Appendices for Online Publication: Patents as a Spur to Subsequent Innovation?

APPENDIX A Anecdotal Evidence

This section reproduces two quotes from the popular press.

A Belsomra vs. Ambien

The following quote from *The New Yorker* reproduces the explanation given by a Merck neuroscientist in response to a question about how Merck evaluated the decision to pursue the development of Belsomra, a competitor to the blockbuster insomnia drug, Ambien. The quote suggests Merck was concerned about the fact that a generic version of Ambien would be available shortly.

> The perception at that time was, "You have a lot of medications available – should we be working on this? How large was the population of insomniacs poorly served by Ambien? *Should Merck invest in a market dominated by a drug that, within a few years, would become a cheap generic?*"
>
> Parker (2013), emphasis added

B Lipitor vs. Zocor

The following quote from *The New York Times* suggests Lipitor was expected to lose market share to Zocor's generic, when it became available.

> Today, Merck's cholesterol-lowering drug Zocor loses its United States patent protection, becoming the largest-selling drug yet to be opened to cheap generic competition.
>
> That change will cost Merck billions of dollars a year. *But it could be nearly as damaging to Pfizer, whose rival cholesterol drug, Lipitor, is the world's most popular medicine, with global sales last year of $12 billion.*
>
> ?, emphasis added

APPENDIX B Theory Appendix

This section presents the algebra relevant for the welfare analysis in Section I. There are two relevant cases for welfare analysis: (1) the state of the world in which E does not enter and (2) the state of the world in which E does.

A Case 1: E does not enter

In the state of the world in which E does not enter, I is a monopolist for the first t_I periods, after which I is available at price 0. Recalling the outside option has utility u_0, it is easy to see that consumers choose I if $\delta_I - \frac{1}{\alpha_i} p_I > u_0$. This means demand for I is

$$D_I(p_I) = \int_{\frac{p_I}{\delta_I - u_0}}^{\infty} \frac{1}{\lambda} \exp\left(-\frac{\alpha}{\lambda}\right) d\alpha = \exp\left(-\frac{p_I}{\lambda(\delta_I - u_0)}\right).$$

Taking first order conditions, we obtain the price of I in the monopoly case to be $p_I^M = \lambda(\delta_I - u_0)$. The resulting per-period profit while I is on patent is $\lambda(\delta_I - u_0)e^{-1}$, while it is 0 after patent expiry. Per-period consumer surplus is the integral under the demand curve: $\int_{p_I^M}^{\infty} D_I(p_I)dp_I = \lambda(\delta_I - u_0)e^{-1}$ while I on patent and $\int_0^{\infty} D_I(p_I)dp_I = \lambda(\delta_I - u_0)$ after expiry. Altogether, this makes total discounted consumer and social surplus:

$$\begin{aligned} CS_I =& \frac{1-\gamma^{t_I}}{1-\gamma}\lambda(\delta_I - u_0)e^{-1} + \frac{\gamma^{t_I}}{1-\gamma}\lambda(\delta_I - u_0), \\ SS_I =& CS_I + \frac{1-\gamma^{t_I}}{1-\gamma}\lambda(\delta_I - u_0)e^{-1}. \end{aligned} \tag{7}$$

B Case 2: E does enter

In the state of the world in which E does enter, there are three distinct sets of market conditions. For the first t_I periods, I and E compete in a Bertrand duopoly with prices described in Section I. In the next set of $t_E - t_I$ periods, I is available at marginal cost of 0 and E is available at market price $\lambda\Delta$. Finally, after t_E periods have passed, both products are available at price 0. Deriving surplus in each of these sets of market conditions:

1) **Both I and E are on patent.** Plugging the equilibrium prices into the demand functions presented in Section I, we obtain that I's per-period profit is $(1-\exp(W(e^2)-2))\lambda\Delta(W(e^2)-1))$, while E's per-period profit aside from the fixed cost F of entry is $\lambda\Delta e^{W(e^2)-1}$. Consumer surplus in the two product case is a line integral: $\int_{p_E^*}^{\infty} D_E(p_I^*, p_E)dp_E + \int_{p_I^*}^{\infty} D_I(p_I, \infty)dp_I$.[49] Evaluating this expression yields per-period consumer surplus of $\lambda\Delta\exp(W(e^2)-2) + \lambda(\delta_I - u_0)\exp(-\frac{\lambda(W(e^2)-1)}{\delta_I - u_0})$.

2) **I is off patent, E is on patent.** Now, I's profit is 0 while E's profit

[49] Recall that line integrals are path-independent as long as the cross-partials of the demand functions are equal – which, in this case, they are.

is $\lambda\Delta e^{-1}$. Evaluating the line-integral above yields per-period consumer surplus of $\lambda(e^{-1}\delta_E + (1-e^{-1})\delta_I - u_0)$.

3) **Both drugs are off patent.** Per period consumer surplus is now $\lambda(\delta_E - u_0)$.

