

# **No Parking Here: A Review of Generic Drug 180-Day Exclusivity and Recent Reform Proposals**

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Abstract:

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) to facilitate the market entry of generic drugs after brand-name drugs' patent exclusivity ended. To incentivize generic manufacturers to challenge brand-name manufacturers' patents, a 180-day exclusivity accrued to the first manufacturer to successfully litigate the validity or scope of a brand-name drug patent. However, brand-name and generic manufacturers have found ways to strategically “park” the 180-day exclusivity to delay generic entry and competitive drug markets. Congress revised the statute in 2003, but concerns continued. In 2019, three congressional bills were introduced to further revise the 180-day exclusivity framework. This Article reviews the history of the 180-day provision, evaluates what types of strategic behavior remained after 2003, and considers whether the recent legislative proposals are likely to offer improvement.

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## INTRODUCTION

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) to rebalance the interests of patent holders and generic drug companies in the wake of the 1962 Kefauver-Harris Drug Amendments. One of the law’s major innovations was a new framework designed to facilitate the market entry of generic drugs by incentivizing generic manufacturers to challenge brand-name manufacturers’ patents.<sup>1</sup> To this end, the law required brand-name manufacturers to disclose to the Food and Drug Administration (FDA) those patents that were claimed to cover their drugs. The agency would then list those patents in a publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (informally known as the “Orange Book”). Because it can be difficult to determine which of the approximately 350,000 patents issued each year are relevant to a given drug,<sup>2</sup> this new system promoted transparency and helped generic drug manufacturers assess the risk and feasibility of entering the market. The Act also provided that filing a generic drug application with the FDA could be an act of patent infringement, allowing any patents listed by the brand-name manufacturers to be reviewed in court and potentially invalidated.<sup>3</sup> Traditional patent infringement rules generally require patent owners to wait to sue until a potentially infringing product is made, used, sold, offered for sale, or imported into the United States. Through the Act’s process, the intellectual property landscape could potentially be resolved sooner than was previously possible.

Patent litigation, however, is expensive, time-consuming, and, if successful, could in some cases immediately open the market to all competitors and not just the patent challenger.<sup>4</sup> To incentivize a generic drug manufacturer to engage in patent challenges, the Act offered as a prize a period of generic drug exclusivity to the first manufacturer that asserted the invalidity or non-infringement of the brand-name patents. Exclusivity would be granted even if the patent holder did not bring suit or if the case settled rather than leading to patent invalidation or a finding of non-infringement.<sup>5</sup> Then, for 180 days after the FDA received notice

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1 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585; 21 U.S.C. § 355(j)(5)(B)(iv) (2018).

2 Reed F. Beall & Aaron S. Kesselheim, *Tertiary Patenting on Drug-Device Combination Products in the United States*, 36 NATURE BIOTECHNOLOGY 142, 143 tbl.1 (2018) (indicating an average of approximately three unique patents per new drug by 2016).

3 35 U.S.C. § 271 (2018).

4 Evan J. Wallach & Jonathan J. Darrow, *Federal Circuit Review of USPTO Inter Partes Review Decisions, by the Numbers: How the AIA Has Impacted the Caseload of the Federal Circuit*, 98 J. PAT. & TRADEMARK OFF. SOC’Y 105, 118 (2016).

5 Food & Drug Admin., *Guidance for Industry: 180-Day Exclusivity: Questions and Answers*, U.S. DEP’T HEALTH & HUM. SERVS. 10 (Jan. 2017), <https://www.fda.gov/regulatory->

that the first generic was being marketed, the FDA could not approve other competing generics. Free-riding by other generic manufacturers on the patent challenger's efforts would therefore be temporarily curtailed. For those 180 days, only the first generic product and the brand-name product could be sold, creating a potentially lucrative duopoly for the generic manufacturer that would allow it to sell its product for a much higher price than it could if other generic competitors were allowed to enter the market.

The Hatch-Waxman Act has been widely viewed as a success. In the years following its enactment, annual generic drug approvals increased from a median of 136 in the years 1970–1984, to 284 in 1985–2012, and to 588 in 2013–2018.<sup>6</sup> But the 180-day exclusivity incentive has remained controversial. Generic manufacturers consider it to be a crucial feature supporting the growth of the international generic drug industry.<sup>7</sup> But enterprising brand-name and generic manufacturers have found ways to strategically use the 180-day exclusivity to delay generic entry and competitive drug markets. For example, in the years following 1984, some brand-name and generic manufacturers settled patent litigation with payments made to the generic that prevented or delayed the start of the 180-day period. Such “parking” also prevented entry of other generic competitors that were required by law to wait until the 180-day period had elapsed.

