Understanding the Hatch-Waxman Act Through Effective Patent Length

By

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Abstract

The Hatch-Waxman Act was made law September 24, 1984. The goal of this law was to decrease the barriers to enter into the market for generic drugs while maintaining incentives for researching new drugs. The Act decreased the time it took to approve a generic through the ANDA and allowed generic companies the right to research using the original drug while it was still patented. In return the originally marketed drug received the right to recoup some of the time lost on its patent from the FDA approval process. To measure if this it true, I looked at the effective patent length of original drugs before and after Hatch-Waxman. The effective patent length is the time the original drug has no market competition. In order to maintain incentives to research, this length needs to stay the same or increase. This is due to low switching costs from original to generic drugs. To show that the Act decreased barriers to entry into the market, I looked at new generic market entries for specific compounds before and after Hatch-Waxman. Overall, the Hatch-Waxman Act was ineffective at maintaining incentives for research and development by keeping the effective patent length the same (or market exclusivity), but was successful in increasing generic competition.

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Introduction

The Hatch-Waxman Act was passed in 1984 with the goal of lowering pharmaceutical drug prices ([Redacted] 2016). In order to achieve this the authors of the Act employed a basic principle that increased competition would drive down prices. To do this, the Act sought to lower the barriers to entry for generics ([Redacted] 2016). By doing lowering entry costs, the incentives for producing new drugs had to be maintained as well, to not stifle innovation ([Redacted] 2016). This balancing act posed a challenge for the act as these two tasks seem to conflict with each other. This paper seeks to evaluate the success of the Hatch-Waxman Act through the lens of these two mandates. This is done through effective patent length, or the time a drug has no market competition, as well as an evaluation on number of market entrants pre and post Hatch-Waxman. The former is a gage for incentives for new drug innovation as lowering the market exclusivity of a drug in favor for generics lowers the value of producing these new patented drugs.

Drug Approval Process Prior to the Hatch-Waxman Act

Prior to Hatch-Waxman, the approval process for generic and brand drugs was similar. It is important to note that patent approval and US Food and Drug Administration (FDA) approval are two separate processes ([Redacted] 2016). Similarly, the United States Patent and Trademark Office (USPTO) can grant a company a patent that the FDA does not approve and vice-versa ([Redacted] 2016). Because these paths are separate, the patent timeline is not always the same, however it must begin prior to filing an Investigational New Drug Application (IND)[1] with the FDA ([Redacted] 2016). The reason, is that after the IND is filed other firms will be aware of the compound and may seek to patent it. The patent approval process typically takes 20-24 months

[1] If patents were not filed prior, any company could file for a patent and begin research

(USPTO, "Section 1(b)." 2021). The first step is to file, where the USPTO reviews the patent. After approval, the granted patent lasts for 20 years, starting at the original file date (USPTO, "Section 1(b)." 2021)[2]. While waiting for patent approval, companies preform internal research to determine drug effectiveness and safety. After they are granted a patent, the company will file for an IND[3] and submit their internal research to the FDA ([Redacted] 2016). Once granted, the company is allowed to test their compound further ([Redacted] 2016). Following their research, the company files for a New Drug Application (NDA) with the FDA ([Redacted] 2016). Finally, after the NDA approval process, the company can market the compound to the public ([Redacted] 2016). This process lasts roughly a decade (Gieringer 2015). The compound is patent protected for the remaining patent duration, roughly 8 years.

Generic drugs had the same process, but they had to wait until the brand's patent expired to begin research ([Redacted] 2016). One difference is the generic did not have to file for a patent[4]. After completing the IND process, they could file a "paper" NDA ([Redacted] 2016). This NDA used previously published research, but the FDA often required additional research, in essence, eliminating this shortcut ([Redacted] 2016).

Drug Approval Process After the Hatch-Waxman Act

The Hatch-Waxman did not create the Orange Book[5] but it standardized it. The act required all patents, as well as useful NDA/ANDA information, to be published in it (Center for Drug Evaluation and Research 2021). This improved both the patent clarity and the generic ANDA

[2] There are different types of patents the main being a utility patent and it lasts 20 years. The other main two are design (15 years) and reapply (20 years from original file date) (USPTO, "Reissue." 2021). Design Patents are denoted differently in the data.
[3] This application needs to include both trial design and the internal research gathered.
[4] They could still patent other processes
[5] The Orange Book contains information on all FDA certified drugs and their patents

process. The main benefit for brand compounds is patent extension. First, the brand can only extend one patent relating to the compound, as they typically hold several ([Redacted] 2016). Once a patent is extended with the FDA, the company has 60 days to complete the filing with the USPTO or else the patent isn't extended ([Redacted] 2016)[6]. The extension recoups half the time between the IND and NDA phases of the approval process and the entire NDA approval process ([Redacted] 2016). These extensions are capped at five additional years and no patent may have 14 years total when years are added ([Redacted] 2016).

