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UNDERSTANDING CURRENT TRENDS AND OUTCOMES IN GENERIC DRUG PATENT LITIGATION: AN EMPIRICAL INVESTIGATION

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Understanding Current Trends and Outcomes in Generic Drug Patent Litigation: An Empirical Investigation

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Abstract

This thesis examines the role of patent litigation in the generic drug approval process. Generic drug companies wishing to enter a brand-name drug market early may challenge a brand-name's patents by filing for an Abbreviated New Drug Application (ANDA) with a paragraph IV certification. While anecdotal evidence on the characteristics of paragraph IV lawsuits abound, there has yet to be a comprehensive study on these unique cases. Leveraging a new dataset of district court cases, this thesis presents an empirical investigation into some of the current trends in generic drug litigation from January 1, 2006 to August 1, 2011. Using several basic econometric specifications, I study the determinants of settlement and other outcomes in these cases, observing that factors such as declaratory judgment, the size of a pioneer company, the level of patent protection, and remaining exclusivity may be significant factors.

Keywords: ANDA, pharmaceuticals, Hatch-Waxman, paragraph IV certifications

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Introduction

Debates over the future of healthcare in America have dominated dinner tables and lecterns alike in recent years. These discussions highlight the country's growing concern with the cost of medical care. As our population ages, costs will soar higher still, exacerbating existing inefficiencies within the system.

Increased spending on pharmaceutical drugs has been a highly visible contributor to these rising costs. From 1998 to 2008, prescription drugs accounted for roughly 13 percent of the total growth in national health expenditures (Centers for Medicare & Medicaid Services 2012). While this is only a modest percentage compared to the proportion of total spending attributed to hospitals and physician services, drugs became an increasingly significant constituent over time, seeing double digit growth rates until the early 2000's (Kaiser Family Foundation 2010).

Similarly, insurance coverage for pharmaceuticals has grown rapidly. In 1965, private insurance only paid 3.5 percent of total dollars spent on prescription drugs, with most of the remaining spending (92.6 percent) coming from consumer out-of-pocket expenditures (Berndt 2002). By 1999, the share paid by private insurance and Medicaid grew to 69.8 percent of total dollars spent on prescription drugs, far outpacing the out-of-pocket share. These numbers are particularly concerning in the wake of national controversy over the implementation of President Barack Obama's Affordable Care Act.

One of the chief factors that has contributed to this spending growth is a corresponding increase in drug prices. From 1998 to 2008, average retail drug prices rose from $38.43 to $71.69 (Kaiser Family Foundation 2010). Consumers unable or unwilling to pay the high

prices charged by brand-name drug companies ultimately turned to their cheaper generic counterparts. Generic drugs are alternatives to brand-name drugs that typically contain the same active ingredients as the brand-name drug. Competition from generic drug companies, which traditionally face lower costs compared to brand-name companies, resulted in significant savings for consumers. In 2008, the average price of a brand-name drug was $137.90, almost four times greater than $35.22, the average price of a generic drug (Kaiser Family Foundation 2010). The Congressional Budget Office (2010) has estimated that the availability of generics resulted in a savings of $33 billion to consumers just in 2007. Along with drug price reduction, generic entry brings about an increase in drug quantity. Aitken et al. (2009) report that within 18 months of a generic version of simvastatin coming on to the market, prescriptions increased from 2.8 million to 4.8 million per year, a greater than 70 percent growth. Given these benefits, one would assume that 100 percent generic substitution would be desirable for society. However, while lower drug prices are an important consideration, maintaining the incentives to produce new and better drugs is just as crucial.

Brand-name or "pioneer" drug companies are responsible for developing innovative drugs that can improve the quality of life of millions of people. But, bringing a new drug to market involves a huge investment of time and capital, and each new drug a pioneer chooses to pursue comes at an enormous risk. The pioneer company must submit to extensive tests before the FDA before gaining approval to market their drug. Even if a drug is ultimately marketed, there is no guarantee as to its commercial success, and the pioneer may never re-coup its original investment. Low-cost price competition from generic drugs cuts into a pioneer company's profits and consequently mitigates the returns to new drug development.

Thus, patents are particularly valuable assets in the pharmaceuticals industry. They reward pioneer drug companies with the limited monopoly rights to exclude competitors from making, using, and selling a claimed drug or drug component. Through both market exclusivity and patent licensing, pharmaceutical companies can recuperate some of the investment costs to research and ultimately fund additional drug development.

