The Generic Exclusivity Period and the Market Life of Drugs

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ABSTRACT

Generic drug sellers are relied on to challenge brand drug patents, but invalidation allows other sellers to enter. The 180-day exclusivity period, awarded to the first challenger of a drug's patent(s), was created to address this potential free-rider problem. The exclusivity period incentivizes challenges but also delays entry by later-filing firms, so has the potential to harm competition overall. This paper examines whether a drug's effective market life (time between brand and generic entry) is longer when the value of the exclusivity period is diminished, which happens when it is shared (by firms filing simultaneously) or forfeited. Among 141 drugs experiencing generic entry during 2015-2025, the average effective market life was over three years shorter when the exclusivity period was shared and similar when forfeited, even after controlling for drug and patent characteristics. These results challenge the notion that a lucrative exclusivity period is necessary to encourage drug patent challenges.

Introduction

Pharmaceutical policy aims to encourage innovation while also making drugs affordable for patients. The U.S. balances these competing objectives with the Hatch-Waxman Act of 1984 (officially titled the Drug Price Competition and Patent Term Restoration Act), which protects new brand drugs from competition initially while also encouraging entry by generic suppliers.

Brand drug sellers attempt to block competition by acquiring and asserting patents. However, drug patents – especially patents claiming characteristics or uses of a drug rather than the chemical itself – are often invalid or easily invented around.[1] The U.S. system relies on generic drug firms to challenge patents that may not be upheld in court. In practice, generic drugs are often launched well before the expiration dates of all a drug's patents.[2]

A generic drug seller that successfully invalidates a brand drug's patents in court may pave the way for other generic competitors to also enter. If enough competitors enter quickly, the original challenger may not profit from the challenge on net. This free-rider problem could discourage firms from pursuing patent challenges in the first place.[3,2]

To address this conceptual issue, the Hatch-Waxman Act created the 180-day exclusivity period, which is awarded to the first generic drug seller to challenge a patent in an application for approval from the Food and Drug Administration (FDA). During the exclusivity period, other generic drug sellers cannot receive FDA approval, so the "first filer" can sell at a high price and benefit from a first-mover advantage that allows it to retain a high volume of sales even after other generic drug sellers enter.[4,5]

In addition to rewarding patent challenges, the Hatch-Waxman Act also made them less costly (i.e., under $10 million) by allowing generic drug firms applying for FDA approval to rely on studies previously conducted by the brand drug seller.[6,7] Thus, although patent challenges

have become common (now affecting over 90 percent of top-selling brand drugs[2]) the extent that the exclusivity period has accelerated generic competition is unclear. The increase in patent challenges could simply be the result of an inexpensive and by now familiar regulatory process.

While the 180-day exclusivity period rewards firms for filing patent challenges, it also reduces generic competition. First, during the exclusivity period, the number of generic drug sellers is restricted so that generic drug prices are higher than they could otherwise be with more generic drug sellers. Second, first filers commonly settle patent challenges by agreeing to "park" the exclusivity period in the future, which blocks later filers that may have otherwise entered earlier.[8,9] The parking problem is exacerbated by settlements including brand-to-generic reverse payments that further delay generic entry.[10,11]

Several proposed policies aim to deter or prevent parking and pay-for-delay. For example, the "Bringing Low-cost Options and Competition while Keeping Incentives for Generics Act" (the BLOCKING Act) would allow FDA to approve later-filing generics unless the first filer entered quickly.[12] Critics argue that, because of the potential free-rider problem described above, any policy that erodes the value of the exclusivity period would harm competition.[13,14]

This paper assesses the potential benefits of the exclusivity period that might offset the known delays it causes. We start by examining how frequently the exclusivity period is shared (by multiple firms filing simultaneously) or forfeited, which both diminish its value. We then investigate whether drugs with shared or forfeited exclusivity have a longer effective market life (time between brand and generic entry) compared to the commonly described circumstance where one firm has sole eligibility for the exclusivity period. We also examine the frequency of patent challenges by first filers and later filers that are eligible and ineligible, respectively, for the exclusivity period.