The next type of exclusivity created by the Hatch-Waxman is the New Chemical Entity (NCE). This is a five-year exclusivity granted to a company when their drugs active ingredient has no prior FDA approval (Lal 2015). This exclusivity begins after NDA approval During this time the FDA cannot accept NDAs or ANDAs relating to this active ingredient (Lal 2015). This is unless a paragraph four[7] ANDA or NDA is submitted in which case the NCE is shortened to four years exclusivity (Lal 2015).

Finally, there is a new clinical investigation exclusivity. This exclusivity is for when a previously approved drug needs new clinical investigations. These investigations must be necessary to the drugs approval and cannot be done with the original methods. (Patel pp.16). An example of this would be developing an over-the-counter (OTC) drug from a prescription (Rx) (Patel pp.16). When a compound switches to OTC, they need to further show the compound is safe enough, meaning it's hard to overdose, and there are few negative, mild, side effects. This

[6] Patent's typically span all product numbers (these can be different dosages of a drug) associated with a NDA so extending a patent will benefit all products the same within the NDA.
[7] Paragraph four challenges the legality/ reach of the patent and if successful, the ANDA can be approved and the generic can be put to market, except in this case where it waits four years.

exclusivity runs for 3 years (with or without patents and it does not stack onto the end) (Patel pp.16).

The other main part of the Hatch-Waxman Act was to create a streamlined/ incentivized generic drug approval process. To do this, the act created the Abbreviated New Drug Application (ANDA). This process allowed drug companies to use the research of the brand drug when producing the generic as long as the two were "bioequivalent" ([Redacted] 2016). This was created as a way to reduce costs for manufacturing generic drugs. Generic drugs would also be allowed to begin research prior to the original compound's patent expiration ([Redacted] 2016).

Finally, a company can challenge an existing drug patent and gain exclusivity. With this exclusivity no additional ANDAs can be approved for 180-days, but the existing drug will remain on the market as the only competition (Patel pp. 28). This exclusivity starts once either the generic is marketed or when the court rules a patent invalid (Patel pp. 29).

Literature Review

Mossinghoff (1999) provides historical context into the pharmaceutical markets prior to the Hatch-Waxman Act. Most of the requirements that pertained to safety, efficacy, and generics were written in 1962 with the Federal Food, Drug, and Cosmetics Act. This act put the FDA in charge of regulating safe products and therefore the FDA was in charge of the Drug approval process. Incorporated in this Act was a clause called the "paper" NDA. This, as previously mentioned, was a way for generics to expedite the approval process and be put to market sooner. Mossinghoff (1999) explains the shortcomings of the "paper" NDA stating only fifteen drugs used this process. This was not because generics had a faster process, it was due to the lack of incentives to produce them. Mossinghoff (1999) reiterates this by stating Congress, while discussing this bill, cited over

150 drugs that were eligible for generics but companies refused to compete due to cost barriers. Mossinghoff (1999) cites an example of a generic that, upon market entry, secured 75% of that compounds market within three months. This makes it seem as if generics are a profitable opportunity, and it's not profitability that's preventing the entrants. Also, it's worth noting this is a misleading anecdote. Peskoe (1985) found that the "paper" NDA process could last around the same amount of time as a typical NDA, due to the similar nature between the two processes. Norman (2016) showed an NDA can be riskier, and 90% drugs fail to get approved[8], and more fail to obtain patents, but a generic lacks the exclusivity needed to recoup the costs and time of the approval process.[9]

[Redacted] (2016) is a congressional report distributed by a redacted scholar. Roche v. Bolar is mentioned as the final reason for the passing of the Hatch-Waxman Act ([Redacted] 2016). The trial centered around the research and development of generic drugs, for which the patented drug, that they competed against, still had an existing patent. Bolar Pharmaceutical Co. argued they could research the compound under "experimental use privilege", however this claim not previously used to justify a potential market competitor ([Redacted] 2016). Bolar subsequentially lost the trial and had to suspend experimental trials until the patent fully expired. This brought the issue of market exclusivity to the forefront of congress, because a patented drug received exclusivity for not only their patent length but also the approval process of the first generic ([Redacted] 2016). This timeline does not include the period that a generic company will wait to produce their compound. This was also shown to be an issue with the drug approval process prior to the Hatch-Waxman Act (Mossinghoff 1999).