Congress substantially revised the statute in 2003 to address parking, yet sixteen years later, legislators and commentators continue to worry about it.<sup>8</sup> In 2019, three congressional bills were introduced that sought to further revise the 180-day exclusivity framework. To understand whether such additional changes to the 180-day exclusivity period are needed, we reviewed the history of the provision and evaluated what types of strategic behavior remained after 2003. Finally, we considered whether the recent legislative proposals are likely to improve the current framework.

## I. THE 180-DAY EXCLUSIVITY FRAMEWORK

Under the Hatch-Waxman Act, brand-name manufacturers were required to

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information/search-fda-guidance-documents/guidance-industry-180-day-exclusivity-questions-and-answers.

<sup>6</sup> Jonathan J. Darrow, Jerry Avorn & Aaron S. Kesselheim, *FDA Regulation and Approval of Pharmaceuticals*, 1983-2018, 323 JAMA 164 (2020).

<sup>7</sup> *AAM Position Paper on the HHS 180-Day Exclusivity Proposal*, ASS'N FOR ACCESSIBLE MEDS. (Mar. 2018), <https://accessiblemeds.org/resources/fact-sheets/aam-position-paper-hhs-180-day-exclusivity-proposal>.

<sup>8</sup> *House E&C Health Subcommittee Holds Hearing on Reducing Barriers to Market Competition for Prescription Drugs*, ERNST & YOUNG: TAX NEWS UPDATE (Mar. 13, 2019), <https://taxnews.ey.com/news/2019-0671-house-e-and-ampc-health-subcommittee-holds-hearing-on-reducing-barriers-to-market-competition-for-prescription-drugs>.

list with the FDA information about key patents claiming their drugs. Generic manufacturers later seeking FDA approval of copies of brand-name drugs were required to make one of four certifications with respect to these patents: (1) that no patents covering the drug had been listed by the FDA (Paragraph I certification); (2) that any listed patents had expired (Paragraph II certification); (3) that the drug would not be marketed until the patents expired (Paragraph III certification); or (4) that listed patents were invalid or would not be infringed by the generic product (Paragraph IV certification). A Paragraph IV challenge was deemed an artificial act of infringement, which allowed brand-name manufacturers to initiate litigation over the validity and scope of the patents years earlier than under traditional patent law rules. The Act provided that the generic drug could not be approved until that litigation ended or thirty months elapsed from when the patent holder received notice of the Paragraph IV certification, whichever came first. In facilitating litigation and adjudication of patents protecting a brand-name drug, Paragraph IV challenges served a social utility function: since a Paragraph IV challenge could lead to the invalidation of patents that should not have been granted in the first place or could help demonstrate how to manufacture a bioequivalent generic product without infringing the patents, cheaper generics could be made available to patients sooner. To incentivize Paragraph IV challenges, the Act offered the first generic filer of an application containing a Paragraph IV certification the ability to earn 180 days of generic exclusivity.

The 180-day duopoly could be very lucrative for generic manufacturers. Unlike in many countries around the world, drug manufacturers in the United States are treated like manufacturers of nearly all other products in that they can freely set the prices of their offerings. When the existing patent system (established in 1790) and this traditional free-market pricing philosophy were joined by expanding drug insurance coverage beginning with the federal Medicare and Medicaid programs in the 1960s, U.S. drug prices were free to rise to unprecedented levels, at least until patents expired.<sup>9</sup>

Following patent expiration, drug prices can drop dramatically. Generic manufacturers have much lower research, development, and marketing expenditures than brand-name manufacturers and can sell their products at a profit for a price much closer to the marginal cost of production. For large markets that can attract ten or more generic manufacturers, prices have eventually dropped 79% or more compared to the brand-name price<sup>10</sup> (though

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<sup>9</sup> Jonathan J. Darrow & Donald W. Light, *Beyond the High Prices of Prescription Drugs: A Framework to Assess Costs, Resource Allocation, and Public Funding*, 40 HEALTH AFFS. 281 (2021).

<sup>10</sup> Chintan V. Dave, Abraham Hartzema & Aaron S. Kesselheim, *Prices of Generic Drugs*

most generic drug markets have four or fewer competitors<sup>11</sup>). Even in markets that will eventually attract many competitors, the duopoly facilitated by the 180-day exclusivity period means that the sole generic manufacturer is not pressured by other generics to sell its product for such low prices and may introduce its product at only a 10–15% discount compared to the brand-name product.<sup>12</sup> Generic manufacturers could therefore make substantial profits during the six-month period when prices would be close to the brand-name drug price.