Maintaining the balance between strong incentives for innovation and affordable drug prices for consumers is a core challenge of healthcare policy. Congress attempted to address these conflicting interests through the Drug Price Competition and Patent Term Restoration Act of 1984, commonly called the Hatch-Waxman Act. The Hatch-Waxman Act modified the regulatory pipeline for generic drug approval by permitting generic drug makers to enter the market before a pioneer drug maker's patents expire, provided the generic can show in court that the patents covering the pioneer drug are invalid, not infringed, or unenforceable. This is a so-called "paragraph IV certification."

Despite the close link between patent law and drug policy, the Hatch-Waxman Act's effects on patent litigation have not been well studied until more recently. Generic drug cases are, however, a growing research interest among lawyers, economists, and policy makers. Using a novel dataset of 1,095 district court patent cases involving paragraph IV certifications, this thesis attempts to contribute to the on-going discussion by providing quantitative descriptive data and empirical analysis for these unique cases. This thesis addresses two main questions. First, what are the current trends in generic drug litigation? Next, what factors have led to these outcomes in litigation?

More specifically, this paper examines the most frequent districts that these cases are filed

in, the trend in total case filings over the last few years, the most common litigants and drug products involved, and the distribution of case outcomes. I will also provide some basic econometric analysis on the determinants of settlements and pioneer victories in ANDA cases. Using several linear probability model specifications, I look at the factors that impact the ultimate case outcomes. These independent variables include lawsuit-level features like venue, parties-in-suit, and the strength of patent protection, as well as, drug-level data like sales and drug class.

Ultimately, I find that factors such as declaratory judgment cases and expanded patent scope appear to decrease the likelihood of settlement. On the flip side, cases with large pioneer companies and longer time of remaining patent exclusivity tend to settle more. These findings may confirm some of the troubling trends in adverse drug settlements which have cropped up over recent years. I also find that factors such as declaratory judgment cases, the time of remaining patent exclusivity, and a top pioneer litigant also have some impact on pioneer win rates. Some models suggest that the number of strong patents increases the rate that a pioneer will win, while the number of times a drug has been litigated decreases the win rate. This thesis provides many opportunities for future extensions and can fuel additional qualitative and quantitative research.

The remainder of this thesis is split into six parts. Part 1 will focus on the background of the Hatch-Waxman Act and the generic drug approval process. Next, part 2 will survey the existing literature on generic paragraph IV certifications and ANDA patent litigation. Part 3 will introduce the Lex Machina dataset and discuss my methodology for collecting and refining the data. Part 4 will provide an overview of the summary statistics and insights

from the data, while Part 5 will explain the econometric framework for modeling outcomes and analyze the results therein. Finally, Part 6 will conclude this thesis by discussing the policy implications and extensions of this work.

1 Background

The US patent system and the FDA both play important and distinct roles in the drug approval process. While the FDA focuses primarily on protecting consumers from potentially unsafe and ineffectual new drugs, the patent system is concerned with securing the intellectual property rights of the new drug's developer.

Pioneer drug companies rely heavily on their patents to keep out competitors. Unlike in other industries, once the chemical formula for a drug is disclosed, it can be relatively cheap and simple for competitors to copy and manufacture the exact same product (Hemphill 2006). Patents allow the pioneer drug company to temporarily exclude others from making, using, and selling a claimed drug or process for manufacturing a drug. While patents are slated to last for 20 years from the filing date of the patent application, the effective life of a pioneer drug patent is estimated to be only about 12 years (Grabowski and Kyle 2007) compared to 18.5 years in other industries. This shorter effective life is in part due to the long demands of the FDA's new drug approval process.

Before any drug can be marketed, the FDA must ensure that the drug is both safe and effective for the drug's proposed uses. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301) requires that all new drugs undergo an extensive approval process meant to determine if the drug's benefits outweigh its potential safety concerns. An applicant seeking the approval

of a new drug must prepare a New Drug Application (NDA) and file it before the FDA. The pioneer drug company must submit data from preclinical research (e.g. animal tests) and clinical trials on human subjects to demonstrate the new drug's safety and efficacy. Along with this information, the pioneer applicant must cite all patents that cover the particular drug or a method of using the drug for which a claim of patent infringement could be reasonably asserted. A study conducted by the Tufts Center for the Study of Drug Development (DiMasi et al. 2003) found that, beginning from pre-patent research and development, it costs a company roughly $802 million and 12 years to get a new drug to market (their methodology is contentious as it includes marketing expenses). Studies that attempt to determine the costs associated with marketing a new drug are highly controversial and have produced figures ranging from under $250 million to $2 billion (see Glasgow 2001; Adams et. al 2006). Once an NDA is approved, it is listed in a published manuscript called the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is referred to commonly as the "Orange Book."