Altogether, this yields total discounted consumer and social surplus:

$$\begin{aligned} CS_{I,E} = & \quad \frac{1-\gamma^{t_I}}{1-\gamma}\lambda\left(\Delta e^{W(e^2)-2} + (\delta_I - u_0)e^{-\frac{\Delta(W(e^2)-1)}{\delta_I - u_0}}\right) \\ & + \quad \frac{\gamma^{t_I}(1-\gamma^{t_E-t_I})}{1-\gamma}\lambda(e^{-1}\delta_E + (1-e^{-1})\delta_I - u_0) \\ & + \quad \frac{\gamma^{t_E}}{1-\gamma}\lambda(\delta_E - u_0), \\ SS_{I,E} = & \quad CS_{I,E} - F + \frac{1-\gamma^{t_I}}{1-\gamma}\zeta + \frac{\gamma^{t_I}(1-\gamma^{t_E-t_I})}{1-\gamma}\lambda\Delta e^{-1}, \end{aligned} \tag{8}$$

where the constant $\zeta = (1-e^{W(e^2)-2})(W(e^2)-1) + e^{W(e^2)-1}$.

APPENDIX C Data Appendix

This section provides more detail as to how I compute various components of the data set described in Section II.

A Dates of Approval and Generic Entry

Dates of first approval come from New Drug Applications (NDAs) in the Drugs @ FDA database. Next, I obtain the date of first generic entry, if available, by matching drugs by active ingredient to Abbreviated New Drug Applications (ANDAs) in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluation (the Orange Book). Following Hemphill and Sampat (2012), I include only generic alternatives with therapeutic equivalence ratings of "A" to ensure that the date of generic entry used corresponds to the date a generic alternative became available that is chemically equivalent to the branded drug.

B Expected Exclusivity

Firms sometimes file dozens of patents on a single drug so identifying key patents by hand is difficult. My strategy is to exploit the fact that the Hatch-Waxman Act of 1984 allows pharmaceutical manufacturers to extend a single patent for as much as half of the time a drug spent in development. As Hemphill and Sampat (2012) note, patents selected for extension typically pertain to active ingredients – i.e., the extended patent is typically a drug's primary patent.

Indeed, as mentioned in the body of the text, Hemphill and Sampat (2012) codify patents for drugs that went generic in the 2000's and find that the extended patent represents the patent on the drug's active-ingredient in 79% of drugs analyzed. I obtain a list of extended patents from the USPTO, and the dates of filing and expiration for each patent from Thomson Innovation. I additionally note here that the FDA provides a floor of 5 years of market exclusivity for any new molecular entity, so I impute a market of 5 years for the 18 drugs that receive less than 5 years of exclusivity from the patent extension. This is conservative, since the floor of five years is often supplemented by additional extensions for pediatric indications and for orphan drugs.

C Market Size

My measure of market size is derived from the total number of patients afflicted by the primary condition treated by class of drugs. Using the Medical Expenditure Panel Survey's (MEPS) Prescribed Medicines data, I first determine the ICD-9 code that is most commonly associated with each class of drugs. Cleaning the Prescribed Medicines data is cumbersome because the same drug often is often listed with several different names, so I aggregate the MEPS data by matching prescribed medications listed in MEPS with an extensive list of drug names and NDC codes provided by the American Society of Health-System Pharmacists (AFHS). The match rate is roughly 95%. The Prescribed Medicines files do not include records for drugs in 38 classes, likely because they are drugs prescribed in inpatient settings. For these classes, I identify primary ICD-9s from FDA approval documents.

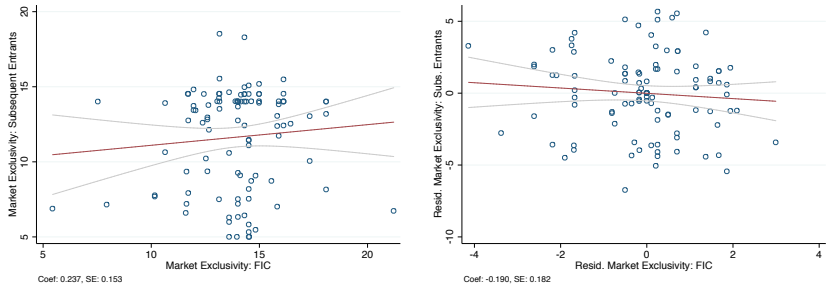
Then, using the MEPS Medical Conditions data, I compute the national prevalence of that ICD-9 in each year. My main measure of market size is then the mean market size for that ICD-9, averaged over the period 1996-2011 for which MEPS data are available. I use the average of market size to capture market sizes over the entire period; using market sizes in the year of approval, or year before approval, does not affect the main results.

D Patent Start and Expiry Dates

The patent priority date, sometimes called the "effective filing date" is the earliest date date any claim listed in the patent was filed. A patent's priority date is always no later than its filing date. If all claims are submitted for the first time in the application for the patent at issue, then the priority date is the same as its filing date. However, if some claims were filed in other patent applications, then the priority dates can be substantially earlier than the filing date of the patent at issue. This can occur, for example, because the patent filer seeks to delay publication of claims, or simply because the patent filer keeps adding claims to subsequent patent applications. It can also occur if a firm files a patent in one country and then later files the same patent in another – the earlier

date is the priority date. I focus on priority dates because they reflect the first time intellectual property protection was sought and cannot be manipulated.

APPENDIX D Appendix Figures



(a) Unresidualized (b) Residualized

FIGURE D.1. MARKET EXCLUSIVITIES WITHIN CLASS

Note: These figures respectively show plots of the market exclusivities of entrants subsequent to the FIC against the market exclusivities of the FIC. Panel A shows the relationship without controls, and Panel B shows the relationship conditional on mean development time, market size, and year of FIC approval fixed effects. The specification of the controls and sample are as described in Section II. The slope of the line of best-fit and its associated robust standard error clustered by drug class are presented in the bottom left of each figure.