#### *A. Early Problems with 180-Day Exclusivity*

With massive revenues sometimes at stake, manufacturers figured out how to strategically deploy the Hatch-Waxman Act process in ways that did not result in a timely court resolution facilitating widespread generic entry. These tactics were motivated by the manufacturers' goal of disincentivizing generic entry and preserving market exclusivity which, in turn, would safeguard profits. In some cases, generic and brand-name drug manufacturers entered into settlement agreements arising from the patent litigation, leaving the patents intact. When these settlements involved an agreement to delay generic entry (and thereby the start of the 180-day exclusivity period) in return for cash payments from the brand-name manufacturer to the alleged generic infringer, they became known as "reverse payment" (or "pay-for-delay") agreements. These agreements caught the attention of the Federal Trade Commission (FTC) for potentially violating antitrust laws.

In a 2002 report, the FTC observed that from 1992 through 2000 there were 82 brand-name drug products associated with a Paragraph IV certification (excluding 22 products for which patent litigation was pending court resolution).<sup>13</sup> Of these, the patent holder did not sue the first filer in 29 instances (35%). Of the remaining 53 brand-name products with resolutions, 14 ended with settlement agreements, including 9 (11% of 82) that involved cash payments of between \$1.75 million and \$132.5 million by the brand-name manufacturer to the first generic applicant.<sup>14</sup> Although reverse-payment settlements were therefore

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*Associated with Numbers of Manufacturers*, 377 NEW ENG. J. MED. 2597, 2598 fig.1 (2017).

11 Chintan V. Dave, Aaron S. Kesselheim, Erin R. Fox, Peihua Qiu & Abraham Hartzema, *High Generic Drug Prices and Market Competition: A Retrospective Cohort Study*, 167 ANNALS INTERNAL MED. 145, 146 tbl.1 (2017).

12 *Id.*

13 *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, FED. TRADE COMM'N 15 (July 2002), [https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy\\_0.pdf](https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf). A total of 130 brand-name drug products were subject to at least one Paragraph IV certification from 1984 to January 2001, but the FTC study included only the most recent 104 of these. *Id.* at 10.

14 *Id.* at 32 tbl.3-3; *In re Nexium Antitrust Litigation*, PUB. CITIZEN, <https://www.citizen.org/re-nexium-antitrust-litigation> (discussing *In re Nexium Antitrust Litig.*,

small in number compared to the 8,019 generic drug applications filed between 1984 and 2000,<sup>15</sup> the incentive to enter into such settlements would be greatest in markets with the largest profit potential, and could thus exert a significant impact on public expenditures.

Brand-name manufacturers used other tactics to undermine the 180-day exclusivity incentive. For example, brand-name manufacturers could sell their already-approved product in the form of an “authorized generic.” Although the authorized generics are exactly the same drug products as those packaged and sold under the corresponding brand name, they simulate a three-manufacturer oligopoly that increases price competition and thereby reduces the value of the 180-day exclusivity to the first generic entrant. Another tactic involved brand-name manufacturers listing with the FDA new patents covering their drugs that were issued after the filing of the generic drug application, which in turn meant that the first-filer had to provide a new Paragraph IV certification as to those patents. Because the FDA considered each Paragraph IV certification to trigger a 30-month stay during which time no other generics could be approved, brand-name manufacturers could obtain additional exclusivity when such patents were issued.<sup>16</sup> Yet another brand-name manufacturer strategy involved delisting patents that were the subject of Paragraph IV challenges if it appeared the patents would be invalidated in court. The FDA initially took the position that the practice of patent delisting canceled the 180-day exclusivity, but the FDA’s interpretation was later overturned in court, removing the incentive to delist.<sup>17</sup>

Gaming related to the 180-day exclusivity period also arose on the generic side. For example, in their zeal to win the race to be first-filers, some generic manufacturers submitted their Paragraph IV certifications even before their testing, applications, and manufacturing facilities were ready. With the right to 180-day exclusivity in hand, the generic manufacturer might then take an extended period of time to cure application deficiencies and obtain FDA approval, preventing other generic drug companies from marketing their products in the meantime.<sup>18</sup> For example, in 2002, Ranbaxy submitted its application for generic atorvastatin (Lipitor), a blockbuster treatment for high cholesterol, which

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777 F.3d 9 (1st Cir. 2015)); *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, *supra* note 13, at 31.