[8] Once they reach human the human testing phase of trials
[9] Darrow (2020) found that drug approvals have remained consistent prior to and after the act passed

Darrow (2020) researched legislations impact on the pharmaceutical markets. Darrow (2020) compiled generic drug data from 1970 to 2018, to find how different legislation impacted competition.[10] Darrow (2020) used graphs to display the number of generics entering the market, yearly, as well as the overall number of drugs entering the market. Darrow (2020) found that the number of NDAs from 1982 to 2018 fluctuated between 25 to 40 approvals per year with fluctuations. This differs from his findings, using data from 1970 to 2018, on ANDAs which shows a great increase in usage shortly after 1984, but a sharp decline around 1990. Darrow (2020) continues to show the impact of the Act as the number of generics entering the market grew from a median of 136 (1970-84) to 284 (1985-2012) in approvals per year, but again there is no comparison to patented drugs during this period. Finally, Darrow (2020) goes on to show that generics increased in their portion of market share post Hatch-Waxman as they increase from 9% in 1970 to 43% in 1996. This growth increase to 90% in 2017. These facts would point to the success of the Act from the prospective of generic manufacturers, but the increased market share might suggest a decreased incentive to produce new drugs. It's also worth pointing out that market share doesn't show the act was successful in increasing competition and lowering prices for the consumer. The goal was to increase competition in individual drug markets not the collective market. It's possible that a majority of the 90% number for generic fulfilled prescriptions is dominated by a select-few in-demand drugs. Darrow (2020) alludes to this premise as generics only accounted for 22% of all spending.

Grabowski and Vernon (1995) explored both the Acts impacts on generic competition and incentives for research and development. They tested whether brand drugs experienced a "brand

[10] It is worth noting that Darrow's research goes beyond this scope, but the out-of-scope analysis portion all starts at or just after 1984 and does not seek to make claims on the Hatch-Waxman Act.

loyalty" over their generic competition. Like Darrow (2020) Garbowski and Vernon (1995) showed that consumers switched to generics (in 1991) which resulted in losses in revenue upwards of 50% after only the first couple of months. This study was conducted by focusing on 22 brand drugs however which could result in the same error that the Hatch-Waxman Act only benefitted a select few individual drug markets. Grabowski and Vernon (1995) explore research and development incentives through effective patent length, but only accounted for the time the drug was patented, meaning the effective patent length is the amount of time the drug spent on the market until its patent expired. This ignores the exclusivity granted by a lag of generic drug approval. This is critical because drugs prior to Hatch-Waxman experienced more time in this lag period because of a lack of an expedited process (ANDA).

Data

The dataset used is comprised of two separate datasets. The first dataset is from the FDA's website. This dataset contains drug NDA and ANDA information from 1901 until March 2021. It is worth noting that though the data collection began in 1901 the first entries didn't appear until after 1945. This dataset originally contained 187,638 observations. The unit of observation was a specific drug filing, meaning anything from a new drug application to a label update. This dataset was then cleaned to only contain new drug filings, either generic of patented. The final observation count was 21,768 units.[11] This dataset contained no variable for generic or patented drugs which is why it needed to be combined with Williams (2021). The second dataset contained data from the FDA Orange Book from 1985 until 2016. This dataset originally contained 130,259 observations. This was due to repeated patent listings as the drug would be listed until its patent expiration. This was

[11] This was later decreased to 19,063 observation as drug duplicates remained

decreased to 2,000 observations with the unit of observation being an orange book listed patented drug in its last year in the orange book. This was done because of the extensions that were previously mentioned. This is because companies have to go through a process to claim these extensions, so they don't always appear in the first edition the drug is published in. The datasets were combined using the ANDA and NDA numbers of each dataset. These numbers are specific to a drug filing but do not differ between dosages and admission type. The unit of observation was the ANDA/NDA number of a particular drug. This dataset contains information on NDA/ ANDA application date, patent expiration date (if applicable), a drug's market name, the company's name, the submission type[12], and most current year in Orange Book. The total observations remained at over 19,000. Because the Orange Book, which contains drug patent information wasn't published with full detail[13] until 1985, the dataset only contains patent information for drugs who still had patents in 1985[14]

Methods

The goal of this paper is to see if the Hatch-Waxman act succeeded in it's dual mandate of lowering the barrier to entry while retaining the incentives to produce new drugs. I created a variable for effective patent length for each original drug. This variable measures the amount of time a drug has exclusivity in a market. To measure this variable's reliability when not using patent information, I ran a t-test that compared the effective patent length for the data that contained patent information and the effective patent length of the data that didn't contain patent information.

