured witnesses from or allied with generic companies.<sup>318</sup>

The discussions that followed, from July 1983 to May 1984, happened mostly behind closed doors.<sup>319</sup> The dynamics are important to understand.

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that pharmaceutical companies are “the Nation’s fourth most profitable industry”).

<sup>312</sup> *Accomplishments*, PUB. CITIZEN, <https://www.citizen.org/about/accomplishments/accomplishments-1885-1980> (last visited Oct. 24, 2018).

<sup>313</sup> Mossinghoff, *supra* note 24, at 188.

<sup>314</sup> *E.g.*, S. 1306, 98th Cong. (introduced May 17, 1983); H.R. 3502, 98th Cong. (introduced June 30, 1983).

<sup>315</sup> *See Waxman, Henry Arnold*, HISTORY, ART & ARCHIVES: UNITED STATES HOUSE OF REPRESENTATIVES, [http://history.house.gov/People/Listing/W/WAXMAN,-Henry-Arnold-\(W000215\)/](http://history.house.gov/People/Listing/W/WAXMAN,-Henry-Arnold-(W000215)/) (last visited Oct. 24, 2018).

<sup>316</sup> *See supra* note 280.

<sup>317</sup> H.R. 3605, 98th Cong. (introduced July 19, 1983).

<sup>318</sup> *E.g.*, *Drug Legislation: Hearings on H.R. 1554, H.R. 3605, H.R. 1055 and H.R. 1097 Before the Subcomm. on Health & the Env’t of the Comm. on Energy and Commerce*, 98th Cong. 51 (1983).

<sup>319</sup> Lewis Engman and Peter Hutt (president of and counsel to PMA, respectively) handled the discussions for the innovative industry, and William Haddad and Alfred Engelberg (president of and counsel to GPIA, respectively) represented the generic industry. Lourie, *Account*, *supra* note 24, at 534. Rep. Waxman and his staff were also deeply involved. Much

Patent owners had lost the vote on patent term restoration, which meant they could not secure its passage on their own. In addition, patent owners were seeking a remedy for the *loss* of their patent term, which meant that any offer would be better than the status quo, and they had nothing to bargain with—the only thing they could give, so to speak, was the opposite of what they sought, that is, exclusivity in the market. Because of the House vote, patent owners could make no credible threat of tabling the discussion and trying a more favorable Congress, and because they had nothing to offer, this would not have been an effective threat in any case. Furthermore, because the generic companies not only opposed restoration but sought the *opposite* outcome—not merely to defeat the push for longer patent life, but actually to *shorten* exclusivity in the market—the innovators would do well to cling to the status quo.

Patent owners and their allies continued to argue at hearings that restoration would restore incentives to innovate and ensure that regulated patent owners were not treated differently. Professor Grabowski explained, for instance, that patent term restoration would restore lost incentives.<sup>320</sup> Because patent term restoration “increases the expected returns from new drug innovation and also provides firms that are successful in new product introductions with increased profits and cash flow,” he told a Senate subcommittee, “we would expect it to lead to significant increases in R&D investments.”<sup>321</sup> The Administration remained firmly in support. For instance, the Deputy Commissioner of Food and Drugs testified in 1983 that eighteen percent of new drugs had five or fewer years of effective patent life remaining, and five to seven percent had no patent protection left.<sup>322</sup> The Commissioner of Patents explained that the Administration “recognizes the need for remedial action to increase innovation” and “strongly” supported enactment of patent term restoration.<sup>323</sup> One inventor “should not be treated differently from another.”<sup>324</sup>

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of the back-and-forth (especially beginning in January 1984) was leaked to and reported by the trade press.

<sup>320</sup> See *The Patent Term Restoration Act of 1983: Hearings Before the Subcomm. on Patents, Copyrights and Trademarks of the Comm. on the Judiciary*, 98th Cong. 130 (1983) (statement of Henry Grabowski).

<sup>321</sup> *Id.*

<sup>322</sup> *Drug Legislation: Hearings on H.R. 1554, H.R. 3605, H.R. 1055 and H.R. 1097 Before the Subcomm. on Health & the Env't of the Comm. on Energy and Commerce*, 98th Cong. 13–16 (1983) (statement of Mark Novitch).

<sup>323</sup> *The Patent Term Restoration Act of 1983: Hearings Before the Subcomm. on Patents, Copyrights and Trademarks of the Comm. on the Judiciary*, 98th Cong. 16 (1983) (statement of Gerald Mossinghoff).

<sup>324</sup> *Id.* at 17 (statement of Gerald Mossinghoff); see also *id.* at 17–18 (“Certain sectors of our industry dealing with technologies which are subject to premarket regulatory review, and among the most innovative of our industries, are not receiving the full benefit of the patent system to which they are entitled by virtue of having disclosed their inventions to the



A federal court ruling in October 1983 strengthened the generic industry's hand by *permitting* generic companies to engage in experimentation during the patent term.<sup>325</sup> Roche Products held a patent for flurazepam hydrochloride, the active ingredient in Dalmane. Bolar Pharmaceuticals imported five kilograms from a foreign manufacturer, intending to produce flurazepam capsules, which it would study for purposes of submitting its own application. It planned to apply to the FDA before patent expiry in January 1984, but it would not market the product until after patent expiry. The trial court ruled that Bolar's "limited experimental use of flurazepam" did not infringe Roche's patent.<sup>326</sup> Bolar had persuaded the court that its use was *de minimis* and that it would not realize any commercial benefit before patent expiry.<sup>327</sup> If Bolar could not begin the testing process until after patent expiry, the court commented, Roche would enjoy a *de facto* patent extension of several years, which was "not a right or benefit granted by the patent law."<sup>328</sup>

Negotiators agreed in principle in January 1984, but Waxman's first full draft—not circulated for comment until April 1984—caught patent owners off guard with provisions that had not been part of the agreement.<sup>329</sup> On April 23, while stakeholders were considering the language, the newly constituted United States Court of Appeals for the Federal Circuit reversed the New York ruling.<sup>330</sup> Bolar's manufacture and testing did *not* fall within the common law experimental use privilege. While Bolar was indeed performing experiments, "unlicensed experiments conducted with a view to the adaption of the patented invention to the experimenter's business" violate the patent owner's right to exclude others from using his invention. Bolar was not engaged in "scientific inquiry"—it had "definite, cognizable, and not insubstantial commercial purposes."<sup>331</sup> Although the court of appeals was sympathetic to complaints that regulatory approval requirements effectively extended the patent, it declined Bolar's invitation to create a "new

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public.").

<sup>325</sup> Roche Prod., Inc. v. Bolar Pharm. Co., 572 F. Supp. 255 (E.D.N.Y. 1983), *rev'd*, 733 F.2d 858 (Fed. Cir. 1984).

<sup>326</sup> *Id.* at 258.

<sup>327</sup> The New York court distinguished the California ruling, because IRC had reaped commercial value over a two-year period. *Id.* at 257.

<sup>328</sup> *Id.*

<sup>329</sup> Lourie, *Account, supra* note 24, at 534–35. See *ANDA/Patent Restoration Proposal Has Reached First Legislative Form: Discussion Draft Distributed in DC on April 5, After Two Months in the Mil*, PINK SHEET, Apr. 9, 1984 (referring to the draft as "the product of two months of work by Waxman's Health Subcmte. staff").

<sup>330</sup> *Bolar*, 733 F.2d at 858.

<sup>331</sup> *Id.* at 863.

exception” for “FDA-required testing.”<sup>332</sup>

With this ruling, Waxman’s language, which included an experimental use exception for a patent owner’s competitors, *reversed* settled law. The patent bar became “increasingly distressed” about this exception.<sup>333</sup> Legislative staff made only modest changes before releasing a second discussion draft, however, and left the exception in place.<sup>334</sup> The hostility of the drafts to drug patents prompted agrochemical companies to seek severance from the pending bill, but the drug patent owners did not have this option.<sup>335</sup> The primary negotiator for PMA, representing the innovators, later commented that he had “no leverage” after loss of the House vote, and that “negotiating” with Representative Waxman was “one of the worst experiences” of his career.<sup>336</sup> Further discussions did not materially improve prospects for drug patent owners.

Senator Orrin Hatch (R-UT) and Representative Waxman introduced the revised language on June 12 and 21, respectively, presenting it as a *fait accompli*.<sup>337</sup> The one-paragraph provision for generic applications had evolved into nearly thirty pages governing the content of, and procedures for, submission and review of abbreviated applications, as well as a complex scheme for premarket resolution of patent disputes between drug patent owners and generic applicants.<sup>338</sup> An abbreviated application would cite the innovator’s application and, rather than containing its own safety and effectiveness data, rely on the data the innovator had submitted.<sup>339</sup> For a new chemical entity approved between January 1982 and enactment, however, these data could not be used—the FDA could not approve an ANDA—until ten years had passed.<sup>340</sup> No other timing restrictions applied; the data in other innovator applications—whether approved before 1982 or after enactment—could be used immediately. The bill also reversed the Federal Circuit ruling, permitting a patent owner’s competitors to manufacture and test infringing

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<sup>332</sup> *Id.* at 863–64.

<sup>333</sup> Lourie, *Account*, *supra* note 24, at 540.

<sup>334</sup> *Id.* at 538.

<sup>335</sup> See H.R. 5529, 98th Cong. (introduced April 26, 1984) (proposing patent term restoration for animal drugs and biologics, pesticides, and chemicals regulated under TSCA).

<sup>336</sup> Email from Peter Hutt to Erika Lietzan (Aug. 21, 2017) (on file with author); *Representative Henry Waxman, Author of the Hatch-Waxman Act*, CLAUSE 8 30:11–30:45 (Oct. 11, 2018), <https://www.clause8.tv/> (“They did not have leverage after that loss and when I was chairman of the subcommittee.”).