15 *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, *supra* note 13, at 10; *ANDA (Generic) Drug Approvals in 2002*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/first-generic-drug-approvals/anda-generic-drug-approvals-previous-years>

16 *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1340 (Fed. Cir. 2003).

17 *Ranbaxy Lab’ys Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006).

18 Shashank Upadhye, *There’s a Hole in My Bucket Dear Liza, Dear Liza: The 30-Year Anniversary of the Hatch-Waxman Act: Resolved and Unresolved Gaps and Court-Driven Policy Gap Filling*, 40 WM. MITCHELL L. REV. 1307, 1326 (2014).

the FDA did not approve until 2011, following 14 amendments.<sup>19</sup> Another example of delaying the 180-day exclusivity trigger entailed a manufacturer that sought approval of a generic version of carbamazepine (Tegretol), a treatment for seizures.<sup>20</sup> Its Abbreviated New Drug Application (ANDA) had been submitted in 2003 and was amended over 20 times before it was finally approved in 2011.<sup>21</sup>

### *B. Reforms of the 2003 Medicare Modernization Act*

Recognizing that the Hatch-Waxman Act created opportunities for strategic behavior that undermined the goals of the 180-day exclusivity incentive, legislators included corrective provisions in the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA).<sup>22</sup> The MMA included provisions to reduce the problem of brand-name manufacturers listing later-issued patents necessitating additional challenges and leading to multiple 30-month stays. Only one 30-month stay could be obtained per ANDA, regardless of the number of patents listed with the FDA, and these stays would be triggered based only on patents listed at the time of ANDA filing.<sup>23</sup> Legislators addressed patent delisting by providing that delisting would generally not result in canceling the 180-day exclusivity.<sup>24</sup>

The MMA also provided that 180-day exclusivity could be triggered only by commercial launch, rather than by either commercial launch or a final court decision on patent infringement, as was the case under the Hatch-Waxman Act.<sup>25</sup>

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19 Letter from Food & Drug Admin. to Ranbaxy Inc. (2011), [https://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2011/076477Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/076477Orig1s000ltr.pdf) (regarding ANDA 076477).

20 *Nostrum Pharms., LLC v. U.S. FDA*, 2011 No. 11-3111 (JAP), 2011 WL 2652147 (D.N.J. July 6, 2011).

21 *Approval Package for: Application Number: ANDA 76-697*, FOOD & DRUG ADMIN. 225 (May 20, 2011), [https://www.accessdata.fda.gov/drugsatfda\\_docs/anda/2011/076697Orig1s000.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/anda/2011/076697Orig1s000.pdf) Using the search tool at *Drugs@FDA: FDA-Approved Drugs*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/lll.cfm>, one can count the number of amendment dates listed by the FDA for an ANDA; this application shows twenty amendments.

22 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, 117 Stat. 2066; Federal Food, Drug, and Cosmetic Act (FFDCA), Pub. L. No. 75-717, § 505(j)(5)(D)(i), 52 Stat. 1040 (1938).

23 21 U.S.C. § 355 (j)(5)(D)(iii) (2018); *see also* 149 Cong. Rec. 31,783 (2003) (statement of Sen. Kennedy) (“The Hatch-Waxman provisions in this bill also make the exclusivity available only with respect to the patent or patents challenged on the first day generic applicants challenge brand drug patents, which makes the exclusivity a product-by-product exclusivity rather than a patent-by-patent exclusivity.”).

24 MMA § 1102(a), 117 Stat. at 2457-60. The MMA was not retroactive, and the D.C. Circuit later interpreted the pre-MMA statute in a similar manner. *See supra* note 17 and accompanying text.

25 21 U.S.C. § 355 (j)(5)(B)(iv) (2018) (amended in 2003 by the MMA); FFDCA § 505(j)(5)(B)(iv)(I); *see also* 21 C.F.R. § 314.3(b) (2020) (“Commercial marketing is the

In situations in which a generic firm challenged a secondary patent while waiting for the underlying active ingredient patent to expire, eliminating the court-decision trigger helped to ensure that the 180-day period would not begin to run before the generic manufacturer was lawfully able to enter the market. By providing assurance to generic manufacturers that they would enjoy the entire exclusivity period, the MMA maximized the incentive to bring a Paragraph IV challenge. The change also encouraged earlier challenges of secondary patents.<sup>26</sup>