[12] Drugs apply via different submission types, this information is used to identify brand/generic drugs prior to Hatch-Waxman.
[13] The Orange Book didn't contain all necessary patent data until the Hatch-Waxman Act (1984) it was published prior to the act.
[14] Patents last 20 years so assuming a drug was patented once on market that would make the oldest possible drug patented in 1965, but most drug only have about eight years left so the year is closer to 1977.

I ran this t-test for before and after the act as well as the entire timeline itself. The main test of note being the t-test after the act. If the t-test couldn't reject the hypothesis that the effective patent lengths differed then I proceed to the next step. Now I compare the effective patent length before and after the act using the data from without patent information. I also ran it using the data with patent information. This was to check if the Hatch-Waxman Act was effective in maintaining effective patent length, and therefore maintaining research incentives. Then I used this data to produce both Figure 1 and Figure 4, which shows the average effective patent length by the year the first generic was introduced into the market. This sought to eliminate drugs who have no competition because they still hold patents and eliminate drugs who have no competition because their market isn't profitable or has other high entry reasons. The goal of this graph is to show that original drugs prior to Hatch-Waxman had longer effective patent length, showing that the bill was ineffective. The next graph plots generic market entry before and after Hatch-Waxman, compared to brand drug market entry before and after. This was to show the lower barriers to entry for generic drugs, while market entry for brand drugs remains the same.

Results

Table 1 is the results of the t-test

$$H_0: \text{Effective\_Patent\_Length\_1} - \text{Effective\_Patent\_Length\_2} = 0$$

$$H_A: \text{Effective\_Patent\_Length\_1} - \text{Effective\_Patent\_Length\_2} \neq 0$$

where Effective_Patent_Length_1 is the effective patent length for the dataset with patent data after 1984 and Effective_Patent_Length_2 is the effective patent length for the dataset without patent data after 1984. As the confidence interval in Table 1 suggests, the null hypothesis could

not be rejected. Because of this, the dataset without patent information can be used to represent the effective patent length prior to 1984 as well as post 1984.

Table 2 is the results of the t-test

$$H_0: \text{Effective\_Patent\_Length\_1} - \text{Effective\_Patent\_Length\_2} = 0$$

$$H_A: \text{Effective\_Patent\_Length\_1} - \text{Effective\_Patent\_Length\_2} \neq 0$$

where Effective_Patent_Length_1 is the effective patent length for the dataset with patent data before 1984 and Effective_Patent_Length_2 is the effective patent length for the dataset without patent data before 1984. This test was run as a check to make sure the dataset prior contained identical information, as this data all came from the same original dataset. Looking at Table 2 there are some minor inaccuracies that went unresolved but the error is small enough that the effective patent length for both variables is nearly identical and the null hypothesis could not be rejected.

Figures 1a and 1b are a graph and regression of effective patent length of a drug when it's generic first enters the market. This was done using the patent provided dataset. Figures 4a and 4b are the same but use the dataset without patent information. All these graphs show a decline in effective patent length after the implementation compared to before the Act and 4a shows that after the lag period[15] of Hatch-Waxman the effective patent length trends down in contrast to the sharply increasing trend line prior to the Act's implementation.

Figures 2 and 3 show the new market entrants for new patented drugs and generic drugs respectively. These graphs are nearly identical to those found in Darrow (2020), just with an expanded time window. This expanded time window just reinforces the conclusions drawn by

[15] This lag period is represented by the vertical red lines and lasts for 20 years, the longest possible patent length.

Darrow (2020), that being, generics increased market entry post Hatch-Waxman while new patented drugs hovered between 20-40 new entrants a year.

Discussion

When mentioning the Hatch-Waxman act it is important to look at two specifics; was the Act successful at it dual mandate and did it complete its goal? I showed that the Hatch-Waxman Act successful increase competition but failed at keeping incentives for research and development. Now did these successes lead to lower drug prices? I didn't look into this as I don't have the data to do so. Originally, I thought of using the Medicare pricing database, but failed to find historical prices. Anecdotally, it seems like drug prices have increased, especially in markets where drugs are about to lose their patents. One example of this is the EpiPen, which is currently a part of a class action lawsuit.[16] It's possible to say that the patents are the problem, but that eliminates incentives to produce new drugs; regulating drug prices is also a tricky solution when it comes to recouping costs. Van Norman (2016) shows that only 11.7% of all drugs that start the approval process complete it. So, if regulators only allow companies to recoup costs for their marketed drugs, through price regulation, they will surely fail, or at least lose incentive to produce brand drugs. The final solution is a single-payer system. Mikulic (2021) shows that every passing year Pfizer's revenue becomes increasingly dependent on the United States, with the second highest revenue stream coming from emerging markets. The thought that single-payer will lower drug prices might be true, but the pharmaceutical companies will seek to recoup those losses somewhere. This could present itself in higher prices globally or a decrease in research and

[16] Full disclosure, because I use an EpiPen I am represented in this lawsuit.

development. The National Bureau of Economic Research suggests that cutting prices in half could result in the same loss in research and development (Forbes 2018).