<sup>337</sup> S. 2748, 98th Cong. (1984); H.R. 3605, 98th Cong. (1984) [hereafter JUNE LANGUAGE]; see also *PMA’s Engman and GPIA’s Haddad Will Explain Patent Restoration/ANDA Compromise at Rep. Kastenmeier’s Hearing June 6; PMA Endorses Bill*, PINK SHEET (June 4, 1984), <https://pink.pharmaintelligence.informa.com/PS006685>.

<sup>338</sup> JUNE LANGUAGE, *supra* note 337.

<sup>339</sup> *Id.* at proposed 21 U.S.C. § 355(j)(2)(A).

<sup>340</sup> *Id.* at proposed 21 U.S.C. § 355(j)(4)(D).

products during the patent term.<sup>341</sup>

The patent restoration provisions differed in four respects from proposals of the past. Every difference shortened the time that PTO would restore.

*First*, PTO would restore only half the clinical testing period (after patent issuance).<sup>342</sup> The Kastenmeier bill had applied a fifty percent recovery rule to clinical trials continuing more than ten years after the patent application. The average patentee would thus receive his lost time back and could enjoy the nominal seventeen-year term. Under the Waxman bill, in contrast, no drug inventor could ever receive all of his lost patent life back. Fifty percent of the patent term during testing was permanently forfeited. *Second*, PTO would restore no more than five years, no matter how long testing and FDA review took.<sup>343</sup> The notion of a cap was not new, but prior bills had restored every day of lost life and applied a cap based on average clinical experience, ensuring that the average firm would enjoy the nominal seventeen-year term. The generic drug bill applied the cap *after* the fifty percent penalty, and the number was arbitrary.<sup>344</sup> The cap had no function other than to reduce the amount of patent life restored.

*Third*, total effective patent life would be limited to fourteen years.<sup>345</sup> The bill imposed a number lower than the nominal patent term and the effective patent life enjoyed by other inventors. No one pretended this was anything but an effort to shorten the patent life of drugs.<sup>346</sup> The head of the generic trade association later commented that restoring even just seven years of the lost patent term “would have destroyed the generic industry.”<sup>347</sup> In other words, even after the bill gave generic companies the right to rely on innovator testing data *and* the right to make and use patented drugs for testing during the patent term, drug inventors would have to enjoy a shorter patent term than other inventors for generic companies to have a viable

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<sup>341</sup> *Id.* at proposed 35 U.S.C. § 271(e)(1).

<sup>342</sup> *Id.* at proposed 35 U.S.C. § 156(c)(2).

<sup>343</sup> *Id.* at proposed 35 U.S.C. § 156(g)(4).

<sup>344</sup> Mossinghoff, *supra* note 24, at 191 (“numbers pulled out of the air”); Interview with Bill Corr (Mar. 29, 2018) (characterizing the numbers as “just balancing”).

<sup>345</sup> JUNE LANGUAGE, *supra* note 337, at proposed 35 U.S.C. § 156(c)(3).

<sup>346</sup> There were precedents for the number, to be sure. Before 1861, the initial term of a utility patent had been fourteen years. An Act to Promote the Progress of Useful Arts, § 1, 1 Stat. 109, 110 (Apr. 10, 1790). Today design patents last fifteen years. 35 U.S.C. § 173. But the legislative history does not suggest either precedent was considered. The Commissioner of Patents later reported that the number was arbitrary. Mossinghoff, *supra* note 24, at 191. An economist involved in the discussions reports “folklore” that Haddad “at hearings put up a poster showing that many leading products had a life of 14 years before being largely supplanted by brand competition and that was the basis” for the 14-year limit. Email from Henry Grabowski to Erika Lietzan (Aug. 25, 2017) (on file with author).

<sup>347</sup> Shuler, *supra* note 194, at 27.

business model. *Finally*, the bill limited the patents that could be restored, generally disallowing extension of a patent if the compound had been claimed in an earlier issued patent.<sup>348</sup> This reflected the generic industry's complaints about drug patenting practices, but it would not survive the summer.

With the national conventions and upcoming presidential election preoccupying policymakers and compressing the legislative schedule, Senator Hatch informed the innovative trade association that the generic drug provisions would be enacted with *or without* their support.<sup>349</sup> PMA's board of directors voted, narrowly and over vigorous objection, to endorse the legislation.<sup>350</sup>

The House Energy and Commerce Committee reported the language the day it was introduced, after a hearing that "lasted barely thirty minutes."<sup>351</sup> Representative Bliley complained, calling it "distressing and regrettable that this Committee has reported a complex, lengthy, and highly significant piece of legislation without holding hearings in either the Health Subcommittee or in the full Committee and after what can only be described as a pro forma markup."<sup>352</sup> Six days later, on June 27, a subcommittee of the House Judiciary Committee held a hearing at which the Patent Office objected to the provision disallowing restoration of later-issued patents and to the experimental use exception.<sup>353</sup> Although the two industry trade associations endorsed the legislation, a substantial group of innovators—the ten largest members of PMA—dissented on the same grounds and also objected to use of their testing data.<sup>354</sup> These objections were bolstered by the Supreme Court's decision in *Ruckelshaus v. Monsanto*, released the same week, which confirmed that the takings clause of the Fifth Amendment

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<sup>348</sup> JUNE LANGUAGE, *supra* note 337, at proposed 35 U.S.C. § 156(a)(4).

<sup>349</sup> Engelberg, *supra* note 20, at 396.

<sup>350</sup> See *PMA's Engman and GPIA's Haddad Will Explain Patent Restoration/ANDA Compromise at Rep. Kastenmeier's Hearing June 6; PMA Endorses Bill*, PINK SHEET (June 4, 1984), <https://pink.pharmaintelligence.informa.com/PS006685> (reporting a May 31 vote within PMA of 22 to 12 in favor of the Waxman legislation).

<sup>351</sup> See *Senate Labor & Human Resources Cmte. Hearing on Patent Restoration/ANDA Bill Set for June 28; Waxman Proposal Clears House Commerce Cmte. June 12*, PINK SHEET, June 18, 1984 ("Waxman asked 'unanimous consent' that the compromise amendment be considered as read, and then plunged into an explanation of the legislation before Luken could make a point of order assertion. Dingell then ruled that Luken had not made his point of order in a timely manner, and then cmte. quickly proceeded to the vote. Only Rep. Bliley (R-Va.) voted no.").

<sup>352</sup> H.R. REP. NO. 98-857, pt.1, at 76 (1984) (minority views of Mr. Bliley); see also *id.* at 76 ("We do this institution a disservice by hastily reporting on the very day of introduction, a complex bill outside the expertise of the Committee after a 'markup' that lasted barely thirty minutes.").

<sup>353</sup> *Innovation and Patent Law Reform*, *supra* note 201, at 385–404.

<sup>354</sup> *Id.* at 423–513.

protects some testing data submitted to federal regulators.<sup>355</sup> The Senate Committee on Labor and Human Resources held a brief hearing on June 28, with a few of the same witnesses.<sup>356</sup> Supporters of the legislation, including the generic trade association, emphasized that the compromise was “delicate” and should not be dismantled.<sup>357</sup>

Few changes were made in the summer. Arguments that the legislation reflected a delicate “balance” held sway, given the time pressures.<sup>358</sup> In July, for instance, the House Judiciary subcommittee rejected—on party lines—the Patent Office’s proposal to replace the later-issued patents restriction with an outer limit of expiry twenty-five years after the first patent application.<sup>359</sup> The subcommittee also rejected a proposal that retroactive application of the experimental use exception be a condition of patent term restoration.<sup>360</sup> All proposed amendments failed, except a proposal to delete animal drugs from the bill—these patent owners now had more favorable treatment in a freestanding bill.<sup>361</sup> The full House Judiciary Committee reported the bill on July 31, with one minor amendment.<sup>362</sup> A vote in the House was scheduled for the week of August 6.<sup>363</sup>

The Senate Judiciary Committee had not yet marked up the Senate version of the bill. In this first week of August, with adjournment for the Republican Convention looming, Representative Waxman and Senator Hatch brokered a handful of additional and more significant changes.<sup>364</sup> The ten dissenting drug companies had argued, with academic support, that the experimental use provision would be an uncompensated taking of private property.<sup>365</sup> To ensure their support of this potentially unconstitutional

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<sup>355</sup> Ruckelshaus v. Monsanto Co., 467 U.S. 986, 991–93, 1012–13 (1984).

<sup>356</sup> *Drug Price Competition and Patent Term Restoration Act of 1984: Hearing on S.2748 Before the Comm. on Labor & Human Res.*, 98th Cong. 18 (1984). The FDA testified at this hearing.

<sup>357</sup> *Innovation and Patent Law Reform*, *supra* note 201, at 422 (Rep. Sawyer: “I was just going to say, in the 8 years that I have been here, I have never seen a compromise that wasn’t a delicately balanced compromise, which is code for ‘Keep your damn hands off it.’” Mr. Haddad: “Well put. Well put.”).

<sup>358</sup> Lourie, *Account*, *supra* note 24, at 546.

<sup>359</sup> *Id.* at 545–46 (all Democrats opposed).

<sup>360</sup> *Id.* at 545.

<sup>361</sup> *Id.* at 546.

<sup>362</sup> *Id.*

<sup>363</sup> *Id.*

<sup>364</sup> See Engelberg, *supra* note 20, at 405; Shuler, *supra* note 194, at 29–30; Alan D. Lourie, *A Political History of Patent Term Restoration Part II*, PHARMACEUTICAL EXECUTIVE, Feb. 1985, at 52.