Even before the MMA, if the FDA concluded that a first generic applicant was not “actively pursuing” FDA approval, the FDA could immediately approve subsequent generic applicants that were otherwise eligible.<sup>27</sup> Strengthening the law to ensure against intentional delays by generic manufacturers (either for their own gain or as part of an agreement with a brand-name manufacturer), the MMA specified six events that would trigger first-filer generics to forfeit their 180-day exclusivity. Forfeiture would occur under the MMA if all patents as to which Paragraph IV certifications were filed had expired, preventing the 180-day period from extending the total exclusivity period beyond that otherwise permitted under the patent laws (Event #1). To prevent delays caused by agreements by which the first-filer refrained from or delayed market entry, forfeiture would occur if the first-filer withdrew its application (Event #2), amended its certification from a Paragraph IV to, for example, a Paragraph III (i.e., indicating it would wait until patent expiration to market its product) (Event #3), or failed to market its drug within 75 days after FDA approval (Event #4).<sup>28</sup> To minimize the delays caused by premature filing of generic drug applications that were not ready for FDA review and approval, or by failure to diligently shepherd applications through approval, the MMA provided that forfeiture would occur if the first-filer failed to obtain FDA approval of its ANDA within 30 months of the

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introduction or delivery for introduction into interstate commerce of a drug product described in an ANDA, outside the control of the ANDA applicant, except that the term does not include transfer of the drug product for investigational use under part 312 of this chapter or transfer of the drug product to parties identified in the ANDA for reasons other than sale. Commercial marketing includes the introduction or delivery for introduction into interstate commerce of the reference listed drug by the ANDA applicant.”).

<sup>26</sup> *Examining the Senate and House Versions of the “Greater Access to Affordable Pharmaceuticals Act”*: Hearing before the S. Comm. on the Judiciary, 108th Cong. 96-97 (2003).

<sup>27</sup> See Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28895 (proposed July 10, 1989) (to be codified at 21 C.F.R. pt. 314). This regulation was implemented in 1994. See Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50354 (Oct. 3, 1994) (to be codified at 21 C.F.R. pt. 314); 21 C.F.R. § 314.107(c)(3) (2020).

<sup>28</sup> Complaint for Declaratory Judgment at 8, *Cobalt Pharms. Inc. v. Bayer AG*, No. 1:07-cv-05875 (N.D. Ill. Oct. 17, 2007); Kurt R. Karst, *FDA Determines that Cobalt Forfeited 180-Day Exclusivity for Generic PRECOSE; Agency Is Sued Yet Another Time*, FDA L. BLOG (May 11, 2008), <https://www.thefdalawblog.com/2008/05/fda-determines/>.

filing date (unless caused by a change in FDA approval requirements) (Event #5).<sup>29</sup> Finally, forfeiture would occur if the first-filer entered into an anticompetitive settlement agreement with the patent holder, a provision that directly discouraged such settlements (Event #6).<sup>30</sup>

### C. Post-2003 Implementation of 180-Day Exclusivity

After the MMA, Paragraph IV challenges continued to increase in frequency and occur ever sooner after approval of the brand-name product. The share of new drugs experiencing such a challenge increased from 9% of those first facing generic competition in 1995 to 76% in 2014.<sup>31</sup> The number of years from brand-name approval to first Paragraph IV challenge decreased from 18.7 years for drugs experiencing first generic competition in 1995 to 5.9 years in 2014.<sup>32</sup>

The growth of the generic drug industry and the continued popularity of Paragraph IV challenges after 2003 show that the MMA's anti-parking provisions did not undermine the incentive effects of the 180-day exclusivity provision. However, while parking of the 180-day exclusivity period became more difficult after the MMA, some concerns remained. One of these concerns was that, although the MMA provided for forfeiture of 180-day exclusivity in the case of settlement agreements, it did so only if a final FTC or court decision determined the settlement agreement violated antitrust laws. It was unclear, however, when settlements would meet this criterion. In 2013, the U.S. Supreme Court in *FTC v. Actavis* affirmed that settlements were subject to FTC scrutiny and the potential for liability even if the settlement agreement stayed within the exclusionary scope of the patent.<sup>33</sup> While settlements have continued since *Actavis*, few have involved reverse payments that might violate antitrust laws. By 2016, of the 232 Paragraph IV litigation settlements reported to the FTC, only 16 (7%) involved transfers of cash from the brand-name to the generic manufacturer, all of which involved payment only for litigation costs.<sup>34</sup> The FTC

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29 FFDCA § 505(j)(5)(D)(i)(IV).