Conclusion

The graphical analysis used suggests that the Hatch-Waxman Act was successful in increasing competition, but did not show success in individual markets. It was able to increase competition but unable to keep effective patent length constant. This would fail to keep incentives for research and development. The main questions that come out of this, are, does this solve the drug price problem and if not, what steps should be taken to solve that problem if increasing competition is not the solution?

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Tables

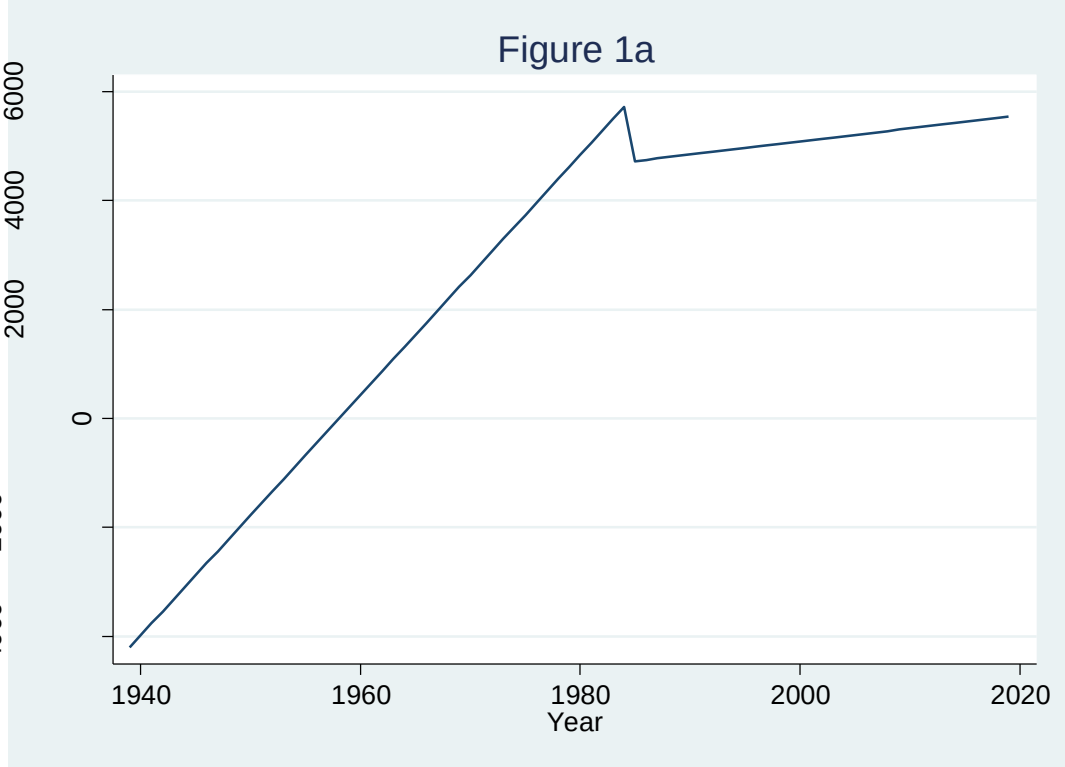
Table 1

Variable	Obs	Mean	Std Err	Std Dev	95% Conf Interval	
epl_one	15,144	143.2771	6.468469	796.016	130.5982	155.9561
epl_two	15,144	142.5649	6.463383	765.3901	129.8959	155.2339
diff	15,144	0.712229	0.693071	85.28998	-0.64627	2.070732

Table 2

Variable	Obs	Mean	Std Err	Std Dev	95% Conf Interval	
epl_one	3,021	1022.034	55.63979	3058.165	912.938	1131.129
epl_two	3,021	1022.26	55.73252	3063.261	912.9823	1131.537
diff	3,021	-0.22608	5.208004	286.2508	-10.4377	9.985508