The most significant contribution of the Hatch-Waxman Act(21 U.S.C. §355) was to simplify and abbreviate the FDA generic drug approval process. Prior to 1984, the FDA required all generic drug makers to undergo the same safety and efficacy procedures as pioneer drug companies before putting their products on the market, without considering the previously compiled data on the pioneer drug. This wasteful practice led to inefficiencies from years of duplicative clinical trials and paperwork, ultimately contributing to the underproduction of generic drugs.

Under the Hatch-Waxman Act, the original applicant for the drug (the pioneer applicant)

is still required to file an NDA and undergo the series of FDA regulated tests. But, any subsequent applicant seeking to make a generic version of an already approved pioneer drug is only required to file a partial NDA called an Abbreviated New Drug Application (ANDA). In order for the ANDA to be approved, the generic applicant must show that the generic drug in question is a "bioequivalent" of a drug listed in the Orange Book and contains the same quantity of active ingredients (21 U.S.C. §355(j)(2)(A)). The ANDA relies on the clinical findings from the original pioneer drug's application and is much less costly than a full NDA (estimated to be between $250,000 and $20 million by Morton 1999).

Another important provision of the Hatch-Waxman Act allows generic companies to begin the ANDA approval process before the pioneer companies' patents expire without the threat of being sued for patent infringement. Prior to the Hatch-Waxman Act, if there were still unexpired patents covering the pioneer drug, even performing the tests necessary for FDA approval of a generic drug constituted an act of patent infringement. Thus, a generic company had to wait until the patents covering the drug expired before they could even begin the approval process, effectively extending the period of market exclusivity to well beyond the term of the pioneer's patents. The Hatch-Waxman Act lays out a patent rights resolution process which allows the generic company to begin drug approval while recognizing the pioneer's patent rights. An ANDA applicant must certify in one of four ways[1] that its generic drug does not infringe each of the patents that the pioneer drug company listed in its NDA. This thesis will focus on the fourth of these ways: the paragraph IV certification.

[1] "(I) that such patent information has not been filed; (II) that such patent has expired; (III)...the date on which such patent will expire; or (IV) that such patent is invalid or will not be infringed". 21 U.S.C. §355(j)(2)(A)(vii).

When an applicant makes a paragraph IV certification, the applicant claims that the patent or patents in question are invalid, unenforceable, or will not be infringed if the FDA approves the generic company's ANDA.

Consequently, if an applicant makes a paragraph IV certification, the ANDA filer must notify the patent holder of its application. A paragraph IV certification is deemed an artificial act of patent infringement that creates the necessary case or controversy and subject matter jurisdiction to enable the NDA holding pioneer to file a patent infringement claim against the generic in federal court. This is true even before the generic drug is ever actually made, used, or sold. The patent holder has 45 days from the receipt of the notification to bring suit against the ANDA applicant for infringement. If the NDA holder does not respond to a certification within the allotted 45 day period, the ANDA applicant may file a declaratory judgment action against the NDA holder for non-infringement and patent invalidity. This reflects Congress' intention to provide generic drug makers with certainty over the patents covering their generic drug product before marketing and producing the generic drug.

In an effort to protect a pioneer drug company's exclusivity, the Hatch-Waxman Act also includes a 30-month stay provision. The law prohibits the FDA from approving any generic version of a pioneer drug for thirty months or until the court enters a final, non-appealable determination of the patents' invalidity, whichever is earlier. This results in essentially an automatic preliminary injunction against the ANDA applicant. Ultimately, if the patent holder prevails in court, the FDA must defer ANDA approval until after the patent expires.

To encourage generic companies to file ANDAs earlier, the Hatch-Waxman Act allows a "180-day exclusivity period" to the first ANDA filer with a paragraph IV certification.