30 MMA § 1102(a)(2), 117 Stat. at 2458-60.

31 Henry Grabowski, Genia Long, Richard Mortimer & Ani Boyo, *Updated Trends in US Brand-Name and Generic Drug Competition*, 19 J. MED. ECON. 836 (2016) [hereinafter Grabowski et al., *Updated Trends*]; Henry G. Grabowski, Margaret Kyle, Richard Mortimer, Genia Long & Noam Kirson, *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 HEALTH AFFS. 2162 (2011).

32 Grabowski et al., *Updated Trends*, *supra* note 31.

33 *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

34 *Pharmaceutical Agreement Filings*, FED. TRADE COMM'N, <https://www.ftc.gov/advice/guidance/guidance/care/agreement-filings>; Brad Albert, Armine Black & Jamie Towey, *MMA Reports: No Tricks or Treats—Just Facts*, FED. TRADE COMM'N: COMPETITION MATTERS (Oct. 27, 2020, 5:15 PM), <https://www.ftc.gov/news-events/blogs/competition-matters/2020/10/mma-reports-no-tricks-or-treats-just-facts>.

has nevertheless emphasized the need to monitor settlements for less transparent forms of compensation that might constitute illegal reverse payments, such as agreements by which patent holders refrain from selling authorized generics in the United States<sup>35</sup> or that allow generic manufacturers to enter foreign markets before patents in those markets expire.

One other source of delay was observed after the MMA but was both uncommon and not clearly attributable to strategic manufacturer behavior. This type of delay occurs when a first-filer fails to obtain FDA approval within thirty months due to a change in FDA-approval requirements rather than the fault of the applicant,<sup>36</sup> in which case forfeiture of 180-day exclusivity will not result.<sup>37</sup> Between 2007 and 2012, changes to FDA review standards were estimated to have led to delays in approximately 20 cases among the more than 3,500 generic drug applications approved in those years (0.006%).<sup>38</sup> For example, a generic version of clobetasol propionate shampoo (Clobex) used to treat eczema and psoriasis was submitted in 2007 but was not approved until 2011,<sup>39</sup> thereby not triggering its 180-day exclusivity for more than fifty months due to changes by the FDA in standards related to vasoconstrictor bioassays that the generic manufacturer needed to conduct to demonstrate bioequivalence and receive FDA approval.<sup>40</sup> A generic version of levocetirizine (Xyzal) allergy tablets retained 180-day exclusivity after a delay of five months beyond the thirty-month limit due to a change in the indication of the brand-name drug from children of “6 months to 5 years of age” to “children 2 years of age and older,” among other labeling changes.<sup>41</sup> Specifically, during its bioequivalence review, the agency asked the drug sponsor, Actavis, to perform comparative vasoconstrictor bioassay studies; the agency later told Actavis the agency was reviewing the appropriateness of vasoconstrictor bioassay studies for topical corticosteroid drug products that are applied to the hirsute scalp, which caused the five-month delay.

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35 Albert et al., *supra* note 34.

36 FFDCA § 505(j)(5)(D)(i)(IV).

37 *Id.*

38 Kurt R. Karst, *Excuses, Excuses! A Round-Up of Exceptions Under the Failure to Obtain Timely Tentative Approval 180-Day Exclusivity Forfeiture Provision*, FDA L. BLOG (Nov. 1, 2012), <http://www.fdalawblog.net/11/excuses-a-round-up-of-exceptions-under-the-failure-to-obtain-timely-tentative-approval-180-d>.

39 Letter from Food & Drug Admin. to Actavis Mid Atlantic LLC (2011), [https://www.accessdata.fda.gov/\\_docs//ltr.pdf](https://www.accessdata.fda.gov/_docs//ltr.pdf) (regarding ANDA 078854). The shampoo contains vasoconstrictive properties in its chemical structure. *Id.* at 2.

40 *Id.*

41 Letter from Food & Drug Admin. to Synthon Pharms., Inc. (2010), [https://www.accessdata.fda.gov/\\_docs//ltr.pdf](https://www.accessdata.fda.gov/_docs//ltr.pdf) (regarding ANDA 090229); *Highlights of Prescribing Information: Xyzal*, FOOD & DRUG ADMIN. (2009), [https://www.accessdata.fda.gov/\\_docs//022157s003lbl.pdf](https://www.accessdata.fda.gov/_docs//022157s003lbl.pdf).