Background

Firms apply for FDA approval to sell a brand drug by submitting a New Drug Application (NDA) that contains information from clinical research about the drug's safety and efficacy.[15] The NDA must also include a list of patents that could be asserted in court. FDA publishes patent information in an electronic database called the *Orange Book*.[16]

A new brand drug that contains no active ingredients previously approved by FDA is categorized as a new chemical entity (NCE). NCEs benefit from a five-year regulatory exclusivity period during which FDA will not approve any generic versions of the drug.[17] However, an application for a generic product with a patent challenge can be submitted to FDA four years after the NDA approval.[17]

A generic drug is a copy of a reference brand drug that has the same active ingredient, form, route of administration, and strength. Firms apply for FDA approval to sell a generic drug by submitting an abbreviated NDA (ANDA). An ANDA can rely on the safety and efficacy data in the reference drug's NDA so generic drug sellers usually do not need to conduct new clinical research before submitting an ANDA.[18]

An ANDA must also include a certification as to the reference drug's patents. Paragraph I and II certifications indicate there are no patents listed in the *Orange Book* or that there are only expired patents, respectively. A Paragraph III certification acknowledges that the applicant is not asking for FDA approval until a specific patent expires. A Paragraph IV certification asserts that a specific patent is "invalid or will not be infringed by" the product described in the ANDA.[19] For drugs with multiple unexpired patents, both Paragraph III and IV certifications are commonly included in the same ANDA for different patents.

A Paragraph IV certification is a patent challenge. An ANDA filer including a Paragraph IV certification must notify the brand drug seller of its submission.[20] If the brand drug seller sues the ANDA filer within 45 days of receiving the notice, the lawsuit initiates a "30-month stay" during which the FDA cannot grant final approval to the ANDA unless a court decision is reached.[21] For NCEs, the 30-month stay is usually added onto the five-year NCE exclusivity period so that the stay expires 7.5 years after the date of the brand drug's FDA approval.

As described above, the first ANDA filer to include a Paragraph IV certification is eligible for the 180-day exclusivity period during which FDA will not approve other ANDAs. However, eligibility for the exclusivity period can be shared by multiple firms submitting ANDAs on the same day.[22] Shared exclusivity is common for NCEs because multiple ANDAs are often submitted on the first possible day they can be submitted: the day after the four-year block ends. Shared exclusivity is rare for non-NCEs because ANDAs can be submitted anytime.[23] With shared exclusivity, the 180-day period starts when any of the first filers begin selling. Any of the first filers can sell during the shared exclusivity period but it only runs once.[22]

Eligibility for the exclusivity period can also be forfeited. Most commonly, a firm forfeits its eligibility by not receiving "tentative" FDA approval within 30 months of its ANDA filing – where tentative indicates the ANDA would otherwise receive FDA's final approval if not for an unchallenged patent or a regulatory exclusivity period such as the 30-month stay.[9] No other generic firms can obtain eligibility after the exclusivity period has been forfeited.

Study Data and Methods

Data We used FDA datasets to identify drugs (i.e., unique active ingredients) with an NCE designation that experienced generic entry between January 2015 and August 2025.

We identified unique NDA and ANDA numbers and their corresponding brand drug names, active ingredients, and forms of administration using drugs@fda.[24] FDA's National Drug Code (NDC) Directory,[25] downloaded in September 2025, was used to identify the earliest "start marketing date" for each NDA and ANDA. Because data are removed when NDCs are delisted, we also downloaded archived versions of the NDC Directory from each year between 2012 and 2024 using the Wayback Internet Archive.[26]

We identified NDAs with an NCE exclusivity and at least one listed patent with *Orange Book* data, which we downloaded in September 2025.[16] To capture delisted information, we also used an archived version from each year between 1985 and 2024.[26,27] We determined the number of listed patents and whether each had drug-substance, drug-product, or method-of-use claims. A patent can include multiple claims so these categories are not mutually exclusive.

For each NDA, we compiled information about the 180-day exclusivity period from FDA's Paragraph IV Patent Certifications List.[28] We included the number of first filers initially eligible for the exclusivity period and whether it was forfeited. We categorized the exclusivity period as forfeited if the status in the FDA's list was "extinguished" or "deferred" – when an ANDA does not obtain timely approval, FDA defers its final decision until another ANDA is approved because there are some exemptions.[22] We categorized the exclusivity period as retained if the status was "eligible" or "non-forfeiture."