Under this provision, the first ANDA filer is granted 180 days of exclusivity that triggers when either the patents covering the pioneer drug expire, the patents are deemed invalid, unenforceable, or not infringed in court, or the generic drug goes on sale in the marketplace, whichever is earliest. Until the first ANDA applicant's 180-day exclusivity period has been triggered and expires, the FDA may not approve any other ANDAs for the same drug, even if the second ANDA is already ready for approval and the drug is ready to be marketed. This 180 day bounty effectively rewards the first ANDA filer by keeping the first-filing company's competitors out of the market temporarily and is meant to encourage generics to challenge pioneer patents with paragraph IV certifications. Because invalidating a pioneer patent will open up the market to all competitors, the provision's intention is to break down the collective action problem associated with challenging pioneer patents (Hemphill and Lemley 2011). Interestingly, a generic does not actually need to win a lawsuit to trigger the bounty, it just needs to avoid losing in court.

The Hatch-Waxman Act has largely been credited with a marked increase in generic drug usage. In 1984, the year of the Hatch-Waxman Act's passage, only 18.6 percent of prescriptions in the US were for generic drugs (Frank 2007). By 2010, that share increased to as much as 78 percent (IMS Institute of Healthcare Informatics 2011). Research has also found that generic companies most often target high-revenue drugs, where consumers may see the greatest benefit (see Hemphill and Sampat 2011a). The Hatch-Waxman Act's consequences on the patent system, however, are not as clear. Colloquially, the law has lead to a steady rise in drug related patent lawsuits over the years through the paragraph IV provision, though the amount of growth and the nature of these challenges is unclear. Besides the large influx

of ANDA cases, a number of other potentially troubling trends have emerged in recent years.

Chief among these concerns is the steady rise of ANDA case settlements that result in "reverse payment" agreements (also called "pay-for-delay" agreements), in which pioneer companies agree to pay generics a substantial sum of money in exchange for delayed generic entry into the market. This delay permits pioneer companies to maintain their high prices for drugs, which may harm consumers. The Federal Trade Commission (FTC) has recently become very concerned with this behavior and has pegged reverse payments as anticompetitive and collusive, allowing pioneer companies to maintain their monopoly profits from market exclusivity. In contrast to the FTC, the courts generally view settlement as a desirable outcome compared to continued litigation, and some appellate courts have been hesitant to adopt the FTC's strict standards[2]. The issue of settlement in ANDA cases remains controversial and unresolved, and the consequences of these trends is still unclear.

2 Literature Review

Since the passage of the Hatch-Waxman Act, ANDAs have played a significant role in patent ligation. Surprisingly, however, there has been relatively little empirical research conducted on the paragraph IV statute. Much of the previous literature, not reviewed here, focuses on explaining the historical, legislative, and judicial underpinnings of the Hatch-Waxman Act. These papers primarily evaluate the law's role in balancing the interests of pioneers, generics, consumers, and regulators (for example Wheaton 1985, Soehnge 2003,

[2]See the Eleventh Circuit in *Valley Drug v. Geneva Pharmaceuticals* 350 F.3d 1181 (2003) (reversing the district court to find reverse payment settlements not per se illegal); also see Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation* 466 F.3d 187 (2006) (finding that there was no antitrust case to be stated in reverse payment settlements); but see Sixth Circuit in *In re Cardizem CD Antitrust Litigation* 332 F. 3d 896 (2003) (affirming the district court and finding that reverse payments were subject to antitrust analysis and were per se illegal)

Miller 2002).

Other papers have looked at the economic ramifications of the Hatch-Waxman Act and generic entry. Grabowski and Vernon (1986) optimistically predict that the law should induce generic entry and substantially increase consumer welfare, though the long-run impacts on research and development incentives are unclear. Their initial findings guess that there should be no major adverse effects on innovation. Berndt (2002) addresses the economics of brand-name drug pricing in response to generic competition, finding that increased generic entry quickly drives down market prices for the generic substitute. Though some of these studies use data to illustrate important points, they mostly make theoretical contributions to the literature. This literature review will focus primarily on data-driven research on paragraph IV certifications and the resulting ANDA litigation. Most of this work centers around understanding when, how, and why the paragraph IV statute is used by generic and pioneer companies to engage in patent litigation.