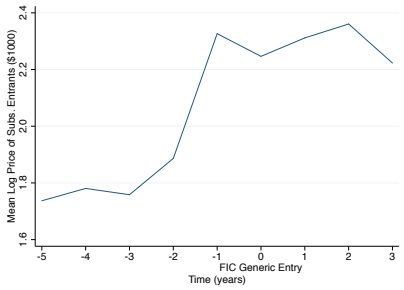


FIGURE D.2. PRICES OF SUBSEQUENT ENTRANTS RELATIVE TO FIC GENERIC ENTRY

Note: This figure shows how the mean log price of subsequent entrants evolves relative to FIC generic entry, which occurs at time 0. The sample is as described in Section II.

APPENDIX E Panel Analysis

This section presents a panel analysis of entry timing relative to FIC exclusivity. In particular, I analyze how entry in class j in year t relates to the first in class

exclusivity remaining in that year, conditional on time since first in class launch fixed effects and class fixed effects. Formally, the model is:

$$NumEntry_{jt} = \alpha + \beta FICExclRem_{jt} + \gamma_t + \zeta_j + \epsilon_{jt}. \tag{9}$$

The independent variable $FICExclRem_{jt}$ takes the same value as the independent variable of interest in my main analysis, $FICExcl_j$, in the year in which the first in class enters ($t = 0$) but then counts down until first in class generic entry occurs; thereafter, the variable takes on a value of 0. Since I am conditioning on time since FIC launch and class fixed effects, the estimate of β tells us how entry relates to first in class exclusivity, conditioning on average entry across classes in year t and average entry within class j.

The sample is the same as the main sample described in Section II, aside from the fact that since I am not conducting an IV analysis, I do not restrict to only those classes for which I have data on the instrument. Thus, I have 127 classes. It is important to note the panel constructed with these data is not balanced because I do not observe the same number of years since FIC launch for all classes. For example, although I observe whether any entry occurs 10 years after FIC launch for classes that experienced FIC launch in 2000, I do not for classes that experienced FIC launch in 2005. In Appendix Section E, presented below, I present results from regressions that handle the censoring problem in a variety of different ways.

The first column presents results from a Poisson model estimated on the unbalanced panel, while the second does the same but restricts the panel to only those classes that experienced FIC launch no later than 2001. This restriction reduces the number of classes to 82 but also makes the sample more balanced. Columns (3) and (4) replicate the analysis in columns (1) and (2) but estimate OLS regressions. Finally, in the fifth column, I handle the censoring problem formally by estimating a Tobit (censored) regression. The results from this model need to be interpreted with caution, however, because Tobit models are non-linear so they suffer from the incidental parameters problem in the presence of fixed-effects. Altogether, although effect magnitudes vary slightly across regressions, the results show that entry tends to occur when the FIC has more exclusivity remaining. This is consistent with the evidence visualized in Section III.C.

APPENDIX F Robustness Tests

This section probes the robustness of the estimates presented in Section IV.C and proceeds in five parts. First, I explore the role of the sample restrictions described in Section II, namely in the definitions of market exclusivity and of first in class drugs. Second, I conduct placebo tests which analyze the role of the exclusivities of non-FICs drugs on entry. Third, I investigate the robustness of the IV estimates. Fourth, since some classes in my data have had only a few

years to accumulate new entrants, I show the Poisson and Poisson-IV results are unchanged when the sample is restricted to only those classes which have had at least 10 years for subsequent to entry to occur. Fifth, to ensure my results are not confounded by class profitability, I show that the Poisson and Poisson-IV results are unchanged when I control directly for sales.

A Sample Definitions

It is useful to remind the reader of how my data are constructed. First, recall that my baseline measure of market exclusivity is a constructed measure: it is the realized market exclusivities for the 56 first in class drugs which have gone generic, and for the others it is expected market exclusivity computed using patent expiry dates. Second, recall that although my data includes this measure for 127 classes, I restrict my baseline analysis to the 111 classes for which I additionally have values of the instrument. Third, recall that I focus on the effective FIC, not the authentic FIC.

Panel A of Appendix Section F.A probes these three choices, one after the other. I focus here on Poisson (not Poisson-IV) specifications because the sample in my main analysis is limited by data on the instrument; it is only by focusing on non-IV specifications that I am able to relax the sample restrictions. For the same reason, these specifications do not include controls aside from year of FIC approval fixed effects. For ease of comparison, the first column repeats my base case analysis from specification (1) of Section IV.C, and the third and second to last rows respectively report the mean of the dependent variable (which changes with the sample) and the exclusivity coefficient multiplied by the mean of the dependent variable. Since these are Poisson regressions, it is this last number which is comparable across columns because it is in units of subsequent entrants per year of FIC exclusivity.