<sup>365</sup> *Innovation and Patent Law Reform*, *supra* note 201, at 437–43; see *id.* at 513–22 (testimony and written statement of Professor Dorsen); *id.* at 721–38 (analysis of Professor Monaghan); see also Engelberg, *supra* note 20, at 405 (noting that Professor Tribe concluded the provision was unconstitutional).

provision, the drafters eliminated the patent term restoration limitation to first-issued patents.<sup>366</sup> Although it would never be possible to achieve a seventeen-year patent term, it might now be possible to reach fourteen years with a continuation patent.<sup>367</sup> Responding, in part, to arguments about the constitutionality of using innovator data grounded in the *Monsanto* ruling, the drafters also delayed generic applicant reliance on these data for five years after FDA approval of a new chemical entity.<sup>368</sup> They also added a separability provision.<sup>369</sup>

The patent litigation provisions were similarly the subject of intense negotiation until the very end.<sup>370</sup> The legislation created an artificial act of infringement, giving the companies an opportunity to obtain certainty about infringement (and any defense of invalidity) *before* generic market launch.<sup>371</sup> It also provided incentives for generic companies to engage in this premarket litigation. The first generic company to challenge an innovator's patent (by arguing that its product did not infringe or that the patent was invalid) was eligible for 180 days of exclusivity in the marketplace.<sup>372</sup> If the innovator's drug was a new chemical entity, any generic company that challenged the patent could file four years—rather than five years—after NDA approval.<sup>373</sup> The legislation also encouraged the innovator—if the innovator converted this challenge promptly into litigation, FDA approval of the generic drug would be stayed for a fixed period of time (or until a court decision, if the decision came first).<sup>374</sup> In the final negotiations of August 1984, this automatic stay was lengthened from eighteen months to thirty months, which counsel for Public Citizen viewed as a “major give” to the patent owners.<sup>375</sup>

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<sup>366</sup> See Engelberg, *supra* note 20, at 404–05.

<sup>367</sup> As explained, a continuation patent could issue later — perhaps within a few years of FDA approval. Because the patent term was seventeen years from patent issuance, this patent would also expire later. As noted, this language imposed a fourteen-year limit on effective patent life. Thus the patent owner could use restoration to extend the patent until fourteen years after FDA approval.

<sup>368</sup> S. 2926, 98th Cong. (introduced Aug. 9, 1984) (proposed 21 U.S.C. § 355(j)(4)(D)(ii)); 130 CONG. REC. 23,769 (Aug. 10, 1984); Lourie, *supra* note 364, at 54.

<sup>369</sup> Lourie, *Account*, *supra* note 24, at 547; Engelberg, *supra* note 20, at 406.

<sup>370</sup> Lourie, *Account*, *supra* note 24, at 547.

<sup>371</sup> 35 U.S.C. § 271(e)(2)(A) (1984).

<sup>372</sup> 21 U.S.C. § 355(j)(5)(B)(iv) (1984).

<sup>373</sup> § 355(j)(4)(D)(ii).

<sup>374</sup> § 355(j)(5)(B)(iii).

<sup>375</sup> Email from William B. Schultz (May 12, 2018). Rep. Waxman characterized this change as pivotal. 130 CONG. REC. 24,410, 24,430 (1984) (“The change from 18 to 30 months was a change that brought on the dissident groups within the PMA and has brought us to a package now that we can say with confidence is opposed by no one and backed by all of the groups concerned . . .”).

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The parties reached agreement in the final hour before the language had to be introduced.<sup>376</sup> Senator Hatch introduced the new language on August 9, and the Senate passed the bill on August 10.<sup>377</sup> The House made several changes, including removal of the separability provision, passing the bill by a vote of 362 to 0 on September 6.<sup>378</sup> The Senate approved the House language by voice vote on September 12.<sup>379</sup> President Reagan signed on September 24.<sup>380</sup>

*D. Splinter Legislation*

Curiously, during this same time period Congress enacted four additional laws restoring specific patents for companies regulated by the FDA and USDA. The failed Kastenmeier bill had covered one of these situations. The Hatch-Waxman bill covered a third until the House made its final set of changes.

In January 1983, Congress restored nearly six years to the patent covering the food additive aspartame.<sup>381</sup> Had it passed, the Kastenmeier bill would have provided the company relief.<sup>382</sup> Approval of the patent owner's petition had been delayed while the FDA considered data integrity issues raised by a third party.<sup>383</sup> A review of the facts gives off a slight whiff of

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<sup>376</sup> See Shuler, *supra* note 194, at 29–30 (“Finally there were 20 minutes left to introduce the bill into the Senate before the end of that session. ‘Hatch made his point of view very clear . . . . Then he left the room.’ . . . Kennedy and Hatch literally ran the bill to the Senate floor at about 2 a.m.”). Rep. Kastenmeier later derided the final language from the Senate as a “backroom deal in the Senate involving the chief executive officer of one of the dissenting drug companies and a lobbyist of one of the generic groups.” 130 CONG. REC. 24,428 (1984).

<sup>377</sup> S. 2926, 98th Cong. (1984); 130 CONG. REC. 23,764–23,774 (1984).

<sup>378</sup> Lourie, *Account, supra* note 24, at 549; 130 CONG. REC. 24,416–24,458 (1984).

<sup>379</sup> Lourie, *Account, supra* note 24, at 548–49.

<sup>380</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984).

<sup>381</sup> Orphan Drug Act, Pub. L. No. 97-414, § 11, 96 Stat. 2049 (1983) (codified at 35 U.S.C. § 155 (2011)).

<sup>382</sup> S. 255, 97th Cong. (1981) (proposed § 155(c)(4)) (“[F]or products approved and for which a stay of regulation granting approval pursuant to section 409 of the [FDCA] was in effect as of January 1, 1981, the period of such patent extension shall be measured from the date such stay was imposed until such proceedings are finally resolved and commercial marketing permitted”).

<sup>383</sup> Searle submitted its food additive petition in February 1973, and the FDA published a regulation approving the first uses of this ingredient in July 1974. 39 Fed. Reg. 27,317 (July 26, 1974). After objections to the approval, Searle voluntarily withheld the product from the market while the FDA conducted a hearing before its new Public Board of Inquiry. *Patent Term Restoration Act of 1981: Hearings Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the Comm. on the Judiciary*, 97th Cong. 424–25 (July 22, September 30, October 1, 7, November 5, 12, and 18, 1981) (statement of John E. Robson, Executive Vice President, G.D. Searle 7 Co.) [hereafter ROBSON STATEMENT]. Meanwhile, concerns arose about the integrity of data generated for Searle by a contract laboratory, so the FDA stayed the effective date of the regulation. 40 Fed. Reg. 56,907 (Dec. 5, 1975). An

mishandling by the FDA, at least during the final three years of delay.<sup>384</sup> “Delays of this type,” the company argued, “especially when a perishable commodity like patent life is in the balance . . . go beyond the bounds of reason or excuse.”<sup>385</sup> Section 155 of the Patent Act described the situation in general terms, and required that any patent encompassing the composition of matter or process of using the composition in such a situation be extended by the amount of time from the stay of the food additive regulation (authorizing market entry) until the FDA finally permitted commercial marketing.<sup>386</sup>

In addition, in 1983, Congress restored five years and three months to two patents covering Forane (isoflurane), a halogenated inhalation anesthetic used for surgery.<sup>387</sup> The drug was ready for approval in 1976, but the FDA issued a non-approvable letter after a study in mice performed by a researcher at the Veterans Administration suggested the drug might be carcinogenic and teratogenic.<sup>388</sup> Further investigation revealed that the mice had been contaminated with polybrominated biphenyls,<sup>389</sup> and the FDA approved the application in December 1979.<sup>390</sup> It cleared the manufacturing facility for operation in May 1981.<sup>391</sup> The patent had issued in 1970, however, and the Senate sponsors explained that “because of an egregiously long approval process demanded by the Food and Drug Administration, only a small part of the seventeen-year patent term to which the company was entitled was effectively available to them.”<sup>392</sup> The “hardship” had been

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independent organization of academic scientists confirmed the authenticity of the data in late 1978. ROBSON STATEMENT, *supra*, at 427. Because the stay had been based on data integrity concerns, this should have ended the matter. The FDA still declined to lift the stay for three more years, however, insisting on the hearing. See 46 Fed. Reg. 38,285 (July 24, 1981).

<sup>384</sup> See generally *supra* note 383.

<sup>385</sup> ROBSON STATEMENT, *supra* note 383, at 427.

<sup>386</sup> Searle held one patent on the use of aspartame as a sweetener (U.S. Patent No. 3,492,131) and assured Congress that it was not aware of other patents captured by the language. ROBSON STATEMENT, *supra* note 383, at 424, 433. In the end, however, PTO extended 32 patents. See PTO, Patent Terms Extended Under 35 U.S.C. § 155. Rich Cooper, who had been chief counsel at the FDA during this process, commented later that this resulted from “poor draftsmanship.” Rich Cooper, *Legislative Patent Extensions*, 48 FOOD & DRUG L. J. 59, 65 n.32 (1993).

<sup>387</sup> Pub. L. 98-127, 97 Stat. 831 (1983).

<sup>388</sup> Thomas H. Corbett, *Cancer and Congenital Anomalies Associated with Anesthetics*, 271 ANN. N.Y. ACAD. SCI. 58, 58 (1976); see also 129 CONG. REC. 11,509 (1983) (remarks of Senator East).

<sup>389</sup> Bijan K. Basak, *Isoflurane as a General Anesthetic: Will it Displace All Other Volatile Anesthetics*, 21 ANESTHESIOLOGY 614 (1984); 129 CONG. REC. at 11,509 (Senator East); 35 U.S.C. § 155A (1983).