The FTC (2002) uses drug data to broadly examine ANDA paragraph IV certifications and their distinguishing characteristics. One issue, among many, that the FTC studies at length is the frequency and outcomes of patent infringement lawsuits involving paragraph IV certifications. Using a sample of 104 brand-name drugs (represented by unique NDAs) appearing in ANDAs filed from 1992 and 2001, the FTC finds that nearly 75 percent of brand-name drug products studied initiated patent litigation against the first filing generic. Looking specifically to the 53 drugs that had some resolved outcome in court, the paper finds that for 38 percent of the products, the parties settled out of court; for 42 percent, the generic applicant prevailed; for 15 percent, the pioneer company prevailed; and for the rest

of the drugs, the case reached some other outcome.

The FTC additionally finds evidence of an increase in paragraph IV certifications as a proportion of ANDAs filed from the passage of the Hatch-Waxman Act to 2000. While only 2 percent of ANDAs contained paragraph IV certifications from 1984 to 1989, paragraph IV certifications appeared in approximately 20 percent of ANDAs from 1998 to 2000. The present day conventional wisdom tells us that the trend has continued from 2000 to now. The FTC's main contribution is its investigation of the growing quantity of paragraph IV ANDA cases and the outcomes that result from litigation. That said, the FTC report suffers from a lack of data, using only 104 observations in all. This thesis will attempt to provide more comprehensive data on measures like the quantity of ANDA cases filed in court and their outcomes in court to add to the FTC's findings.

Besides just looking at the characteristics of paragraph IV challenges over time, previous literature has also looked at the impacts of these challenges. Panattoni (2011) examines paragraph IV decisions and their effects on pioneer drug companies. First, Panattoni constructs a novel dataset of all district court cases involving paragraph IV certifications that went to a decision for either the pioneer or generic company from the period of 1984 to 2007. Her work is some of the first to use patent litigation data from the courts. She observes 72 paragraph IV decisions pertaining to 79 drugs. Using the dataset, Panattoni finds that a significant portion of all brand-name drugs face paragraph IV certifications, and specifically paragraph IV decisions most often involve high revenue drugs. For example, the top 40 percent of drugs in paragraph IV decisions had at least one year of sales in excess of $970.83 million in 2007 dollars (the empirically derived average cost to market a drug estimated by

DiMasi et al. 2003).

Next, Panattoni takes advantage of a natural experiment created by the announcement of a paragraph IV decision by the court to observe the impact on price and other variables. She proceeds by dropping some values from her dataset to 37 district court cases and 39 distinct brand-name drugs and looks at the consequences of a paragraph IV decision on the brand-name firm's value. She ultimately finds that paragraph IV decisions create uncertainty that has considerable implications for pioneer companies, decreasing their research and development incentives and profitability. Panattoni's findings provide insight into how paragraph IV decisions impact pioneer companies. However, like the FTC report, Panattoni's paper is quite limited in scope. Using less than 80 observations, she only examines cases that resulted in a paragraph IV decision for either the pioneer or generic, leaving out many other interesting outcomes, including settlement. My work will expand on the district court data that Panattoni uses by including a comprehensive study of all ANDA paragraph IV cases in my timeframe.

Grabowski and Kyle (2007) measure the effect of generic competition on market exclusivity periods for pioneer drug companies by studying drugs with first generic entry from 1995 to 2005. Grabowski and Kyle show that low selling brand-name drugs (annual sales under $50 million) have significantly longer market exclusivity periods than high selling brand-name drugs (annual sales over $500 million) with 15.1 years of exclusivity compared to 12.7 years. Blockbuster drugs, which sold for over $1 billion in the year prior to generic entry, faced even shorter periods of exclusivity, especially across time. The authors suggest that this marked difference in market life exists because generic companies tend to target pioneer drugs with

high volume sales. Finally, Grabowski and Kyle find through their regression analysis that pioneer drugs that were subject to an ANDA paragraph IV challenge had market exclusivity periods on average 1.5 years shorter than drugs without such challenges. Their work discusses two particularly interesting findings that are relevant for this thesis: that high drug sales are a crucial determinant of why generics seek to challenge a pioneer drug and that paragraph IV challenges decrease market exclusivity.

Hemphill and Sampat (2011b) build on Gabrowski and Kyle's findings. Their econometric analysis rejects the theory that generic challenges are indiscriminate or only depend on drug sales. While they find that drug sales are a significant determinant of paragraph IV challenges, the patent portfolio covering each drug matters even more. Specifically, Hemphill and Sampat find that weak patents make paragraph IV challenges more common. This is true even when the weak patents make the drug's overall patent protection greater (weak patents still add to the patents' overall scope). The authors additionally find that patents which do not cover the active ingredients in a particular drug (non-AI patents) are strongly correlated with increased generic challenges. This finding is consistent with previous work that attributes the rising likelihood of a paragraph IV decision for the generic to a steady drop in pioneer drug patent quality (Berndt et al. 2007).