Figures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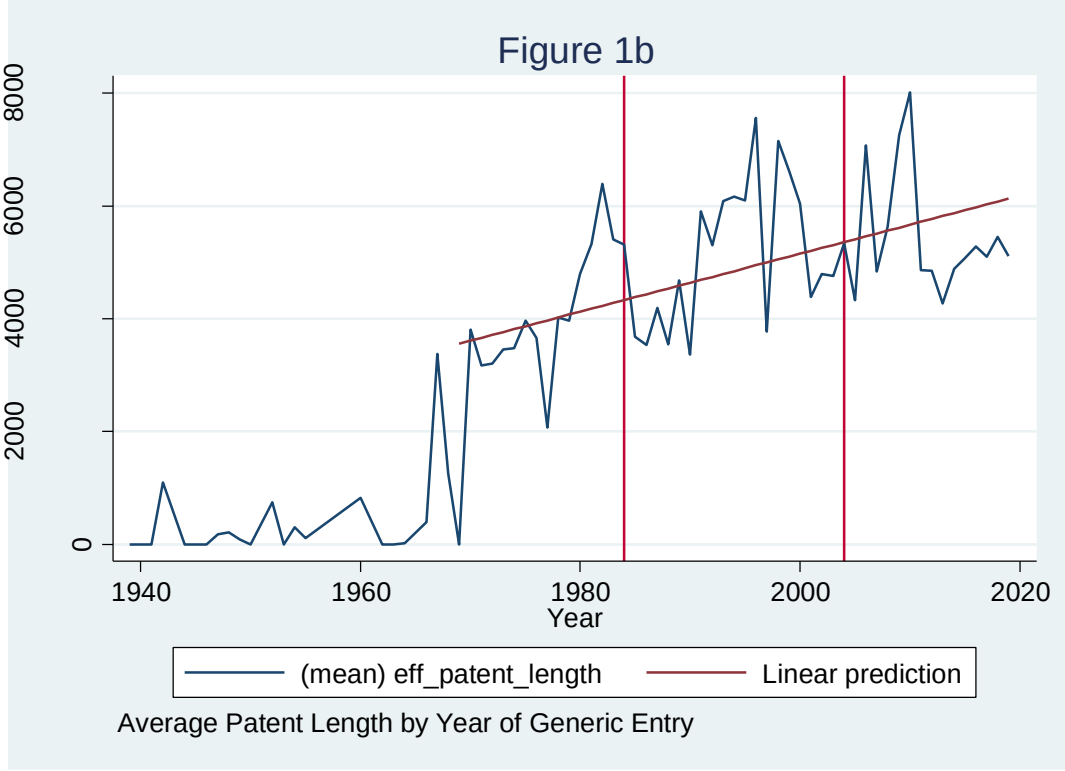
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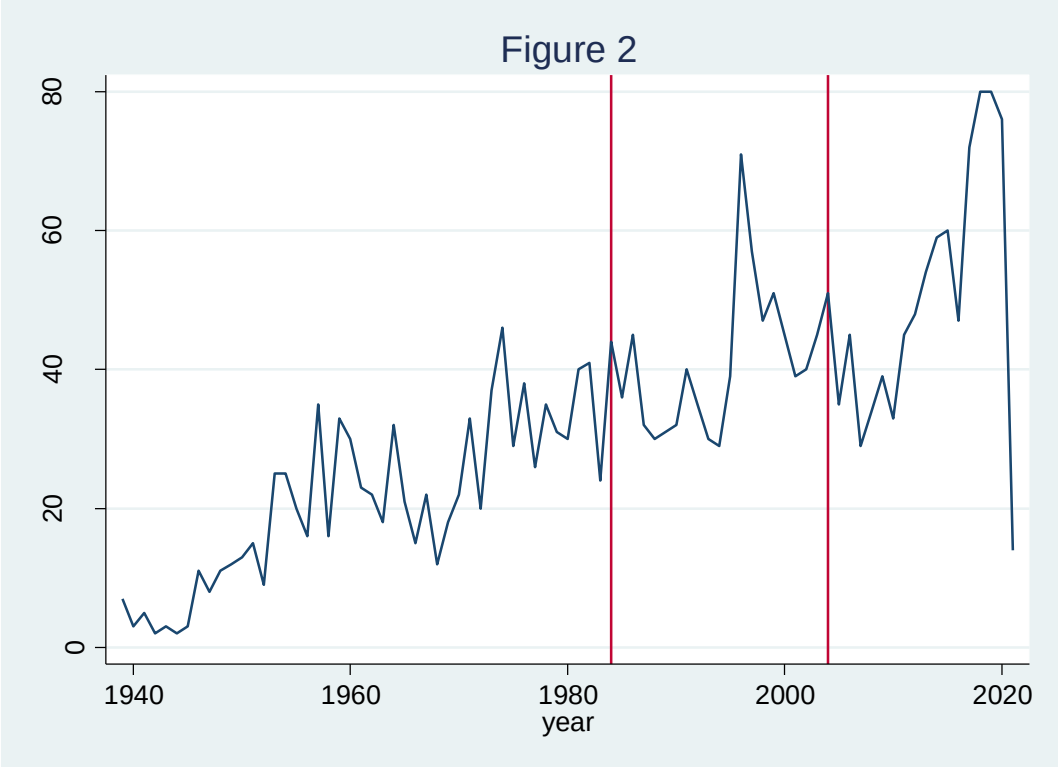
Linear prediction