<sup>390</sup> Approval Letter (NDA 17-624) (Dec. 18, 1979).

<sup>391</sup> 129 CONG. REC. at 11509 (Senator East).

<sup>392</sup> *Id.* (remarks of Senator Thurmond).



“unfair.”<sup>393</sup> Section 155A of the Patent Act restored the time from the initial non-approvable letter in 1976 to removal of the final regulatory impediment in 1981.<sup>394</sup> The proposal was uncontroversial and enjoyed bipartisan support.<sup>395</sup>

On the day that President Reagan signed the Hatch-Waxman Amendments, Congress passed a private bill restoring patents that protected Micronase (glyburide), Diabeta (glyburide), and Glucotrol (glipizide), which were all second generation sulfonylurea drugs intended for management of diabetes.<sup>396</sup> The FDA had found the drugs safe and effective in 1974, which should have resulted in approval. The agency delayed final approval letters, however, while it considered whether to require new safety language in the labeling of *all* oral hypoglycemic drugs.<sup>397</sup> The agency finally settled on class labeling for sulfonylurea drugs in April 1984, and approved the second generation drugs in May 1984.<sup>398</sup> During these ten years, however, the first generation sulfonylurea drugs had remained on the market with the previous labeling in place.<sup>399</sup> The final Hatch-Waxman legislation passed by the Senate on August 10 included separate language restoring these patents,<sup>400</sup> but the House removed it after the August recess when it removed the separability provision.<sup>401</sup> Congress passed a private bill one month later, extending five patents until April 21, 1992, which added about five years to each and resulted in an effective patent life of roughly eight years.<sup>402</sup>

<sup>393</sup> *Id.* (remarks of Senator East).

<sup>394</sup> 35 U.S.C. § 155A (1984).

<sup>395</sup> 129 CONG. REC. at 11,509 (Senator Thurmond).

<sup>396</sup> Priv. L. No. 98-46, 98 Stat. 3434 (1984); *see also* H.R. REP. NO. 98-1060 (1984) (text of private bill), *reprinted in* PRIVATE PATENT LEGISLATION, *supra* note 120, at 75.

<sup>397</sup> The labeling issue stemmed from a controversial study assessing the effectiveness of four other oral hypoglycemic drugs, which found an association between the drugs and increased cardiovascular mortality. *See* Bradley v. Weinberger, 483 F.2d 410 (1st Cir. 1973). Many diabetes specialists believed the study flawed, however, because of deficiencies in trial design and statistical analysis, and the FDA struggled to interpret the findings. CURTIS MEINERT, THE TRIALS AND TRIBULATIONS OF THE UNIVERSITY GROUP DIABETES PROGRAM 91–107 (2015) (describing the reaction in the media and scientific journals); *Oral Hypoglycemic Drugs ‘Reported’ Association with Cardiovascular Death Will Be Required in Labeling for Class of Agents, FDA Final Rule States*, PINK SHEET, Apr. 16, 1984 (summarizing the “14-year debate over how the FDA should handle the UGDP findings”).

<sup>398</sup> PRIVATE PATENT LEGISLATION, *supra* note 120, at 8–9 (statement of Mark Rogart); *see also* Labeling for Oral Hypoglycemic Drugs of the Sulfonylurea Class, 49 Fed. Reg. 14,303 (Apr. 11, 1984) (to be codified at 21 C.F.R. pts. 201, 310) (requiring cardiovascular warning in labeling of oral hypoglycemic drugs because of the study).

<sup>399</sup> PRIVATE PATENT LEGISLATION, *supra* note 120, at 9.

<sup>400</sup> *See* 130 CONG. REC. at 23,773 (proposed 35 U.S.C. § 155A).

<sup>401</sup> Lourie, *Account*, *supra* note 24, at 548–49. The House simply never considered this Title. *See* 130 CONG. REC. at 24,416–24,458 (1984).

<sup>402</sup> H.R. REP. NO. 98-1060 (1984) (text of private bill), *reprinted in* PRIVATE PATENT LEGISLATION, *supra* note 120, at 12, 75.

Finally, in October 1984, Congress restored a patent claiming a sterile solid whey blend used to increase milk production in cows.<sup>403</sup> Impro Products had submitted its application to the Veterinary Biologics Division (VBD) of the Department of Agriculture in 1965, and VBD issued a special two-year license allowing the company to conduct field tests in support of a permanent license.<sup>404</sup> A scientist in another agency persuaded VBD to delay the permanent license for six months while he ran tests.<sup>405</sup> What followed was both irregular and improper. The scientist released his conclusion—that the whey blend did not significantly improve milk production—before finishing his tests.<sup>406</sup> After the study results were rejected for publication, the scientist overcame the rejection by hand-delivering a copy of the manuscript to the President of the American Veterinary Medical Association, whom he persuaded to insist on publication.<sup>407</sup> VBD refused to share his data, even when pressed by a member of Congress.<sup>408</sup> When Impro finally secured the raw data, it became clear that the scientist's team had not followed its own written protocols.<sup>409</sup> By the time Impro came to Congress seeking relief, a district court had found that the study report contained false and misleading statements.<sup>410</sup> Still, the company did not have approval.<sup>411</sup> The USDA and the Department of Justice opposed relief for this reason; the product had not yet been found effective.<sup>412</sup> The Commissioner of Patents, in contrast, supported relief.<sup>413</sup> The Senate Judiciary Committee, which assumed the product would not receive approval before patent expiry in April 1985, concluded that a new seventeen-year patent term was appropriate, “based on the fact that due to unjustified government

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<sup>403</sup> Priv. L. No. 98-34, 98 Stat. 3430 (1984). Secondary accounts sometimes identify the product as “Impro,” but Impro was the manufacturer. The product was known as Whey Blend.

<sup>404</sup> H.R. REP. NO. 98-1061 (1984), reprinted in PRIVATE PATENT LEGISLATION, *supra* note 120, at 83.

<sup>405</sup> *Id.*

<sup>406</sup> PRIVATE PATENT LEGISLATION, *supra* note 120, at 83; see J.W. Smith et al., *Whey Antibody Preparation: Effects of Prepartum Injection on Milk Production in Dairy Cows*, 31 AM. J. VETERINARY RES. 1485 (1970).

<sup>407</sup> *Id.*

<sup>408</sup> *Id.*

<sup>409</sup> *Id.*

<sup>410</sup> *Impro Prods., Inc. v. Block*, 722 F.2d 845, 848 (D.C. Cir. 1983) (citing *Impro Products, Inc. v. Block*, No. 81-1284 (D.D.C. Sept. 2, 1982) (Memorandum and Order)).

<sup>411</sup> PRIVATE PATENT LEGISLATION, *supra* note 120, at 80. The company had been able to market within its home state of Iowa; this did not involve interstate commerce, which deprived the USDA of jurisdiction. See *id.* at 30.

<sup>412</sup> *Id.* at 62 (memorandum from the Department of Agriculture explaining that Impro had neither submitted data to contradict the report's basic conclusion nor submitted its own efficacy data to justify a permanent approval).

<sup>413</sup> *Id.*

involvement, Impro ha[d] never been allowed an opportunity to exploit its patent.”<sup>414</sup> The House settled on fifteen years, reasoning that the company had enjoyed two years of field testing under the special license.<sup>415</sup>

#### IV. POLITICAL ECONOMY OF THE HATCH-WAXMAN AMENDMENTS

The high water mark for patent term restoration legislation lasted from July 1981 (passage of the Kastenmeier bill by the Senate) until September 1982 (rejection of the bill by the House, despite majority support). Drug patent owners supported patent term restoration because it would lengthen their effective patent life and increase their revenues. Rather than simply arguing that restoration was in their economic interests, however, they grounded the justification in concerns about incentives to innovate. In other words, they invoked the public’s interest in a continuing supply of new treatments. Academic economists bolstered these utilitarian arguments. By and large, patent owners eschewed arguments about compensation for sacrificed patent time and about ensuring equal treatment (outcomes) for all types of patent owners, leaving others (such as the PTO) to make these arguments.

Patent owners in other regulated industries supported patent term restoration for the same reason—it would lengthen their effective patent life—and made the same arguments—mainly utilitarian. These other patent owners were fairly engaged in the legislative push through the late 1970s into the early 1980s.<sup>416</sup> When the generic industry engaged fully and the policy debate turned to drug patents and drug prices, these patent owners engaged less and often engaged separately. When Waxman released the generic drug bill in April 1984, many patent owners broke off, realizing that the prospects for patent term restoration had diminished considerably because of joinder with drug pricing issues.

By the late 1970s, the FDA had fully joined the innovating companies in supporting patent term restoration, citing the length of premarket programs, shortened effective patent life, and concerns about incentives to innovate. As late as spring 1982, the agency held the view that innovators should have seventeen years of effective exclusivity. The agency experienced several rapid changes in leadership during this period: two Democrat-appointed Commissioners between introduction of the first patent term restoration bill in April 1979 and January 1981, and two Republican-

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<sup>414</sup> *Id.* at 80.

<sup>415</sup> *Id.* at 81.

<sup>416</sup> *E.g., The Patent Term Restoration Act of 1981—S. 255: Hearing Before the Comm. on the Judiciary, 97th Cong. 59 (1981) (testimony of various individuals from the pesticide industry).*

appointed Commissioners between January 1981 and enactment of the Hatch-Waxman Amendments in fall 1984.<sup>417</sup> Still, the FDA remained fairly consistent in its views. The agency was well aware that its statute, programs, and policies were seen as responsible for the shortened effective patent life. It may have viewed patent term restoration as a way to protect its new and increasingly robust premarket research and development paradigm. This, in turn, might reflect a technocratic commitment to the premarket model that the agency helped to develop, or an effort to protect the agency's reputation and role in the economy.