We combined the datasets based on the NDA and ANDA numbers. For each unique active ingredient, we limited our data to the NDA and ANDA numbers with the earliest entry date and an NCE designation. We also limited the data to NCEs experiencing generic entry in January 2015 or later.

The entry dates in the NDC Directory are reported by manufacturers and are often inaccurate. We checked each entry date against the first quarter of sales in the Medicaid State Drug Utilization Data[29] or another publicly available source, such as a generic entry announcement. We modified 25 percent of the entry dates to match a different source other than the NDC Directory.

All drugs with at least one first filer experienced a patent challenge. We further determined if a non-first filer had been sued for filing a patent challenge by using the Paragraph Four Report,[30] which is a website that organizes legal documents by drug.

Finally, we gathered information about the drugs' annual pre-generic brand sales from publicly available sources, such as generic entry announcements and SEC filings.

Analysis Descriptive statistics were used to examine the NCE drugs in our dataset. We show how frequently the drugs experienced a patent challenge and whether the exclusivity period was shared or forfeited.

Following earlier research, we calculate each drug's effective market life as the years between brand and generic entry and the nominal patent term as the years between brand entry and the latest expiring patent.[31,32] We examine how the effective market life is related to the status of the exclusivity period. We also apply linear regression models to examine this relationship with no controls; controls added for the drugs' sales and dosage form; and further controls added that represent the drugs' patent portfolio.

Finally, we examine the relationship between the effective market life, the drugs' sales, and whether it experienced a patent challenge. We grouped the drugs by quintiles of sales to allow for non-linear relationships. Our analyses are similar to those in Hemphill and Sampat's prior work.[32]

Limitations This study has several limitations. First, although our regression analysis controls for the drugs' characteristics and patent portfolio, incomplete controls mean the partial correlation between the exclusivity period status and effective market life cannot be considered a causal estimate. Second, the generic entry dates were determined from public sources and may be subject to measurement error. Third, some of our forfeited exclusivity classifications that were deferred by FDA may have qualified for exemptions so may be inaccurate.

Results

Almost 80 percent (112/141) of the NCE drugs in our data experienced a patent challenge. Figure 1 indicates that 41 percent (46/112) of the challenged drugs had multiple first filers. Although the other 59 percent had a single first filer, eligibility for the exclusivity period was often forfeited such that only 23 percent (26/112) of the challenged drugs had a single first filer with retained eligibility for the exclusivity period. Forfeited exclusivity was also common for drugs with 2-3 first filers and relatively uncommon otherwise.

The drugs had an average effective market life of 14.7 years and an average nominal patent term of 17.7 years. Figure 2 shows the average nominal patent term and effective market life by the number of first filers. When there was no patent challenge (*i.e.*, 0 first filers), generic entry necessarily occurred after the latest patent expiration date, so no extra patent term is depicted. For drugs with a patent challenge, the effective market life was shorter when there were multiple first filers despite no clear difference in the nominal patent term. Figure 3 indicates that this inverse relationship was unaffected by whether the exclusivity period had been retained or forfeited.

The unadjusted regression model indicates that the effective market life of drugs with multiple first filers was over three years shorter than for drugs with a single first filer ($p<0.001$ for both coefficients). The exclusivity period's forfeiture was not significantly related to the effective market life. Adding controls for the drugs' annual pre-generic sales and their form, and further controls for the drugs' patent portfolio, had little effect on this relationship. (See Table 1.)

Every drug in the top quintile of pre-generic annual brand sales ($945-$9685 million) faced a patent challenge and 96 percent faced a patent challenge from a later filer that was not eligible for the exclusivity period (Figure 4). Among drugs in the top three quintiles of brand sales ($156-$9885 million), 90 percent faced a patent challenge from a first filer and 82 percent faced a patent challenge from a later filer. Although the nominal patent term was longer for drugs with larger sales, the effective market life had no relationship or a slightly inverse relationship with sales.

Discussion

Our results challenge the notion that the prospect of a lucrative 180-day generic exclusivity period is necessary to encourage firms to pursue patent challenges. In fact, the effective market life of drugs with a shared exclusivity period (which diminishes its value) was over three years shorter than for drugs with one first filer. The effective market life was unrelated to whether the exclusivity period was forfeited.