## II. THE PROSPECT OF ADDITIONAL 180-DAY EXCLUSIVITY REFORM

In 2019, three legislative proposals were introduced in Congress to address remaining opportunities for parking: the BLOCKING Act, the Expanding Access to Lower Cost Generic Drugs Act, and the Lower Health Care Costs Act.<sup>42</sup> The BLOCKING Act<sup>43</sup> would have allowed later-filed generic applications to be approved if over 30 months passed since submission of the first-filer's application,<sup>44</sup> even if the first-filer's lack of marketing within 30 months was caused by changes to FDA review standards. But because it can be difficult to predict when or how review standards will change, the BLOCKING Act may disincentivize bringing patent challenges by placing the risk on the first-filer that changes to the regulatory review process—which are generally beyond its control—will delay an application's approval.<sup>45</sup>

The BLOCKING Act thus seeks to address a parking problem that has arisen in an extremely small fraction of generic drug approvals and that may not be the fault of generic drug applicants, at the potential cost of reducing incentives intended to motivate all generic manufacturers to engage in the Paragraph IV certification process in the first place. If reintroduced, the BLOCKING Act could be amended to allow first-filers to justify delays, but this would increase administrative costs and fail to completely eliminate uncertainty. Alternatively, a second, longer time limit (e.g., 40 months) could be added to the bill to apply when review standards change. Yet, this too would increase complexity without eliminating the uncertainty that could chill generic manufacturer incentives for bringing Paragraph IV challenges were the BLOCKING Act to pass.<sup>46</sup> Despite the potential to dampen first-filer enthusiasm, the BLOCKING Act received a Congressional Budget Office score report in 2019 estimating that the bill would save an average of \$44.2 million per year on federal drug spending over the next ten years.<sup>47</sup> By comparison, the U.S. prescription drug market is nearly \$500

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42 Blocking Act of 2019, H.R. 938, 116<sup>th</sup> Cong. (2019); Expanding Access to Lower-cost Generics Act of 2019, S.3092, 116<sup>th</sup> Cong. (2019); Lower Health Care Costs Act of 2019, S.1895, 116<sup>th</sup> Cong. (2019).

43 Michael A. Carrier, Opinion, *Solving the 'Parking' Problem in the Drug Monopoly Game*, HILL (Dec. 27, 2019, 9:30 AM EST), <https://thehill.com/solving-the-parking-problem-in-the-drug-monopoly-game>.

44 This assumes the ANDA contains deficiencies if still not approved after 30 months.

45 Scott Gottlieb, *The HELP Committee's Fix for 180-Day Generic Marketing Exclusivity: Does It Solve the Problem?*, HEALTH AFFS. BLOG (May 30, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190529.223594/full/>.

46 Kurt R. Karst, *The BLOCKING Act: "Oh You Know, Strikes and Gutters, Ups and Downs,"* FDA L. BLOG (June 3, 2019), <https://www.thefdalawblog.com/2019/06/the-blocking-act-oh-you-know-strikes-and-gutters-ups-and-downs/> (proposing a 42-month alternative period to apply when review standards change).

47 *H.R. 938: BLOCKING Act of 2019*, SPENDING TRACKER, <https://spendingtracker.org>

billion per year, with generic drugs accounting for about 20% of that spending. Although a Congressional Budget Office score showing even small amounts of savings can impact a bill's chance of enactment, the estimate of the BLOCKING Act's economic impact may not accurately account for the extent to which first-filers will experience reduced incentives to submit applications.<sup>48</sup>

A second bill, the Expanding Access to Lower Cost Generic Drugs Act, is intended to address two parking-related problems. "First applicants" are defined more broadly than under current law to include later applicants filing Paragraph IV certifications for each of the patents addressed by a previous Paragraph IV certification of an earlier applicant. The bill would cause first applicants to lose their first-filer status if they enter into "disqualifying agreements," defined as those in which a generic applicant agrees with the manufacturer of the brand-name reference product to delay marketing until after the expiration of the 180-day exclusivity period of another applicant. This section of the bill is intended to combat reverse payment settlement agreements, although such agreements are both increasingly rare and already subject to challenge under antitrust laws. The bill also seeks to reduce parking by allowing subsequent filers that challenge patents through a Paragraph IV certification to share the 180-day exclusivity period with first-filers.<sup>49</sup> The threat of having to share the exclusivity could potentially motivate first-filers to trigger the exclusivity as early as possible to avoid overlap with the commercial time frame of a subsequent filer reaching FDA approval and resolving litigation. This would increase the number of competitors during the 180-day window if subsequent filers are able to quickly resolve litigation, but it is unclear how frequently this occurs, and invalidation of previously-challenged patents by subsequent filers is believed to be rare.<sup>50</sup> As with the proposed BLOCKING Act, the bill could lead to reduced incentives to challenge patents, since the potential to share exclusivity would increase uncertainty and, when it occurs, reduce the profits of the first generic manufacturer.