PTO's support for patent term restoration was mostly unqualified, even during the Carter years, and its continuously strong support after Reagan took office probably reflected the new Administration's policy objectives. Beginning in 1982, the Commissioner of Patents was also an Under-Secretary of Commerce, and was thus closely connected to both the White House and the Reagan Administration's policy initiatives to foster innovation in industry. The PTO tended to argue from the economic theory of the patent and the role of patents in stimulating innovative behavior. The Office also focused on equal treatment of patent owners. For instance, the Commissioner of Patents commented repeatedly that it would be "unfair" to establish a different patent term for a highly profitable industry.<sup>418</sup> The Office also tended to focus broadly on *all* patents shortened by premarket regulatory requirements, rather than specifically on drug patents. Indeed, despite supporting an outer limit on the effective life of restored continuation patents, PTO was firmly committed to restoration of *every* affected patent covering a regulated product.

Despite PTO's emphasis on ensuring all patentees enjoyed equal patent rights and on compensating for sacrificed time, the innovative industry's arguments about ensuring adequate incentives for innovation had more traction in Congress. This may explain why the petroleum industry was rebuffed. Although the bills proposing patent term restoration between 1979 and 1984 varied in their approach, they generally included the full range of products subject to premarket review: medical devices, animal drugs, food

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<sup>417</sup> These were Donald Kennedy (April 1979 to June 1979), Jere Goyan (October 1979 to January 1981), Arthur Hayes (April 1981 to September 1983), and Frank Young (July 1984 to December 1989). See FDA, *Commissioners*, <https://www.fda.gov/AboutFDA/History/FOrgsHistory/Leaders/ucm2006081.htm> (last visited Oct. 24, 2018).

<sup>418</sup> *E.g.*, PRIVATE PATENT LEGISLATION, *supra* note 120, at 17; *Innovation and Patent Law Reform*, *supra* note 201, at 46 ("They have pointed to high profit margins of industries which would benefit from this type of legislation and have concluded that, as a consequence, there is no problem. I would suggest that it would be clearly unfair to establish different effective patent terms depending on the potential economic success of a particular sector of technology.").

and color additives, pesticides, and new chemicals.<sup>419</sup> In contrast, there was never any possibility that the legislation would include the petroleum industry.<sup>420</sup> These companies had argued that environmental regulations delay the opening of refineries, precluding enjoyment of patents claiming catalysts used in the refining process.<sup>421</sup> Judge Lourie explained in 1984 why legislators declined their request for restoration.<sup>422</sup> The companies were not marketing a patented product subject to premarket review, and the key business decision—whether to build a refinery—would not be influenced by the length of patent protection for the catalyst.<sup>423</sup> The patent term legislation was grounded in testimony and empirical evidence that patent term distortion affected commercialization decisions. The legislation was intended to restore the commercialization incentive by repairing the distortion, but if the connection between effective patent life and the desired business decision was lacking, there was no basis for restoration.

Patent owners, joined by the PTO, the FDA, and academic economists, argued that the public would benefit from the Kastenmeier legislation through an increase in innovation. Others, however, argued that the public would bear the costs of the legislation—at least with respect to drug patents—because a delay in generic drug entry meant consumers would pay more for a medicine for a longer period of time. Public Citizen made this argument for the public, leading to a clash in arguments about where the public's interest lay. PTO took the opposite view: increased prices would be offset by the development of new products.<sup>424</sup> The generic drug companies made a variety of arguments, such as questioning the need for restoration, but they too were focused on the harm to the public. These companies were acting out of self-interest as much as the patent owners were, as patent term restoration would delay their market entry, but they invoked social welfare arguments and thus aligned their advocacy with that of Public Citizen.

A variety of explanations have been offered for the failure of the bill in September 1982. The bill would have passed, had it not been placed on the suspension calendar.<sup>425</sup> Supporters may have been overconfident. In

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<sup>419</sup> For instance, as previously discussed, the Kastenmeier proposals applied to *any* product subject to federal premarket regulatory review. *See generally* Section III.A.1.

<sup>420</sup> Lourie, *Account*, *supra* note 24, at 529.

<sup>421</sup> *Id.*

<sup>422</sup> *Id.*

<sup>423</sup> *Id.*

<sup>424</sup> *The Patent Term Restoration Act of 1981—S. 255: Hearing Before the Comm. on the Judiciary, 97th Cong. 40 (1981)* (testimony of Rene D. Tegtmeyer) (“Whatever effects it might have, in terms of increasing drug prices, if that does occur to any extent, I think would be more than offset by a return in the form of making available to the public many new drugs or pharmaceuticals, many new pesticides, and other new products.”).

<sup>425</sup> As previously noted, a majority of the House voted for passage. *See supra* Section III.A.4.

addition, several members of the House who likely would have supported the bill were not present to vote, and at least one account suggests their flights were delayed by airport fog.<sup>426</sup> There is, however, a deeper explanation for its failure. The generic companies had coalesced as a group around the issue of patent term restoration, forming a new trade association under a leader who had an influential voice in Washington policymaking circles. During the winter of 1981 to 1982, the generic industry's voice grew stronger, and it continued to focus policymakers on the pricing impact of patent term restoration. Pricing arguments may have been particularly compelling to members concerned about reelection, because prescription drugs were generally not covered by public or private health insurance.<sup>427</sup>

The tide turned when the generic companies shifted to seeking affirmative changes in the law, rather than merely opposing patent term restoration. The key to understanding the final legislation is understanding that the generic companies did not simply seek policies that would have to be married with, or reconciled with, policies sought by patent owners. Instead, they sought precisely the *opposite* policy outcome. Drug patent owners wanted longer exclusivity in the market through longer effective patent life. The generic companies wanted drug patent owners to have *shorter* exclusivity in the market.

The tide turned in 1982 and 1983, in particular, because the generic industry suffered a series of policymaking defeats in those years that prevented them from achieving this policy outcome through other means. An administrative proposal to permit these companies to file ANDAs withered on the vine in March 1982, and the Supreme Court decided the same month it would consider whether they could bring generic drugs to market *without* testing and without submitting applications.<sup>428</sup> A federal court ruled in July 1982 that they could not test their generic products during the patent term.<sup>429</sup> The fact that they pressed hard in August and September 1982 to oppose the Kastenmeier patent term restoration bill now makes sense. In March 1983, the possibility of bringing generic drugs to market as old drugs without marketing applications evaporated with the Supreme

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<sup>426</sup> Lourie, *History, Summary, and Appraisal*, *supra* note 24, at 354.

<sup>427</sup> See Thomas Oliver et al., *A Political History of Medicare and Prescription Drug Coverage*, 82 MILBANK Q. 283, 293 (2004) (noting that prescription drug coverage was limited both for Medicare beneficiaries and for patients insured through private insurance companies). Congress did not add an outpatient prescription drug benefit for Medicare beneficiaries until 2003. Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

<sup>428</sup> *United States v. Generix Drug Corp.*, 455 U.S. 988 (1982).

<sup>429</sup> *Pfizer, Inc. v. Int'l Rectifier Corp.*, No. 73-58, 1982 WL 51039 (C.D. Cal. July 20, 1982).

Court's *Generix* ruling.<sup>430</sup>

With these policymaking defeats, the generic drug companies now sought a policy outcome that was exactly the opposite of the outcome sought by the innovators. They wanted an exception to infringement so they could develop and test their copies during the patent term, and they wanted to rely on the safety and effectiveness data generated by patent owners. These policy changes would *shorten* the effective exclusivity of innovative drugs in the market. The generic drug companies turned to Waxman for support, and he introduced generic drug legislation shortly after.

Because the two sides sought directly conflicting policy outcomes, it is a bit odd to speak of a compromise in which each side benefitted. Unless the law was a wash, the possible outcomes were binary. Either the patent owners would on the whole have more time before generic competition, or they would have less.

With this in mind, the final legislation can be examined—considering each industry before and after enactment. The discussion that follows is not meant to be normative, nor does it make claims about the relative allocation of benefits and costs under the scheme as it stands today (as amended by Congress and as interpreted by the FDA and the courts). Rather, it is a historically contextualized assessment of the benefits and costs *in September 1984*, considering the state of the law as it stood the day before and the day after enactment.

Patent owners came to the table with a problem—a loss of effective patent life because of federal regulatory requirements. They emerged with some of this loss mitigated, and in this respect they benefitted from the legislation. In the process, however, they lost the right to enforce their patents while competitors manufactured and tested infringing products. The lead negotiator for the generic industry association explains that patent term restoration and the experimental use provision were “self-canceling” and “taken together, have no net effect on the length of the exclusive marketing period of most new drugs.”<sup>431</sup> In addition, patent owners lost exclusivity in their testing data five years after approval.<sup>432</sup> Many refer to the five-year period as a benefit the innovative companies received in the legislation, but this is incorrect as a historical matter.<sup>433</sup> There was no pathway for approval of applications relying on innovator data before Reagan signed the statute on September 24. The legislation *removed* all but five years of the data

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<sup>430</sup> United States v. Generix Drug Corp., 460 U.S. 453 (1983).

<sup>431</sup> Engelberg, *supra* note 20, at 392.

<sup>432</sup> 21 U.S.C. § 355(j)(4)(D)(ii) (1984).