I begin with the measure of market exclusivity and the sample restrictions. Column (2) reports results from the same regression as in column (1), but with the sample restricted to only those observations for which I observe realized market exclusivity. Next, column (3) expands the baseline sample to additionally include the 16 classes for which I have a measure of exclusivity but no value for the instrument. In both cases, the coefficient on exclusivity moves slightly but remains positive and statistically significant at the 5% level. In column (4) I conduct an additional test where I expand my sample to include all 156 classes, replacing the data points for which I have no measure of FIC exclusivity with the 14-year threshold suggested by Keyhani, Diener-West and Powe (2006).[50] The scaled

[50]This is motivated by the fact that 14 years is the maximum exclusivity obtained through a patent extension, so drugs that already have 14 or more years of exclusivity would not receive an extension and would thus not have an exclusivity measure in my data. Using 14 years in place of the missing exclusivities represents a worst case scenario as these drugs presumably have longer exclusivities – to the extent that exclusivity and subsequent entry are positively related, censoring exclusivity at 14 years should attenuate the results.

estimate in column (4) has a smaller magnitude (0.121 versus 0.167 in my baseline case), but the relationship remains positive and statistically significant. Overall, I infer that my main effects are robust to alternative definitions of exclusivity.

The last two columns of Appendix Section F.A, Panel A analyze my definition of first in class. In column (5), I restrict the sample to the classes for which my definition of FIC and authentic FIC do not coincide, and analyze how the authentic FIC's exclusivity relates to subsequent entry. As expected, the exclusivity of these drugs has a weaker relationship with subsequent entry: the scaled estimate is positive (0.132) but it is smaller than that of the base case, and it is not statistically significant (but the sample is very small). However, column (6) presents results from classes in which effective and authentic FIC drugs are the same. Here the scaled estimate is larger (0.232) and highly significant (though it is not significantly larger than that in column (5)).[51] I infer that while my focus on effective FIC drugs appears to accentuate the results, it is not driving them.

B Placebo Tests

I conduct two sets of tests which probe the extent to which the exclusivities of non-FIC drugs are related to subsequent entry.

In the first test, I replicate my main analysis, but instead of including only one observation per class, I include one observation for each of the 196 drugs for which I have a measure of exclusivity. In other words, for each drug j, the independent variable is drug j's exclusivity and the outcome is the number of entrants subsequent to drug j.[52] Intuition predicts that this regression should yield a positive relationship but that it should not be as strong as that estimated using only FIC exclusivities (because the first generic should have an outsize effect on prices and thus entry incentives). The results, presented in column (1) of Appendix Section F.A, Panel B, show a small, positive, but statistically imprecise relationship between subsequent entry and exclusivity for all drugs. However, in column (2) I add a control which is the exclusivity of the FIC for class j. In column (2), the FIC's exclusivity shows up as highly significant and the exclusivity of non-FIC drops (the point estimate is actually negative). I infer that FIC exclusivities are indeed most important in determining subsequent entry.

The second test investigates how the exclusivity of the last drug to enter in class relates to the number of entrants subsequent to the FIC. That is, this test is the same as my baseline analysis except that instead of focusing on the exclusivity of the first in class, I focus on the exclusivity of the last in class (LIC). Clearly, the exclusivity of the LIC cannot directly affect the number drugs in the class, so the coefficient should be zero; a non-zero coefficient would suggest endogeneity. For this test, I restrict the sample to classes that have at least two drugs in them, else

[51] The number of observations in columns (5) and (6) do not add up to 127 because I do not have exclusivity measures for 12 authentic FIC drugs. It is not surprising these data are missing: these drugs are less commercially important, so generics may be less likely to be aggressive in pursuing entry.

[52] I cluster standard errors by drug class for these regressions.

the LIC is the same as the FIC. Only 50 classes satisfy this requirement, of which I only have an exclusivity measure for the LIC for 35. The results are presented in column (3). As expected, the scaled coefficient on LIC exclusivity (-0.045) is small (in fact, negative), and statistically insignificant. To make sure that this result is not an odd artifact of this sample, in column (4) I estimate the same regression but this time include also the first in class's exclusivity. The scaled estimate on FIC exclusivity (0.256) is close to that estimated in my main sample, but the scaled estimate on LIC exclusivity remains close to zero (0.021). Both are imprecisely estimated but the sample is small. I interpret this as additional evidence that endogeneity is limited in this context.

C Robustness of IV Estimates

In this section, I probe the robustness of my IV results. I first provide evidence that they are strongest for classes in which the delay between patent filing and the start of trials is large. This is reassuring since it seems unlikely that marginal changes in the date of patent filing for classes in which the date of patent filing already takes place immediately before the start of trials should have a substantive impact on exclusivity and thus subsequent entry. Second, I show that there is a strong relationship in the reduced form of the second stage, and third that the results remain similar in linear, as opposed to Poisson, regression specifications.

Section F.C presents the estimates. All regressions include my full set of controls: development time, market size, and year of FIC approval fixed effects. The first column shows my baseline result from column (6) of Section IV.C, and then the second column includes only classes for which the value of the instrument is greater than its median of 4.43 years. The scaled coefficient in the second column is approximately 50% larger than that in the first column, suggesting the marginal effect of FIC exclusivity on subsequent entry is larger for drugs for which delay between filing and development is larger (though I note the difference in coefficients is not statistically significant). Next, the third column presents results from the reduced form of the second stage (for my baseline sample of 111 classes): I estimate a Poisson regression where the outcome is the number of subsequent entrants in class and the independent variable is the instrument. The estimated coefficient is significant at the 10% level and implies that a one year delay between patent filing and the beginning of development for the FIC is associated with a 7% decrease in subsequent entry.