Average Patent Length by Year of Generic Entry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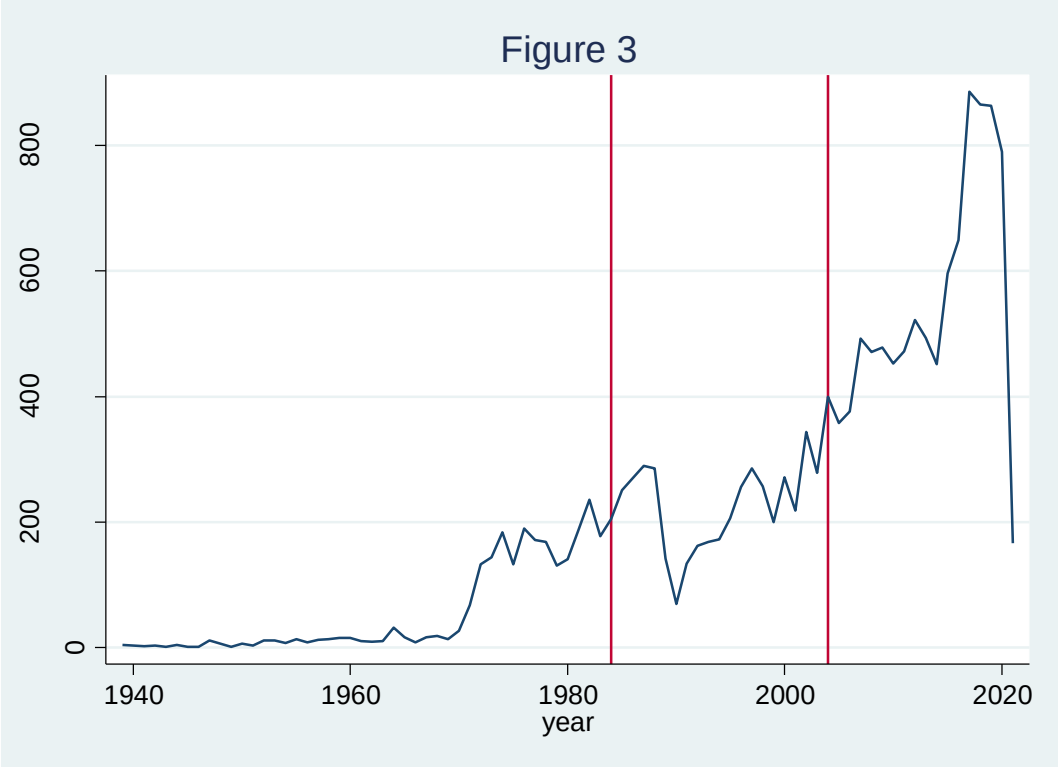
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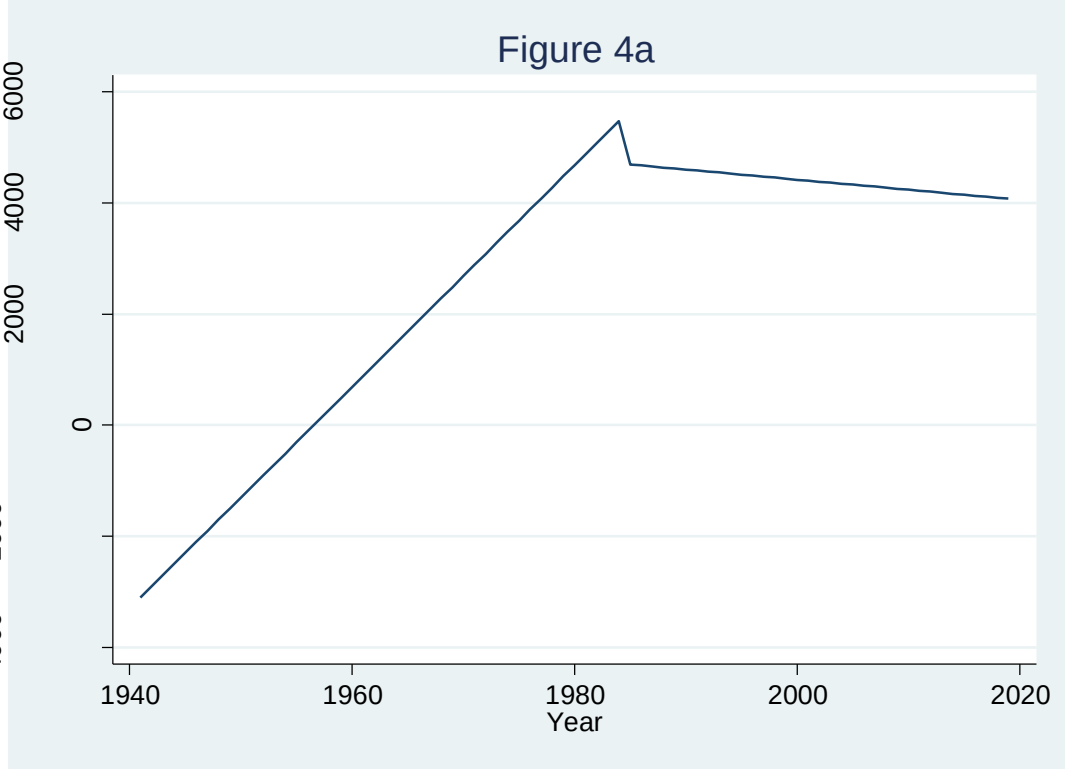