<sup>433</sup> See Erika Lietzan, *The Myths of Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 103–10 (2016).

exclusivity the patent owners had enjoyed before.<sup>434</sup>

The generic drug companies came to the table with a different problem: they were subject to the same regulatory requirements as everyone else, meaning they were required to conduct clinical trials and file full applications. In addition, they were subject to the intellectual property rights of others—patent rights and the FDA's treatment of testing data as trade secrets. They emerged still subject to the patent and, indeed, the patent would be a few years—but never more than five years—longer. They could, however, develop and test their products during the patent term, saving them three to five years.<sup>435</sup> As the lead lawyer for the generic companies explained, these provisions cancelled each other out.<sup>436</sup> Now, however, they could also rely on the patent owner's testing data in their marketing applications, saving them several years and the expense of clinical testing.

This leaves the patent litigation provisions. Although some characterize these provisions as benefiting the patent owners, a historically contextualized reading suggests they were at most a wash and may have benefitted the generic industry. The key is that they cannot be considered in the abstract; they must be read with the remaining patent provisions of the statute—the experimental use exception, the artificial act of infringement, and patent term restoration. The impact can be illustrated best with hypotheticals.

Assume the administrative burdens are comparable. The patent owner must list its patents in its application, and the generic applicant must address those patents in its own application and send a letter to the innovator. Assume these are a wash. To simplify the analysis, also assume there is only one patent, and assume the innovative product is a new chemical entity. In order to draw a comparison, assume further that (1) the effective patent life, without restoration, is nine years; (2) the generic company needed six years to prepare an application before enactment and would need four years to prepare an application after enactment; (3) the innovator enjoys the maximum five years of patent term restoration; and (4) the FDA takes two years to review and approve a generic application both before and after enactment. In other words, assume a small benefit from the law for the generic company (no more than two years shaved off the application process)

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<sup>434</sup> The myth that innovators *received* five years in this legislation may stem from the fact that the June draft permitted copies immediately after NDA approval. The five-year provision was *added* in August. But when one compares the final enacted law with the state of the law before enactment, there can be no dispute that NDA holders *lost* all but five years of exclusivity.

<sup>435</sup> As explained in Section III.C., *supra*, previously generic companies seeking to market copies of post-1962 innovative products were required to perform clinical trials and to submit full new drug applications.

<sup>436</sup> Engelberg, *supra* note 20, at 392.



and the maximum benefit from the law for the innovator (maximum patent term restoration).

Consider first a scenario in which the generic company chooses not to challenge the patent. Under the law of September 23, before enactment, this company waited for the patent to expire (nine years), developed and studied its drug (six years), and waited for approval (two years). The generic company would reach the market seventeen years after the innovator. After enactment of the Hatch-Waxman Amendments, this company could develop and study its drug (for four years) and wait for FDA approval (for two years) *during* the patent term. It could submit its ANDA five years after the innovative drug approval, and the FDA would approve the ANDA when the patent expired—at nine years plus five years patent term restoration. The generic company would reach the market fourteen years after the innovator. The generic company's position improved with the enactment of the Hatch-Waxman Amendments. If the patent owner did not receive the full five years of patent term restoration, of course, the generic company's position after the Hatch-Waxman Amendments would be even more favorable.

Consider second a scenario in which the generic company chooses to challenge the validity of the patent. Assume also that it decides to start developing its copy immediately after FDA approval of the innovative product. Under the law of September 23, this company—believing the patent invalid—did not wait for the patent to expire. Immediately after FDA approval of the innovative product, it developed and studied its copy (six years) and waited for FDA approval (two years). But it took these steps at risk, because there was no experimental use exception. It would reach the market eight years after the innovator and would then face immediate patent infringement litigation and possible damages for infringement. After enactment of the Hatch-Waxman Amendments, this company would still begin work immediately. It would develop and study its drug (four years) and file the ANDA immediately. The statute permits a generic company to file an application with a patent challenge four years after FDA approval of the innovator's drug.<sup>437</sup> The FDA can take two years or more to review the generic application,<sup>438</sup> but this is mostly beside the point because, if the

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<sup>437</sup> 21 U.S.C. § 355(j)(5)(F)(ii) (2018).

<sup>438</sup> The FDA's current goal is to review and act on 90 percent of standard original ANDAs within 10 months of their submission date. *See* U.S. FOOD & DRUG ADMIN., GDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROGRAM ENHANCEMENTS FISCAL YEARS 2018–2022, <https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf> (last visited Oct. 24, 2018). In the first three quarters of 2018 the average time to a tentative approval was 33 months, 21 months, and 31 months. U.S. FOOD & DRUG ADMIN., ACTIVITIES REPORT OF THE GENERIC DRUGS PROGRAM (FY 2018)—GDUFA II QUARTERLY PERFORMANCE, <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm600678.htm> (last visited Oct.

innovator brings a timely suit, the statute precludes approval of the generic drug until seven and a half years after the innovator's drug.<sup>439</sup> Thus, the generic company would reach the market seven and a half years after the innovator. In the meantime, it would have been litigating the patent case. So it would reach the market sooner *and* have an opportunity to test its theory of invalidity without risking infringement damages. The generic company's position improved with enactment of Hatch-Waxman.

Some characterize the thirty-month delay of approval in the event of patent litigation as tantamount to a statutorily imposed preliminary injunction.<sup>440</sup> The patent owner, after all, benefits from an automatic stay of approval, without having to make the showings needed for a preliminary injunction.<sup>441</sup> Perhaps the patent owner would not have won a preliminary injunction if it had gone to court before the Hatch-Waxman Amendments, though the courts were generous with preliminary injunctions.<sup>442</sup> In such a situation, one could say that the generic company is now (after enactment) barred from the market for thirty months *despite* not infringing, though it would not have been barred before the statute was passed. The generic drug companies, however, told Representative Waxman that, as a practical matter, they would generally wait for a court decision before launching a potentially infringing product.<sup>443</sup> Representative Waxman cited this fact in defense of the thirty-month stay.<sup>444</sup> Moreover, this characterization overlooks the *rest* of the scheme. That is, if the statute had not passed, the generic company would have filed a *full new drug application*, after performing its own clinical trials. Thus, the entire timeline would have been shifted later, and the generic company would have launched later.

A generic company challenging an innovator patent might not file its ANDA at the four-year mark. The statute included the 180-day exclusivity incentive for the first to challenge a patent, however, which would tend to lead to submission at the four-year mark. In the interests of completeness,

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24, 2018). The FDA issues "tentative approval" when an ANDA review of the application is complete and the application satisfies the statutory approval standard, but the agency cannot grant final approval (giving permission to market the drug) due to a patent or regulatory exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA).

<sup>439</sup> § 355(j)(5)(F)(ii).

<sup>440</sup> *E.g.*, Eisenberg, *supra* note 58, at 358.

<sup>441</sup> *Id.*

<sup>442</sup> *E.g.*, M.A. Cunningham, *Preliminary Injunctive Relief in Patent Litigation*, 35 *IDEA: J. L. & TECH.* 213, 231 (1995) (finding that courts granted preliminary injunctions in 61 percent of patent cases between October 1, 1982, and December 31, 1993).

<sup>443</sup> 130 CONG. REC. 24,427 (1984) (remarks of Rep. Waxman) ("The facts of life are that a generic drug manufacturer will await, as a practical matter, until the decision of a court on a patent challenge before that manufacturer markets a generic drug. That is the information they have given us as to their practice.").

<sup>444</sup> *Id.*

assume that it instead chose to file at the seven-year mark. In this situation, the numbers would change. If the innovator brought a timely suit, the statute would preclude approval for thirty more months, until roughly nine and a half years after the innovator. In this case, the generic drug company would enter the market *later* than it would have entered the market (at the eight-year mark) before enactment, but this would happen *only* if the generic company delayed submission several years—*not* if it filed at the earliest possible opportunity, which presumably it would do, if it thought the patent invalid and wanted 180-day exclusivity.

One reader of this paper in draft form commented that the benefit to the patent owner from the patent provisions (and 30-month stay in particular) is meaningful, unless one assumes that all patents are valid. The benefit accrues to the patent owner, she remarked, whether or not the patent is valid, and whether or not the patent is infringed. This is correct, as far as it goes, but the question is not whether the patent provisions of the Hatch-Waxman Amendments contain isolated provisions benefitting the patent owner. Undoubtedly they do. They also contain isolated provisions benefitting the generic applicant, such as the experimental use exception and the prospect of 180-day exclusivity. The question is whether drug patent owners (and generic companies) were in a better or worse position after enactment than before enactment. This question must be answered by looking at the scheme as a whole.<sup>445</sup>

On the whole, the new law made generic companies better off, and it made patent owners worse off.<sup>446</sup> But the innovative industry's trade association testified in support of the Hatch-Waxman legislation in June 1984. One might ask why the association did so if the legislation would so

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<sup>445</sup> Professor Sachs contends that the Hatch-Waxman Amendments expanded patentee rights. Sachs, *supra* note 20, at 396. In her view, the two industries would have little difficulty “coming together to lobby for this statute,” given its concentrated benefits, and the “public choice collective action problem”—in which the diffuse public would be unable to prevent enactment—was “more exaggerated” than had been the case when Congress enacted the Federal Courts Improvement Act of 1982 and the Bayh-Dole Act. *Id.* at 384. Consumer groups might have opposed patent term extension, she writes, but would have been placated by the generic drug pathway. *Id.* Public choice theory, she concludes, does not fully explain the Hatch-Waxman Amendments. *Id.* at 396. The broader legislative and regulatory climate and Waxman's legislative entrepreneurship must have contributed to the enactment. *Id.* at 386–89. Although I share her view of Waxman's role, my review of the regulatory and legislative history leads to a different conclusion—that the scheme did not expand patentee rights, that the public had vicarious representation, and that the benefits were unilateral.