To ensure my IV results are not due to the functional form of the Poisson model, in columns (4)-(6) I replicate the analysis in columns (1)-(3) but using a linear framework. Since the outcome is a count variable and is highly skewed (which motivates my use of the Poisson framework), the outcome in these regressions is the log of 1 + the number of subsequent entrants. Columns (4) and (5) present results from linear IV models, while column (6) presents the reduced form of the second stage estimated by OLS. Although the scaled estimates move slightly, all

remain statistically significant.[53]

D Base Case with Sample Restricted to Classes Starting No Later than 2001

In this section, I repeat the base analysis presented in Section IV.C but restrict to the 62 classes that started no later than 2001. The motivation for the restriction is to ensure that all classes included in the analysis have had sufficient time to mature and see subsequent entry. The results are presented in Appendix Section F.D, below.

Although the restricted sample is substantially smaller than that used in the main analysis, and this weakens the first stage of the IV analysis and generally decreases precision, the point estimates presented here are remarkably comparable to in my main analysis. Estimates in columns (3) and (6), which are conditional on my full set of controls, suggest respectively that an extra year of FIC exclusivity is associated with a 27% and 37% increase in subsequent entry. Relative to my full sample, the classes analyzed in this table are on average larger, so the scaled coefficients are also slightly larger than those presented in Section IV.C. Altogether, I conclude that, if anything, including classes that started after 2001 dampens my main results.

E Base Case Controlling for Sales

In this section, I show my main results do not appear to be driven by drug or class profitability. I do this by repeating the base analysis presented in Section IV.C but controlling for sales, for which I employ two measures. The first is the log of the maximum annual revenue ever earned by the first in class, and the second is the log of the maximum annual revenue ever earned by any drug in given class. These measures respectively capture the extent to which the first in class is a top-earner as well the extent to which a class is attractive from a market size perspective.

The results are presented in Appendix Section F.E, with Panel A analyzing the control for FIC revenue and Panel B analyzing the control for class revenue. I do not have these measures for all classes, so I present first my base case results (without the control) on the restricted sample for which I do have the measures. In particular, the first set of two columns in each panel present Poisson results, while the second set of two columns present results from Poisson-IV models, and the first column in each set does not include the control while the second does. Altogether, including the control for sales does not have a statistically nor economically significant effect on the point estimates. I infer that my results are not related to class profitability.

[53] My non-IV results are also robust to a linear specification – see Section IV.A.

APPENDIX G Interaction with Price Elasticity

In the main text I focus on how the effect I analyze is moderated by quality differences between the FIC and subsequent entrants. However, it can be shown that the model's third and fourth predictions are equally true for population price sensitivities (i.e., the comparative statics are true for λ in addition to Δ).

Thus, in this section, I analyze how the effect of FIC exclusivity on subsequent entry is related to price elasticities. I do not directly observe price elasticities and they are difficult to infer directly from the data without imposing strong structural assumptions. Thus, my strategy is simply to use two proxies for price elasticity. The first proxy is a dummy that captures whether a drug treats a chronic condition and the second is the mean household income of patients. Denoting the price elasticity proxy for class j by D_j, I then estimate the same model as before but include a linear term for D_j and also the interaction of $FICExcl_j$ and D_j. Formally, I estimate Poisson models of the form,

$$SubsEntrants_j = \alpha + \beta FICExcl_j + \psi D_j + \phi FICExcl_j \times D_j + \gamma' X_j + \varepsilon_j. \quad (10)$$

The following provides more detail on my measures and then describes the results.

Chronic Conditions. — My first price elasticity proxy is an indicator variable that captures whether a class of drugs treats a chronic condition (as opposed to one that is acute). This is is motivated by prior evidence that demand for acute care tends to be inelastic.[54] This is intuitive: the marginal value of a single, one-time treatment for a chronic condition is likely lower (or at least less salient) than for an acute condition. Moreover, treatment for chronic conditions takes place over longer periods of time, giving patients more opportunity to seek out lower cost options.

To determine whether a given class treats a chronic condition, I augment my data with the Chronic Condition Indicator distributed by the Agency for Healthcare Research and Quality's Healthcare Cost and Utilization Project (HCUP). This specifies whether a specific ICD-9 code pertains to a chronic condition, allowing me to create a dummy for each class which designates whether it treats a chronic condition. For example, the code 185 designates prostate cancer and is classified as chronic, while 041 designates a bacterial infection and is not chronic.[55] Overall, 83% of classes are classified as treating chronic conditions.

The results are reported in columns (1) and (2) of Appendix Section G, with the first column presenting Poisson estimates and the second column presenting Poisson-IV estimates.[56] The results show that, consistent with the theory, the

[54] **?** presents results from the RAND experiment; **?** reviews this literature.

[55] Technically, ICD-9 185 is "malignant neoplasm of prostate" and 041 is "bacterial infection in conditions classified elsewhere and of unspecified site."

[56] I now have two endogenous variables, so I need two instruments. Since the instrument is not binary, I follow convention and include as the second instrument the square of the first.

estimated effect of FIC exclusivity on subsequent entry is significantly stronger for chronic conditions – in fact, the effect seems to be largely driven by chronic conditions, as the non-interacted effect is small and statistically indistinguishable from 0.