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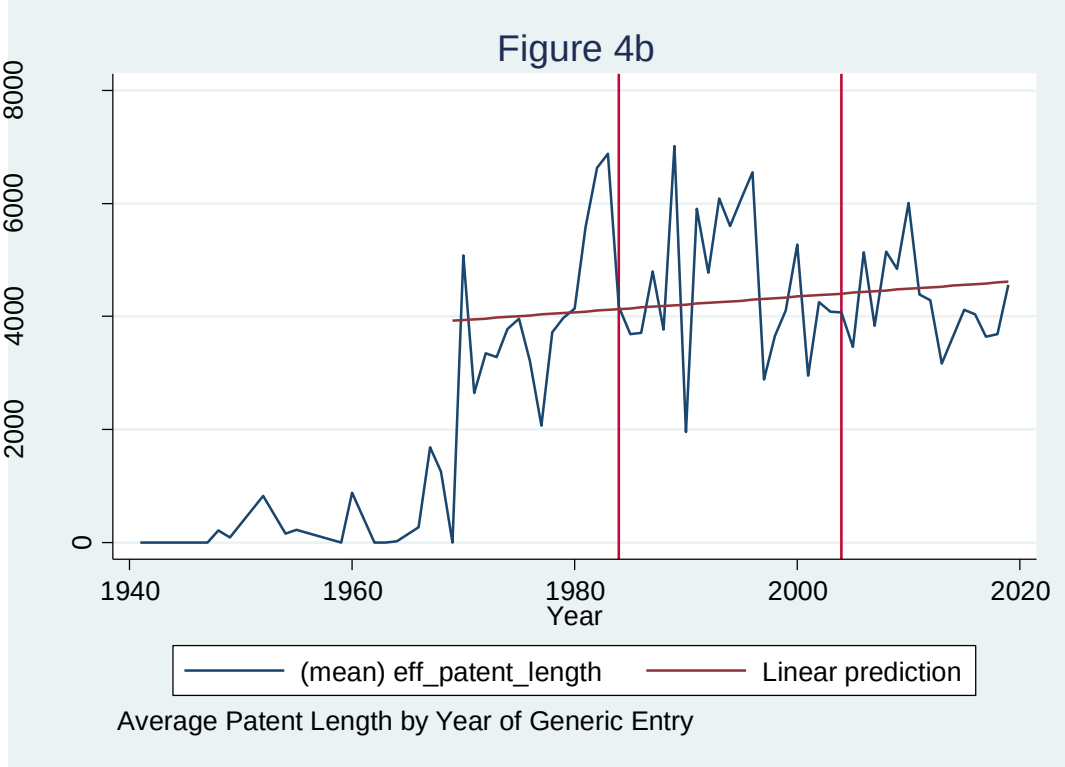
Figure 4b
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Linear prediction
Average Patent Length by Year of Generic Entry