<sup>446</sup> A discussion of the actual impact of the statute on the industries is beyond the scope of this article, but it bears mentioning that both innovating and generic companies could have benefitted significantly simply from the certainty that came with a final legislative resolution of the issues. For one review of the empirical studies evaluating the impact of the statute on innovator market exclusivity, see Aaron Kesselheim, *An Empirical Review of Major Legislation Affecting Drug Development: Past Experiences, Effects, and Unintended Consequences*, 89 MILBANK Q. 450, 477–81 (2011).

clearly leave innovators in a worse position. The answer may simply be that, particularly after Senator Hatch made it clear the legislation *would* be enacted, acquiescing seemed safer than the alternative. Leadership of the trade association may have concluded that this was the best outcome that the industry could achieve. In addition, there always remained a risk that, if the legislation were blocked, the FDA would resuscitate the proposed ANDA regulation, perhaps with a very short exclusivity period under a Democrat-appointed Commissioner.

In truth, though, the innovators were bitterly divided about the legislation. Just as the chemical industry patent owners broke away from the Waxman bill, so too did the ten largest members of PMA—American Home Products, Bristol-Myers, Carter-Wallace, Hoffman-La Roche, Johnson & Johnson, Merck, Norwich Eaton (Procter & Gamble), Schering-Plough, Squibb, and Stuart Pharmaceuticals (ICI Americas).<sup>447</sup> These companies stood to lose the most from the research use exemption, the half-hearted restoration formula, and immediate use of their testing data upon NDA approval. They testified and lobbied through the summer of 1984, focusing on their objections. With Senator Hatch's "with you or without you" threat, they had little leverage, but several prominent legal scholars backed their argument about the constitutionality of applying the new research use exemption to already-issued patents.<sup>448</sup> This, and the *Monsanto* decision—which raised doubts about authorizing companies to rely on data submitted to the FDA with an expectation of confidentiality—gave them a foothold to secure last-minute changes.

If the dynamics were so disadvantageous as to result in legislation that made patent owners worse off, one also has to wonder why the drafters made *any* concessions at the eleventh hour. The last-minute concessions can be explained as a response to genuine concerns about constitutionality. The inclusion of (admittedly weakened) patent term restoration is harder to explain, but it is surely relevant that the chief negotiator for the generic companies viewed it as a "wash" with the experimental use exception.<sup>449</sup> It may also have been the price for Senator Hatch's sponsorship of the legislation, making it possible to characterize the scheme as a compromise in which both sides received a little something.

Finally, the splinter legislation—individual patent term restoration bills for three drugs, a food additive, and a veterinary biologic—may be part of the story. The enactments make sense given the relative allocation of benefits and costs and the distraction of the broader legislative debate. The

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<sup>447</sup> *Drug Price Competition and Patent Term Restoration Act of 1984: Hearing on S.2748 Before the Comm. on Labor & Human Res.*, 98th Cong. 113–15 (1984).

<sup>448</sup> See *supra* note 365.

<sup>449</sup> Engelberg, *supra* note 20, at 392.

benefits of these bills were concentrated, and the companies who stood to benefit were motivated to press for passage. In contrast, the costs of the bills were dispersed; they would be borne by the general public through higher prices during the patent terms, and the narrowness of the bills meant that the impact on any one member of the public would be modest. As to each product, would-be competitors would also bear the cost when their market entry was delayed, but only companies planning to market those particular products would have an incentive to engage in opposition to the bill. The generic drug companies and Public Citizen may have chosen to focus instead on battling the prospective and generally applicable patent term restoration language, which would shape the competitive landscape for years to come.

There is, however, another angle to consider. Four of the companies involved—Searle, Upjohn, Hoechst-Roussel, and Pfizer—were substantial research-based pharmaceutical companies and members of PMA.<sup>450</sup> Congress had resolved Searle's situation in early 1983.<sup>451</sup> The other three companies were covered by separate language specific to their situation included in the Hatch-Waxman legislation until the House vote in September 1984.<sup>452</sup> Each also chose to *support* the Hatch-Waxman Amendments through the summer of 1984.<sup>453</sup> Handling their needs in stand-alone language might have prevented them from joining the dissenters and, thus, might have played a role in ensuring passage of the legislation.<sup>454</sup>

The fracturing of PMA had lasting consequences for the innovative drug industry. By early 1985, the leadership that urged the companies to accept the June deal had been replaced. Indeed, the Commissioner of Patents, who had retired from his government position, assumed the

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<sup>450</sup> *Time is Now for ANDA/Patent Restoration Bill, Sen. Hatch Tells PMA Firms Seeking Changes: Second Look by Coalition Would be Welcome, He Adds*, PINK SHEET, July 2, 1984 (listing 13 members of PMA that supported the legislation, including these three and Searle).

<sup>451</sup> Orphan Drug Act, Pub. L. No. 97-414, § 11, 96 Stat. 2049 (1983) (codified at 35 U.S.C. § 155 (2011)).

<sup>452</sup> 130 CONG. REC. at 23,773 (proposed 35 U.S.C. § 155A); *see also supra* Section III.E.

<sup>453</sup> Hoechst-Roussel, *Upjohn & Pfizer Would Get Eight Year Patent Extensions for Second Generation Oral Hypoglycemics Under Amendment Introduced by Thurmond*, PINK SHEET, July 9, 1984 (noting that Upjohn, Hoechst-Roussel, and Pfizer were “nominal supporters” of the Hatch-Waxman bill).

<sup>454</sup> That this might have been a deliberate strategy to split the innovators was suggested to me by someone involved at the time, but two people in a position to confirm this as strategy were unable to recall it. Nevertheless, twelve members of PMA opposed the legislation, and if these four (who presumably supported the legislation, as they were listed as supporters in June) had voted the other way, the vote would have been much closer—eighteen to sixteen, rather than twenty-two to twelve. *See PMA's Engman and GPIA's Haddad Will Explain Patent Restoration/ANDA Compromise at Rep. Kastenmeier's Hearing June 6; PMA Endorses Bill*, PINK SHEET (Jun. 4, 1984), <https://pink.pharmaintelligence.informa.com/PS006685/> (reporting a May 31 vote within PMA of 22 to 12 in favor of the Waxman legislation).

presidency of PMA.<sup>455</sup> That the generic trade association was not similarly bitterly divided is telling.

This leaves the ultimate question: how did seven years of policy discussions and full engagement by both affected industries result in legislation that clearly benefitted one group rather than the other?

The legislative process turned out the way it did because the generic companies benefitted from a classic “Baptists and bootleggers” alliance. Professor Yandle first articulated the Baptists and bootleggers theory of regulation in 1983.<sup>456</sup> Both groups had vigorously supported Sunday Blue Laws, which closed bars and liquor stores on Sundays in southern states.<sup>457</sup> Baptists supported the blue laws on moral grounds, while bootleggers supported them for economic reasons (they had exclusive sales on Sundays).<sup>458</sup> Yandle’s theory holds, in brief, that “durable social regulation evolves when it is demanded by both of two distinctly different groups.”<sup>459</sup> Baptists, he explained in 1999, “point to the moral high ground and give vital and vocal endorsement of laudable public benefits promised by a desired regulation.”<sup>460</sup> Bootleggers, in contrast, “are simply in it for the money.” They “grease the political machinery with some of their expected proceeds.”<sup>461</sup>

The generic companies argued that their proposed policy changes would increase and accelerate the supply of less expensive drugs. They urged these policy changes because they would be selling the drugs in question and would profit from the legislation’s passage. But, just as the patent owners had done with respect to patent term restoration, they invoked the public’s interest—here, in cheaper drugs. As a result, they received strong support from the public sector, especially Public Citizen.<sup>462</sup> The key

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<sup>455</sup> *Mossinghoff Joins PMA Full-Time on Jan. 22: Stetler’s Continued Affiliation with Assn. Should Make FDA Learning Period and Relations with Board Easier*, PINK SHEET (Dec. 17, 1984), <https://pink.pharmaintelligence.informa.com/PS007621/>.

<sup>456</sup> Bruce Yandle, *Bootleggers and Baptists—The Education of a Regulatory Economist*, REG., May–June 1983, at 12.

<sup>457</sup> *Id.*

<sup>458</sup> *Id.*

<sup>459</sup> Bruce Yandle, *Bootleggers and Baptists in Retrospect*, REG., Fall 1999, at 5.

<sup>460</sup> *Id.*

<sup>461</sup> *Id.*

<sup>462</sup> By way of contrast, the Federal Trade Commission (FTC)—which today engages in policymaking discussions, generally in support of measures to facilitate earlier generic drug entry—did not play a meaningful role in the political process that led to enactment of the Hatch-Waxman Amendments. It had been deeply involved in development of a model state law to guide generic drug substitution, but it did not engage in the discussions relating to patent term restoration or the generic drug bill. The FTC did not have the reputation and influence then that it has today. After a series of hostile oversight hearings in 1979 and 1980 and unambiguous comments from members of Congress that it had “overstepped its bounds,” the FTC cut back on consumer protection activities and became “relatively inactive” for most

Public Citizen Litigation Group attorney involved in these negotiations, William Schultz, would eventually become a prominent lawyer for generic companies and, in this capacity, was deeply involved in the parallel policy debate from 2003 to 2010 relating to copies of biological medicines.<sup>463</sup>

In the enactment of the Hatch-Waxman Amendments, the generic companies played the role of the bootleggers, and Public Citizen played the role of the Baptists. This alliance was particularly effective because—whether arguing against patent term restoration or for the generic drug legislation (meaning the ANDA provision and the experimental use exception)—the generic companies had one argument, which merged their own economic interests (selling their wares) with the public’s interest (less expensive alternatives to patented products, sooner). Representative Tom Kindness (R-OH) even commented during the final debate before passage in the House that he had “never known generic manufacturers to be clothed quite so heavily in the cloak of consumerism and protection of senior citizens” as had “been the case in the discussion” of the Hatch-Waxman Amendments.<sup>464</sup>

To be sure, the patent-owning companies had invoked the public’s interest, as well, in favor of the robust patent term restoration of the Kastenmeier bills, in which they had a financial interest. The interest in question, however, was both distant in time and necessarily imprecise—a greater likelihood of unspecified new treatments in the future. Also the PTO would not play the role of the Baptist to the innovating industry’s bootlegger; it generally leaned on the theory of the patent rather than extolling concrete benefits that the public would receive. Thus, a Baptists-and-bootleggers alliance could not bring the patent term restoration bills over the finish line. Indeed, the innovative industry faced a basic problem that continues to challenge scholars and policymakers; it could not prove the counterfactual. There was no easy way to show that longer effective patent life would result in more approved new drugs. Although some companies described research programs forsaken,<sup>465</sup> this testimony could be dismissed as self-serving. By

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of the decade. Ross D. Petty, *Reflections on My Experience with the Federal Trade Commission Transition in the Early 1980s*, 33 J. PUB. POL’Y & MARKETING 212 (2014).