Consistent with prior research, we found that most drugs with moderate-to-high sales experienced a patent challenge.[2] Additionally, we found that patent challenges from later-filing generics were also extremely common. Thus, it seems unlikely that the share of drugs that

experienced a patent challenge would be substantially lower without the exclusivity period, though the timing and number of patent challenges could be affected.

Our results extend the work of Hemphill and Sampat who found that manufacturers of top-selling drugs have generally been acquiring more patent protection over time, but that patent challenges have kept the average effective market life relatively stable.[32,2] As background, the authors have described the exclusivity period as helping to overcome the free-rider problem by motivating *the* first filer to pursue its patent challenge.[2] Our research indicates that the exclusivity period's role is more complicated. Top-selling drugs often have a shared exclusivity period (sometimes by 10 or more first filers) which may accelerate generic competition compared to when there is a more valuable exclusivity period that that can be parked in the future by a single generic firm.

Although we studied NCEs, the results are relevant to non-NCEs. Due to the regulations described above, non-NCEs usually have a sole first filer eligible for the exclusivity period. Non-NCEs are thus more likely to suffer from the parking and pay-for-delay issues that are enabled by the exclusivity period.

Our findings indicate that the exclusivity period may provide little-to-no benefit. Thus, dismantling the 180-day exclusivity period or altering it with a policy like the BLOCKING Act could plausibly lead to substantially earlier generic competition.

List of Tables and Figures

TABLE 1

Caption: [Effective Market Life of Drugs Versus the 180-Day Generic Exclusivity Period Status, Drug Characteristics, and Patent Portfolio]

Notes: [* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$. Parentheses contain standard errors. The dependent variable in each model is the effective market life of drugs measured as the years between brand and generic entry.]

	(1)	(2)	(3)
Number of first filers			
0	2.78** (0.84)	2.00* (0.88)	2.79** (0.91)
1	Ref	Ref	Ref
2-5	-3.25*** (0.81)	-3.24*** (0.79)	-2.71*** (0.79)
6-30	-4.08*** (0.86)	-3.76*** (0.85)	-3.55*** (0.85)
Exclusivity period status			
Retained	Ref	Ref	Ref
Forfeited	0.19 (0.68)	-0.46 (0.69)	-0.60 (0.68)
Annual pre-generic brand sales			
First quintile		Ref	Ref
Second quintile		-1.32 (0.87)	-1.51 (0.85)
Third quintile		-0.93 (0.89)	-1.23 (0.91)
Fourth quintile		-1.61 (0.88)	-2.09* (0.89)
Top quintile		-0.23 (0.96)	-0.84 (0.97)
Dosage form			
Oral		Ref	Ref
Non Oral		2.08** (0.63)	2.23** (0.66)
Nominal Patent Term			
First quintile			Ref
Second quintile			3.10*** (0.84)
Third quintile			2.55** (0.89)
Fourth quintile			3.04** (0.97)
Top quintile			2.76** (1.03)
Total patents			-0.16 (0.17)
Drug substance patents			0.05 (0.21)
Drug product patents			0.11 (0.13)
Method of use patents			0.10 (0.17)
Constant	15.20*** (0.57)	15.64*** (0.88)	13.56*** (1.02)
R squared	0.342	0.417	0.495
F statistic	17.693	10.410	7.099
p value	0.000	0.000	0.000
Observations (drugs)	141	141	141

FIGURE 1

Caption: [Distribution of the number of generic first filers and whether their generic exclusivity period was forfeited for drugs with generic entry in 2015-25]

Source/Notes: SOURCE [Analysis of FDA's Paragraph IV Certification List, Drugs@FDA, National Drug Code Directory, and *Orange Book* data] NOTES [This chart shows the number of first ANDA filers challenging at least one patent for the 141 new chemical entities that experienced first generic entry between 2015 and 2025. It also shows the frequency that the first filers forfeited their eligibility for the 180-day generic exclusivity period.]