Household Income. — My second proxy for price elasticity is the mean household income of patients. The idea is simple: consumers with higher incomes are likely to be less sensitive to prices. That price elasticities are related to income has a long tradition in the industrial organization literature and is straightforward to derive out of a standard demand framework.[57]

To perform this analysis, I compute the average household income of patients in each ICD-9 code using data from MEPS.[58] The resulting measure appears consistent with existing evidence on the incidence of specific conditions by socioeconomic status. For example, ICD-9 code 250 designates diabetes mellitus and has a mean household income of about $50,000, while 692 designates eczema and has a mean household income of about $80,000.[59]

I then estimate models which are analogous to those estimated for chronic conditions except that they use the log of mean household income as D_j. The results are reported in columns (3) and (4) of Appendix Section G again with the first column presenting Poisson estimates and the second column presenting Poisson-IV estimates. Consistent with the theory, the interaction effect is significantly negative: i.e., the effect of FIC exclusivity on subsequent entry is significantly stronger for conditions more prevalent among lower income patients.[60] Indeed, the estimates suggest that the effect is moderated substantially by income: the effect on subsequent entry of an extra year of FIC exclusivity is 13% in classes where patient incomes are 10% higher than average, while it is 43% in classes where patient incomes are 10% lower.[61]

[57] See, e.g. **?** for a derivation and **?** for a review.

[58] Household incomes come from the Full Year Consolidated data files, which I match to ICD-9 codes in the Medical Conditions files. To avoid the endogeneity of demand choices, I use incomes from the year before the first in class was approved. Since the MEPS data only begin in 1996, I use 1996 incomes for classes in which the first in class was approved before 1996, and I deflate incomes to constant 2000 dollars using the GDP deflator provided by the St. Louis Fed.

[59] **?** find that diabetes is more prevalent among low SES populations while **?** find the opposite is true of eczema. ICD-9 692 technically refers to "contact dermatitis and other eczema."

[60] It is also worth noting that the coefficient on the log of mean household income is positive: intuitively, classes in which patients are relatively higher income see more entry (conditional on market size).

[61] Mean annual household income is $64,000 in the sample.

TABLE E.1—REMAINING FIRST IN CLASS EXCLUSIVITY AND THE TIMING OF SUBSEQUENT ENTRY

	Dependent Variable is Number of Subsequent Entrants in Class in Year				
	QML Poisson Models		OLS Models		Tobit Model
	(1)	(2)	(3)	(4)	(5)
Remaining Market Exclusivity of FIC (years)	0.375*	0.375*	0.0158***	0.0159***	0.0374***
	(0.208)	(0.208)	(0.00597)	(0.00595)	(0.00741)
Drug Class Fixed Effects	yes	yes	yes	yes	yes
Time Since Launch Fixed Effects	yes	yes	yes	yes	yes
Sample Restriction	Uncensored	Uncensored & FIC Approval ≤ 2001	Uncensored	Uncensored & FIC Approval ≤ 2001	All
Mean of Dependent Variable	0.067	0.073	0.067	0.073	0.036
Number of Classes	127	82	127	82	127
N	1,639	1,376	1,639	1,376	3,048

Note: This table presents panel model results from regressions of the number subsequent entrants approved in a given year on the remaining exclusivity of the FIC drug conditional on drug class fixed effects and time since launched fixed effects. Observations are censored if an observation's associated year takes place after the sample ends in 2011. Columns (1) and (2) present Poisson models estimated by quasi-maximum likelihood. Column (1) includes only uncensored observations and column (2) truncates the sample further to include only uncensored observations for which at least 10 years of entry data post-FIC launch are observed. Columns (3) and (4) replicate columns (1) and (2) using OLS models. As an additional robustness check, column (5) presents results from a Tobit model that includes all observations. Note that the Tobit model suffers from the incidental parameters problem so estimates are inconsistent and should be interpreted accordingly. Robust standard errors clustered at the drug class level are reported in parentheses. *** $p<0.01$, ** $p<0.05$, * $p<0.1$.

TABLE F.1—ROBUSTNESS OF POISSON ESTIMATES TO SAMPLE SPECIFICATION AND PLACEBO TESTS

Panel A: Robustness of Sample Restrictions
Dependent Variable is Number of Subsequent Entrants in Class

	(1)	(2)	(3)	(4)	(5)	(6)
Market Exclusivity of FIC (years)	0.229***	0.137**	0.162**	0.165**	0.0500	0.322***
	(0.0604)	(0.0651)	(0.0633)	(0.0682)	(0.0503)	(0.103)
Year of FIC Approval Fixed Effects	yes	yes	yes	yes	yes	yes
Sample Restriction or Exclusivity Measure	Base	Realized Exclusivities Only	All Expected Exclusivities	Col (3) and Missing Exclusivity is 14 yrs	Authentic FIC & Restr. to Classes with Priority Next	Authentic FIC & Excluding Classes with Priority Next
Mean of Dependent Variable	0.730	1.500	0.827	0.731	2.632	0.719
Exclusivity Coef x Mean of Dep Var	0.167	0.206	0.134	0.121	0.132	0.232
N	111	56	127	156	19	96