A third bill, the Lower Health Care Costs Act would allow the FDA to approve a subsequent generic application if a first-filer did not receive final approval of its ANDA within 33 months of submitting its application. This grants

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/bills/hr938-116.

48 EZEKIEL J. EMANUEL, *REINVENTING AMERICAN HEALTH CARE: HOW THE AFFORDABLE CARE ACT WILL IMPROVE OUR TERRIBLY COMPLEX, BLATANTLY UNJUST, OUTRAGEOUSLY EXPENSIVE, GROSSLY INEFFICIENT, ERROR PRONE SYSTEM* 75 (2014).

49 Expanding Access to Low Cost Generic Drugs Act, S. 2476, 115th Cong. (2018).

50 Kurt R. Karst, *Reshaping 180-Day Exclusivity: The FAIR Generics Act Returns as the Expanding Access to Low Cost Generic Drugs Act*, FDA L. BLOG (MAR. 5, 2018), <https://www.thefdalawblog.com/2018/03/reshaping-180-day-exclusivity-the-fair-generics-act-returns-as-the-expanding-access-to-low-cost-generic-drugs-act/>.

three additional months for the first-filer to seek FDA approval in comparison with the time period offered by the BLOCKING Act (i.e., 30 months). Such a provision may be intended to motivate first-filers not to delay seeking FDA approval by setting a firm deadline on when its ability to claim first-filer exclusivity benefits expires.<sup>51</sup> Notably, current law already provides that first-filers forfeit their 180-day exclusivity if no tentative approval is obtained within 30 months of submitting the application.<sup>52</sup> The provision appears to be directed toward those cases in which FDA-approval requirements are changed and the 30-month forfeiture provision does not apply, but such cases are infrequent and occur largely outside the control of the applicant. Thus, this bill, like the other two, offered the possible benefit of fostering competitive markets in a very small number of cases, along with the very real risk of further destabilizing the existing 180-day exclusivity system. None of the bills were taken up by Congress.

#### CONCLUSION

The 180-day generic exclusivity period was established in the Hatch-Waxman Act to provide an incentive for generic manufacturers to invest the time and resources needed to challenge brand-name manufacturers' drug patents without risk that other manufacturers would immediately free-ride on their investments in patent litigation. Unforeseen loopholes in the 1984 legislation created the opportunity for strategic behavior by manufacturers intending to delay generic competition, which Congress addressed in the 2003 MMA, including the addition of a provision for forfeiture of 180-day exclusivity in the case of anticompetitive settlement agreements. In the 2013 *Actavis* decision, the Supreme Court clarified that a broad range of reverse payments could potentially violate antitrust laws, expanding the impact of the MMA. However, concerns about misuse of the 180-day incentive remained, leading to proposals to further reform the law.

Our review of available data suggests that remaining parking issues occur infrequently and, when they do occur, tend to relate to changes in FDA review standards over which generic manufacturers have little or no control. Recently proposed changes to the Hatch-Waxman Act's statutory framework are therefore unlikely to substantially improve generic availability. In addition, such changes risk upsetting existing incentives for generic manufacturers to bring Paragraph IV challenges in the first place by increasing uncertainty with respect to the ability to obtain or retain exclusivity and the extent to which the exclusivity period will be shared. In cases in which exclusivity is in fact shared, profits of first-filers will be reduced.

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<sup>51</sup> Lower Health Care Costs Act, S. 1895, 116th Cong. § 205 (2019).

<sup>52</sup> 149 Cong. Rec. 32,290-93 (2003) (statement of Sen. Hatch); 21 U.S.C. § 355(j)(5)(iv).

It is possible that strategic behavior has become less transparent, rather than less frequent, and further research may uncover more examples of gaming the 180-day exclusivity incentive. Until additional evidence of the frequency, length, and financial impact of strategic behavior emerges, Congress should refrain from revising a system that has helped increase the share of generic drugs from 19% in 1984 to 90% in 2020, and that has led to generic drug prices in the United States that are generally among the lowest in the world. As revisions to the law are considered, legislators must recognize that any changes could inadvertently undo gains, as well as close loopholes. Legislators should avoid statutory amendments that undermine existing incentives to file generic applications containing Paragraph IV certifications.