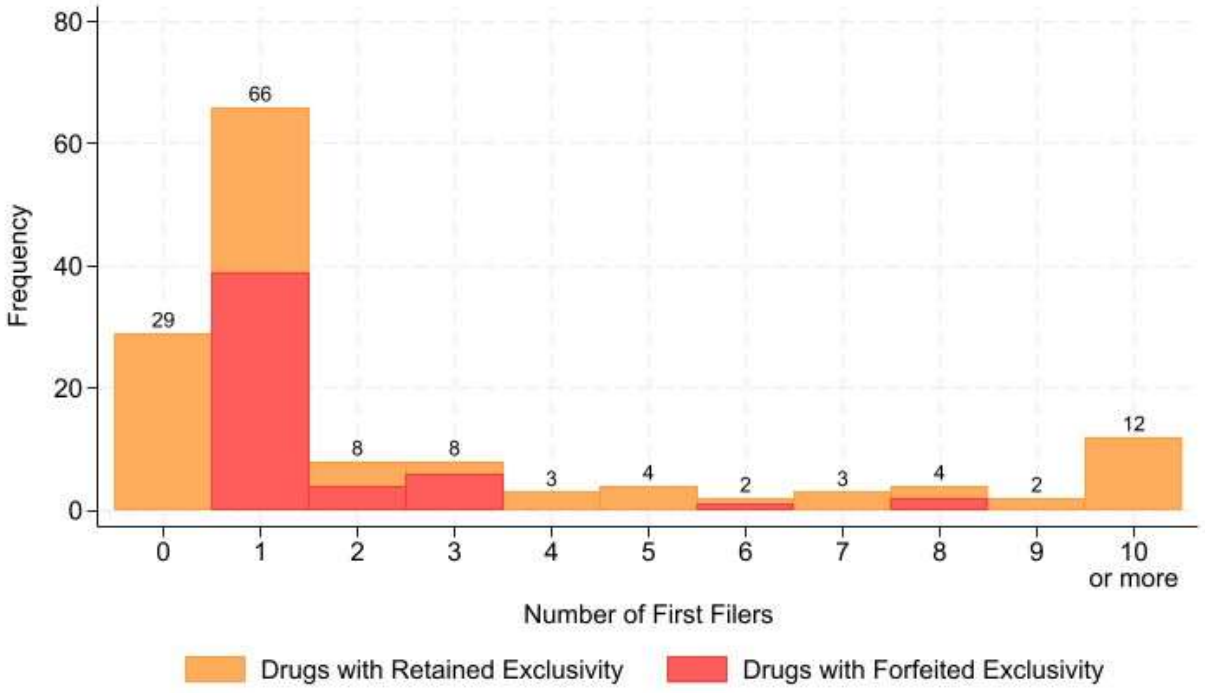


FIGURE 2

Caption: [Effective market life and nominal patent term by number of first filers for drugs with generic entry in 2015-25]

Source/Notes: SOURCE [Analysis of FDA's Paragraph IV Certification List, Drugs@FDA, National Drug Code Directory, and *Orange Book* data] NOTES [This chart shows the average effective market life and nominal patent term for the 141 new chemical entities experiencing first generic entry between 2015 and 2025. The number of first ANDA filers challenging at least one patent are displayed on the horizontal axis. The effective market life is the years between brand and generic entry. The nominal patent term is the years between brand entry and the expiration date of the last expiring patent.]