Panel B: Placebo Tests
Dependent Variable is Num of Subs. Entrants Following

	Any Drug (mean = 1.07)		*The FIC (mean = 2.37)*	
	(1)	(2)	(3)	(4)
Market Exclusivity (years)	0.0701	-0.0237		
	(0.0482)	(0.0520)		
Market Exclusivity of FIC (years)		0.202***		0.108
		(0.0687)		(0.0678)
Market Exclusivity of LIC (years)			-0.0196	0.00942
			(0.0470)	(0.0441)
Year of FIC Approval Fixed Effects	yes	yes	yes	yes
Sample Restriction	All Drugs		Have Exclusivity for Last in Class	
Excl. Coef x Mean of Dep Var	0.075	-0.021	-	-
FIC Excl. Coef x Mean of Dep Var	-	0.216	-	0.256
LIC Excl. Coef x Mean of Dep Var	-	-	-0.045	0.021
N	196	196	35	35

Note: This table presents robustness checks on the sample and definition of FIC in Panel A, and placebo tests in Panel B. All regressions include year of FIC approval fixed effects. Panel A, column (1) repeats the base analysis from column (1) of Section IV.C, where the sample is restricted to include only observations for which the time of the start of clinical trials is known. The sample in column (2) is further restricted to only observations for which generic entry is actually observed. Column (3) includes the 16 additional observations for which the data include a measure of FIC exclusivity but not the timing of the start of clinical trials. Column (4) codes FIC exclusivity as 14 years for observations that are missing it. Column (5) restricts the sample to only those classes for which a priority review drug immediately succeeded the authentic FIC drug and codes the FIC exclusivity as the authentic FIC's exclusivity, and column (6) restricts the sample to only those classes for which a priority review drug did not immediately succeeded the authentic FIC drug. Panel B, column (1) repeats the base case analysis but includes one observation for all drugs (so long as that class's FIC exclusivity is known), and column (2) repeats column (1) but includes a separate control for the FIC's exclusivity. Columns (3) and (4) restricts the sample to classes for which the data include the last in class's exclusivity. Robust standard errors are presented in parentheses and standard errors in Panel B, columns (1) and (2) are clustered at the class level. *** $p<0.01$, ** $p<0.05$, * $p<0.1$.

TABLE F.2—ROBUSTNESS OF IV ESTIMATES

	Dependent Variable is Number of Subsequent Entrants in Class			*Dependent Variable is Log(1+Number of Subsequent Entrants in Class)*		
	QML Poisson-IV		QML Poisson	Linear IV		OLS
	(1)	(2)	(3)	(4)	(5)	(6)
Market Exclusivity of FIC (years)	0.337***	0.482***		0.0583**	0.0988**	
	(0.128)	(0.184)		(0.0277)	(0.0394)	
Patent Filing to Clinical Dev. (years)			-0.0692*			-0.0261*
			(0.0357)			(0.0140)
Mean Development Time	yes	yes	yes	yes	yes	yes
Market Size	yes	yes	yes	yes	yes	yes
Year of FIC Approval Fixed Effects	yes	yes	yes	yes	yes	yes
Sample Restriction	Base	Instr. > Median	Base	Base	Instr. > Median	Base
Mean of Dependent Variable (levels)	0.73	0.78	0.73	1.73	1.78	1.73
Exclusivity Coef x Mean of Dep Var	0.246	0.376	-	0.100	0.174	-
F-Statistic from the First Stage	43.52	19.68	-	24.94	15.99	-
N	111	56	111	111	56	111

Note: Columns (1) and (2) present results from Poisson-IV models estimated by quasi-maximum likelihood and using a control function for the instrument, which is the difference in time between the patent's filing date and the start of clinical development. The first column repeats the analysis from column (6) of Section IV.C, while the second column restricts the sample so that the value of instrument must be greater than its median of 4.43 years. The third column presents results from a Poisson regression of the second stage outcome variable on the instrument. Next, columns (4)-(6) repeat the analysis in columns (1)-(3) but in a linear-IV/OLS framework, where the outcome is the log of 1+ the number of subsequent entrants. All regressions include controls for mean development time in class, market size, and year of FIC approval fixed effects. The sample and controls are specified as described in Section II. All standard errors are robust, and standard errors in the Poisson-IV models (which are estimated by two-stage residual inclusion) are corrected for the two-stage design as described in the text. *** $p<0.01$, ** $p<0.05$, * $p<0.1$.

TABLE F.3—BASE ANALYSIS WITH SAMPLE RESTRICTED TO CLASSES STARTING NO LATER THAN 2001

	Dependent Variable is Number of Subsequent Entrants in Class for Classes such that FIC Approval Occured No Later than 2001 (mean =1.18)					
	QML Poisson Models			QML Poisson-IV Models		
	(1)	(2)	(3)	(4)	(5)	(6)
Market Exclusivity of FIC (years)	0.224***	0.241***	0.248***	0.473**	0.403**	0.402**
	(0.0660)	(0.0699)	(0.0690)	(0.206)	(0.161)	(0.160)
Mean Development Time	no	yes	yes	no	yes	yes
Market Size	no	no	yes	no	no	yes
Year of FIC Approval Fixed Effects	yes	yes	yes	yes	yes	yes
Exclusivity Coef x Mean of Dep Var	0.264	0.284	0.293	0.558	0.476	0.474
F-Statistic from the First Stage	-	-	-	11.96	18.91	20.01
N	62	62	62	62	62	62