<sup>463</sup> E.g., Ramsey Baghdadi, *Flubbing the FOBs Opportunity: Follow-on Biologics Winners and Losers*, PINK SHEET (Oct. 1, 2007), <https://pink.pharmaintelligence.informa.com/PS080341/Flubbing-the-FOBs-Opportunity-Followon-Biologics-Winners—Losers>. Later he held significant positions in government, including as the General Counsel of Health and Human Services under President Obama.

<sup>464</sup> 130 CONG. REC. 24,437 (1984) (“They are making money off of those people. Right? They are making money off of those people just as surely as the innovators who invent drugs.”).

<sup>465</sup> E.g., *Health and the Env’t Misc.—Part 2: Hearings Before the Subcomm. on Health and the Env’t of the Comm. on Energy and Commerce*, 97th Cong. 340 (1981) (statement of Dr. Lewis H. Sarett) (noting that Merck had abandoned development of treatments for cystic

way of contrast, the short-term benefits of earlier generic drug entry and cheaper generic drugs were easy to describe in tangible terms and were indisputable, and because American voters lacked meaningful insurance coverage for prescription drugs, these benefits were compelling.

Although the FDA had supported patent term restoration, addition of generic drug approval provisions put it in a position to support the broader bill. The agency generally supported a statutory solution to the generic drug approval issue. It had struggled for decades to find a lawful pathway to market for generic drugs, whether those drugs copied pre-1962 products or post-1962 products. Although the agency had not lost a case in the Supreme Court within recent memory, it had suffered several bruising defeats in the lower courts. These included losing to an innovator that had challenged its decision to allow pre-1962 generic drugs to remain on the market while the companies prepared ANDAs.<sup>466</sup> By 1983, the FDA may have felt it had done everything it could do to facilitate generic drug access. It was publishing therapeutic equivalence ratings to assist states with substitution of lower cost generics.<sup>467</sup> It had considered regulatory solutions, such as old drug monographs and ANDAs through rulemaking, but had abandoned these due to the specter of another court defeat. It had proposed legislation creating a monograph system, but this had also failed. Finally, it was now embroiled in litigation brought by the generic companies to *force* it to implement ANDAs through rulemaking—though moving forward would undoubtedly trigger litigation by the innovators. Indeed, innovators had intervened in the litigation brought by the generic companies. Arguably there was little to do but support a statutory ANDA provision. So while the agency had been an influential voice with respect to enactment of the Kastenmeier bills, the nuances of the innovative industry's opposition to the final Hatch-Waxman legislation related to issues of patent law outside its purview, and the broader legislation would remove a significant source of stress on the agency.

In addition to the Baptists-and-bootleggers alliance, Representative Waxman's support for the generic industry's policy goals was pivotal. Professor Sachs, in describing the history of the Hatch-Waxman Amendments, has referred to Waxman as a legislative entrepreneur, which is clearly correct. Waxman was a member of the House for only four years and at the start of a long career when the first patent restoration bill was

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fibrosis, myasthenia gravis, and emphysema).

<sup>466</sup> *Hoffmann-La Roche, Inc. v. Weinberger*, 425 F. Supp. 890 (D.D.C. 1975); Conditions for Marketing Human Prescription Drugs, 40 Fed. Reg. 43,531 (Sept. 22, 1975) (withdrawing policy in response to court's order).

<sup>467</sup> The agency published the first list in 1980. U.S. FOOD & DRUG ADMIN., APPROVED PRESCRIPTION DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (1st ed. 1980).



introduced—he was in his early 40s during the key years of the debate.<sup>468</sup> In the negotiations leading to the enactment of the Hatch-Waxman Amendments, Waxman positioned himself as a champion for the public's interest in earlier access to less expensive drugs. This was one of his first pieces of health legislation, and it would bear his name and be viewed as one of his most significant accomplishments.<sup>469</sup> For the remainder of his career, Waxman would be deeply involved in health legislation and amendments to the FDCA.

## V. CONCLUSION

By reviewing the history of the Hatch-Waxman Amendments from a public choice perspective, this Article discounts the role of ideas, and perhaps it should not. The innovators and generic companies sought policy outcomes that would further their respective financial interests, to be sure, but policymakers may have seen the policy choices in terms of a deeper philosophical dispute and may have been, at times, relatively unmoved by lobbying. The many materials that collectively comprise the history of this legislation give the impression that the principals, at least, meaning Senator Hatch, Representative Waxman, and possibly others, were motivated, in part, by a desire to enact legislation that would solve a difficult problem the *right* way by setting the *right* length of time for innovators to enjoy exclusivity. This surely played a role in the outcome.

Nevertheless, it is also clear that the alliance between the generic companies and Public Citizen, and the virtual equating of the generic industry's financial interests and the public's interests, made enactment of the Hatch-Waxman Amendments possible.

The contextualized history of the legislation thus leads to a conclusion that differs from conventional assumptions in the scholarship and cases. As enacted, from a pure before-and-after perspective, the Hatch-Waxman Amendments imposed a net cost on the innovating drug companies and conferred a net benefit to the generic drug companies. The innovators received patent term restoration, but it was neutralized by an experimental use exception to infringement. They did not *receive* data exclusivity; they lost rights to their data after five years. Although the innovators obtained a statutory stay on generic drug approval during patent litigation, this litigation

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<sup>468</sup> See Waxman, Henry Arnold, HISTORY, ART & ARCHIVES: UNITED STATES HOUSE OF REPRESENTATIVES, [http://history.house.gov/People/Listing/W/WAXMAN,-Henry-Arnold-\(W000215\)/](http://history.house.gov/People/Listing/W/WAXMAN,-Henry-Arnold-(W000215)/) (last visited Oct. 24, 2018).

<sup>469</sup> E.g., U.S. HOUSE OF REPRESENTATIVES COMM. ON ENERGY AND COMMERCE MINORITY STAFF, REP. HENRY A. WAXMAN'S RECORD OF ACCOMPLISHMENTS (2014), <https://kaiserhealthnews.files.wordpress.com/2014/01/waxman-record-of-accomplishments-2014-1-30.pdf>.

would be happening a handful of years earlier in the lifecycle of their drugs, thanks to the abbreviated application pathway and experimental use exception. Not only is it incorrect to state that the scheme benefitted patent owners, but when the legislation as a whole is examined, the notion that the generic drug bill advanced more than one private interest should be rejected.

The central claim of this Article—that, because of a Baptist-and-bootleggers alliance between generic drug companies and Public Citizen, the legislation benefitted the generic industry rather than the innovating industry—is descriptive, not normative. It may, however, have implications for normative scholarship today.

Over the last thirty years, some stakeholders and policymakers have been reluctant to discuss reform (let alone replacement) of the Hatch-Waxman framework because of the conventional wisdom that the compromise was hard-fought, and the balance between innovators and generic companies both careful and fragile. In recent years, though, others have advocated reform—although not a fundamental reassessment—on the ground that the scheme *is too favorable for innovators*. Some claim that it was always pro-patent-owner. Most claim that the scheme has *become* too favorable. Under the circumstances, the notion that the Hatch-Waxman legislation may have *harmed* the innovating industry should give scholars, stakeholders, and policymakers pause.

A great deal has happened in the more than thirty years since enactment of the legislation. The FDA and the courts have interpreted provisions differently than perhaps was expected—sometimes in ways that favored innovators, and at other times in ways that favored generic companies. Regulated companies—both innovators and generic companies—have naturally found ways to use the enacted law (and the new interpretations) to their advantage, including in ways that probably no one expected. Criticisms of the innovators, in particular, focus on perceived attempts to extend exclusivity in the marketplace. Innovators are accused of “evergreening” and “product hopping,” using citizen petitions to block generic approval, and inappropriately refusing to sell products to their competitors for comparative tests, for instance, all with a view to achieving a longer period of exclusivity in the market. Thus, many argue, the “balance” in 1984 between innovators and generic companies has now been “tilted”—by the innovators, if not also perhaps the courts and agency—in favor of patent owners. A large body of normative scholarship, working from a historical baseline of balance in 1984, presses policymakers to take steps to rein in the actions of patent owners, but if the Hatch-Waxman Amendments of 1984 were actually a policymaking *defeat* for the innovating industry, this normative work may be starting from the wrong premise.

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The 1984 legislation created what is now a multi-billion dollar generic drug industry. Consumers and payers benefit from generic drug pricing on important medicines every day. But serious normative work on the future of the Hatch-Waxman framework should start with a clear understanding of what actually happened in 1984. And it may need to be bolder, that is, reflecting on the consequences of that defeat, the arguments made then by the patent owners, and the possibility that the public's interest would actually be best served by reforms that shift the landscape in the *other* direction.