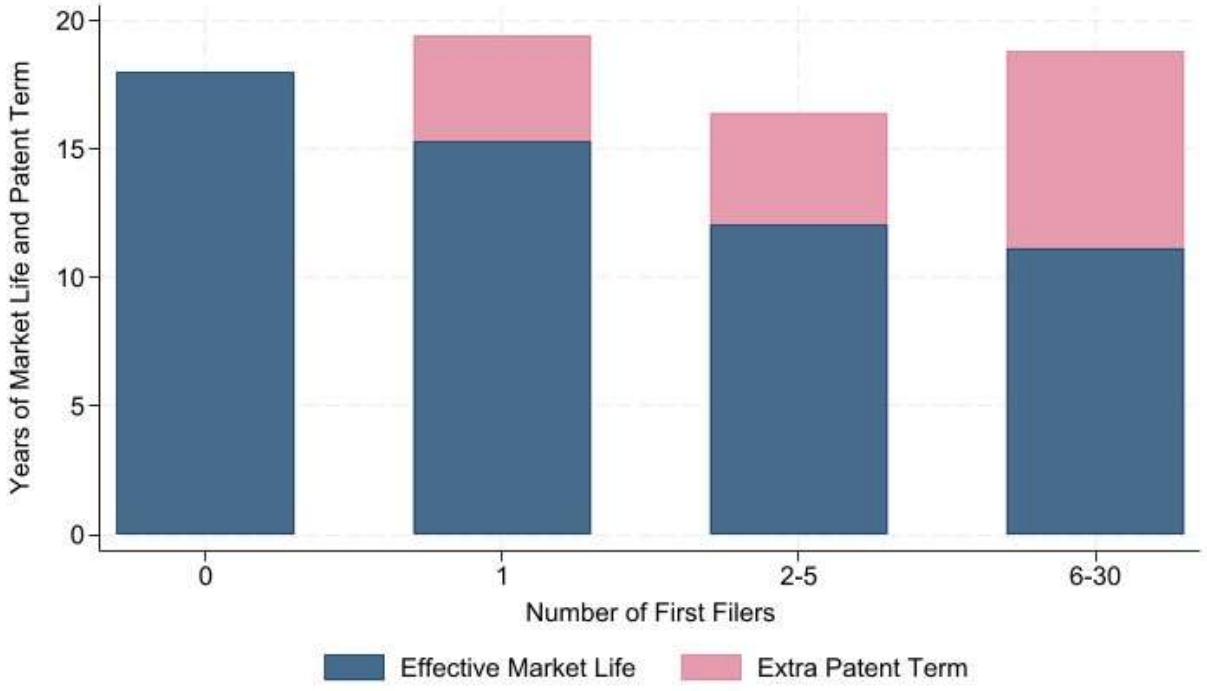


FIGURE 3

Caption: [Effective market life and nominal patent term by number of first filers and exclusivity period status for drugs with generic entry in 2015-25]

Source/Notes: SOURCE [Analysis of FDA's Paragraph IV Certification List, Drugs@FDA, National Drug Code Directory, and *Orange Book* data] NOTES [This chart shows the average effective market life and nominal patent term for the 141 new chemical entities experiencing first generic entry between 2015 and 2025. The number of first ANDA filers challenging at least one patent are displayed on the horizontal axis, which is also broken out by whether the first filer(s) had retained or forfeited eligibility for the 180-day generic exclusivity period. The effective market life is the years between brand and generic entry. The nominal patent term is the years between brand entry and the expiration date of the last expiring patent.]