Note: This table repeats the base analysis presented in Section IV.C but restricts to the 62 classes that started no later than 2001. Columns (1)-(3) present results from quasi-maximum likelihood Poisson models which incrementally add controls for mean development time in class and market size. Columns (4)-(6) replicate columns (1)-(3) but instrument for FIC market exclusivity using the time between patent filing and the start of clinical development, where the start of clinical development is defined as the date on which an Investigational New Drug Application, a required precursor to the start of human clinical trials, is approved. All models are conditional on year of FIC approval fixed effects. The IV models are implemented using a control function and first stage estimates are presented in the final rows of the table. The sample and controls are specified as described in Section II aside from the sample restriction. Robust standard errors are reported in parentheses and standard errors for the IV models are corrected for the two-stage design as described in the text. *** $p<0.01$, ** $p<0.05$, * $p<0.1$.

TABLE F.4—BASE ANALYSIS CONTROLLING FOR SALES

Dependent Variable is Number of Subsequent Entrants in Class

Panel A: Controling for Max Annual Revenue of FIC

	QML Poisson Models		QML Poisson-IV Models	
	(1)	(2)	(3)	(4)
Market Exclusivity of FIC (years)	0.224***	0.170**	0.380**	0.374**
	(0.0808)	(0.0840)	(0.173)	(0.171)
Max Annual Revenue of FIC	no	yes	no	yes
Mean Development Time	yes	yes	yes	yes
Market Size	yes	yes	yes	yes
Year of FIC Approval Fixed Effects	yes	yes	yes	yes
Mean of Dependent Variable	0.871	0.871	0.871	0.871
Exclusivity Coef x Mean of Dep Var	0.195	0.148	0.331	0.326
F-Statistic from the First Stage	-	-	17.59	18.16
N	85	85	85	85

Panel B: Controling for Max Annual Revenue in Class

	QML Poisson Models		QML Poisson-IV Models	
	(1)	(2)	(3)	(4)
Market Exclusivity of FIC (years)	0.200***	0.229**	0.279*	0.261
	(0.0767)	(0.0972)	(0.159)	(0.188)
Max Annual Revenue in Class	no	yes	no	yes
Mean Development Time	yes	yes	yes	yes
Market Size	yes	yes	yes	yes
Year of FIC Approval Fixed Effects	yes	yes	yes	yes
Mean of Dependent Variable	0.886	0.886	0.886	0.886
Exclusivity Coef x Mean of Dep Var	0.177	0.203	0.247	0.231
F-Statistic from the First Stage	-	-	17.61	17.38
N	88	88	88	88

Note: This table repeats the base analysis presented in columns (3) and (6) of Section IV.C but adds controls for sales. In Panel A, the control for sales is the log of the maximum annual revenue ever earned by the FIC, and in Panel B, the control for sales is the log of the maximum annual revenue ever earned by any drug in that class. The sample is restricted to those classes for which the sales measure is available throughout each panel. Columns (1) and (2) present results from quasi-maximum likelihood Poisson models and columns (3) and (4) replicate columns (1) and (2) but instrument for FIC market exclusivity using the time between patent filing and the start of clinical development, where the start of clinical development is defined as the date on which an Investigational New Drug Application, a required precursor to the start of human clinical trials, is approved. All models are conditional on year of FIC approval fixed effects, mean time in development, and market size. The IV models are implemented using a control function and first stage estimates are presented in the final rows of the table. The sample and controls are specified as described in Section II. Robust standard errors are reported in parentheses and standard errors for the IV models are corrected for the two-stage design as described in the text. *** p<0.01, ** p<0.05, * p<0.1

TABLE G.1—DEMAND ELASTICITIES

	Dependent Variable is Number of Subsequent Entrants in Class			
	(1)	(2)	(3)	(4)
Market Exclusivity of FIC (years)	-0.00510	0.0694	16.49**	16.66***
	(0.120)	(0.134)	(6.654)	(6.050)
Chronic	-2.702	-3.616*		
	(1.853)	(1.975)		
Chronic x Market Exclusivity of FIC (years)	0.251*	0.322**		
	(0.136)	(0.148)		
Log Income			19.00**	18.98**
			(8.174)	(7.379)
Log Income x Market Exclusivity of FIC (years)			-1.472**	-1.480***
			(0.601)	(0.544)
Mean Development Time	yes	yes	yes	yes
Market Size	yes	yes	yes	yes
Year of FIC Approval Fixed Effects	yes	yes	yes	yes
Estimation	Poisson	Poisson-IV	Poisson	Poisson-IV
F-Statistic from the First Stage	-	21.22	-	20.49
N	111	111	111	111

Note: This table replicates the base analysis in Section IV.C but analyzes, in columns (1) and (2), the interaction of FIC exclusivity with a dummy for whether an ICD-9 code is a chronic condition, and in columns (3) and (4), the interaction of FIC exclusivity with the log of mean income of patients in that ICD-9. Results are from Poisson and Poisson-IV models estimated by quasi-maximum likelihood. The instrument, which is the difference in time between the patent's filing date and the start of clinical development, is implemented as a control function. The sample and controls are specified as described in Section II. Robust standard errors are reported in parentheses and standard errors for the IV models are corrected for the two-stage design as described in the text. *** $p<0.01$, ** $p<0.05$, * $p<0.1$.