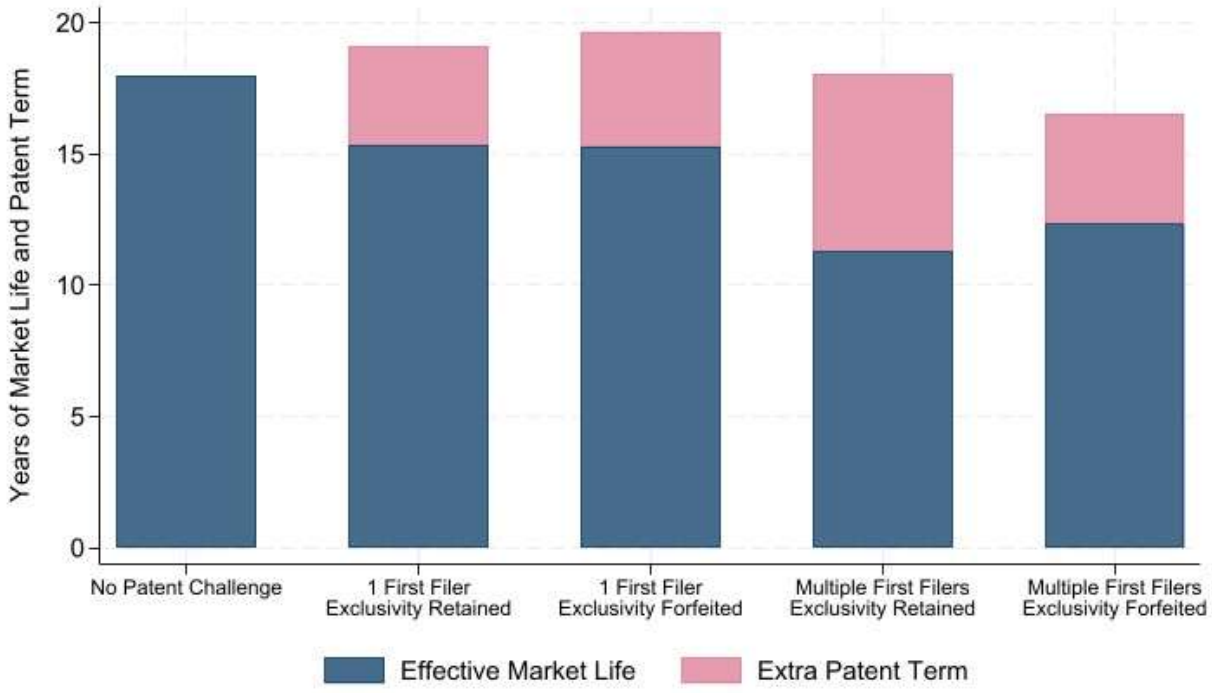
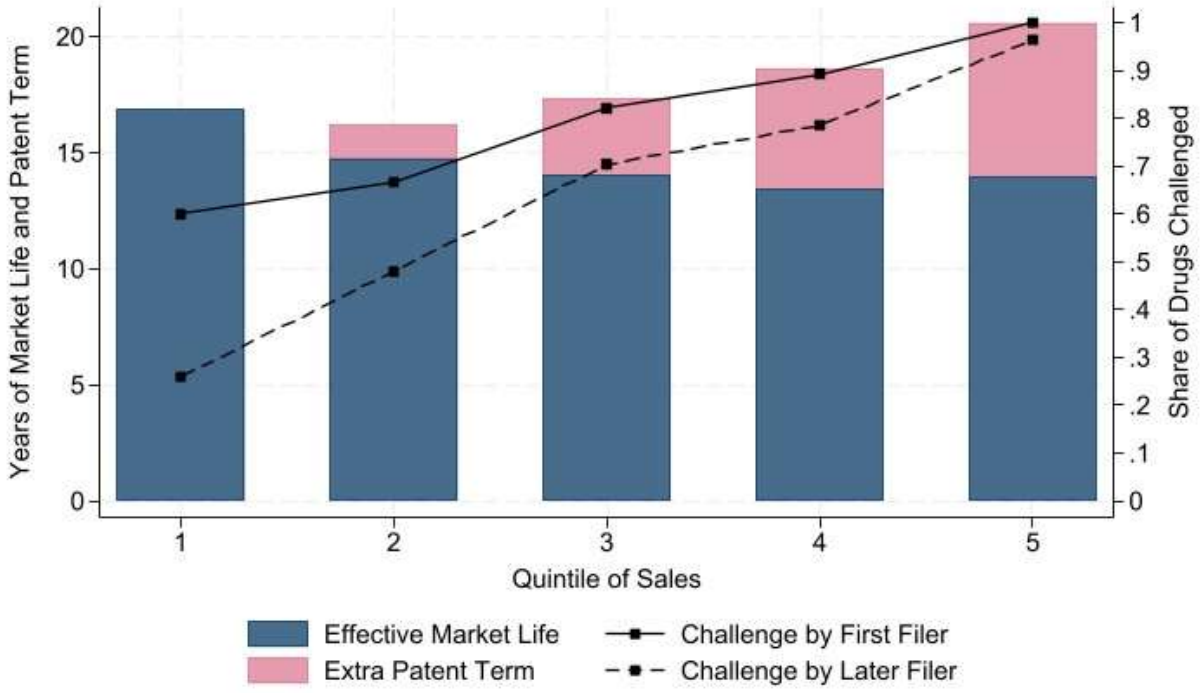


FIGURE 4

Caption: [Effective market life, nominal patent term, and share of drugs with a patent challenge by sales for drugs with generic entry in 2015-25]

Source/Notes: SOURCE [Analysis of FDA's Paragraph IV Certification List, Drugs@FDA, National Drug Code Directory, and *Orange Book* data; Publicly Available Sales Data; and Litigation Information from the Paragraph Four Report] NOTES [This chart shows the average effective market life, nominal patent term, and the share of drugs with a patent challenge by a first filer or non-first filer (i.e., ineligible for the exclusivity period) by sales quintile for the 141 new chemical entities experiencing first generic entry between 2015 and 2025. Quintiles of sales are displayed on the horizontal axis. The effective market life is the years between brand and generic entry. The nominal patent term is the years between brand entry and the expiration date of the last expiring patent.]



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