Most of the previously referenced papers explain the factors that contribute to a generic filing an ANDA with a paragraph IV certification, but they rarely study the impact that these factors may have on the litigation itself. As such, my thesis will contribute to the existing literature by providing comprehensive summary statistics on ANDA paragraph IV litigation, a study of the outcomes associated with this litigation, and some basic econometric

analysis explaining the factors that contribute to the ultimate outcome.

3 Data

This section now presents the dataset I constructed for my empirical analysis. It covers all ANDA paragraph IV litigation from January 1, 2006 to August 1, 2011. My main unit of analysis for this thesis is individual patent cases. The best way to analyze patent case characteristics is to look at the case dockets for all relevant lawsuits, which includes all the documents filed in a case. Most of the action in litigation happens at the lowest level of the court system rather than at the appellate level and patent cases are always filed in federal court. So, I look just at federal district court cases and dockets. I build my dataset using the patent case database from Lex Machina, Inc.[3], a legal information company which has indexed and codified patent cases from all of the 94 US District Courts from 2000 to the present.

Very few studies have made use of new electronic resources such as Lex Machina, which provides full case dockets and other relevant data for intellectual property law cases. While the Lex Machina data is based on existing data from PACER, the federal court system's official electronic filing database, Lex Machina has performed a significant amount of error correction and tagging on top of PACER's docket reports. For instance, some cases have been corrected to account for errors in coding by the courts, case types have been resolved of false positives and negatives, and a vast amount of meta-data has been added to each case. Most importantly, the Lex Machina data includes important features such as case

[3]Source: `https://www.lexmachina.com`

outcome; litigants; patents-in-suit; and tags for case events like summary judgments, trials, and appeals (which the PACER data does not include).

To find my specific subset of patent cases, I use Lex Machina's robust patents in-suit data (which lists all of the patents disputed in a single case) and match those patents with the FDA's Orange Book data. The FDA's Electronic Orange Book database publishes a list of all patents cited across all submitted NDAs[4]. This should be an exhaustive list of all the patents that could potentially be disputed in a relevant generic drug case, as the pioneer company can only invoke the Hatch-Waxman Act's patent litigation process based on the patents cited in their NDA. Thus, searching Lex Machina for all cases where any one of these patents are in dispute should provide a complete list of all potential ANDA cases.

I then limit my dataset to only cases filed between January 1, 2006 and August 1, 2011. While the Lex Machina data is excellent for all available years (2000 to present), it is particularly good after 2004, when most federal courts completed efforts to modernize their court filing systems. By 2006, all federal district courts had adopted an electronic filing system connected to PACER, so the data from 2006 to present should represent the most complete set of cases available electronically. I use only cases after January 1, 2006 both in acknowledgement of the particular robustness of this set of data and the time limitations present in writing this thesis. After removing false positives, I end up with 1,095 ANDA patent cases in my dataset. False positives were often cases that involved brand-name companies suing other brand-name companies or were antitrust cases.

After identifying the 1,095 relevant cases, I go through every case and extract by hand the

[4]Data available at: `http://www.fda.gov/Drugs/InformationOnDrugs/ucm129689.htm`

drug product information and the brand-name and generic litigants from the set of pleadings and complaints that begin each docket. I also code a final outcome for the case if it was resolved, or I mark it as on-going as of August 1, 2011. Finally, I automatically extract from the Lex Machina database information on the judge, the patents-in-suit, the jurisdiction the case was filed in, the filing date, and, if available, the termination date. I can confirm the accuracy of these data in the hand review of all my cases. Though slight errors may have prevented me from correctly identifying and coding all ANDA paragraph IV patent cases in my time period, I believe that my dataset is very close to comprehensive.

4 Summary Statistics and Insights

Just from looking at the data broadly, we can already see some interesting trends and confirm some widespread anecdotes about generic pharmaceutical patent litigation.

Venue

We can first look to see where these ANDA cases are most often filed. The District of New Jersey is home to some of the biggest pharmaceutical drug companies in the world, including Johnson & Johnson, Sanofi-Aventis, Pfizer, Schering-Plough, and Novartis. So, we expect that the District of New Jersey court would rank as one of the most popular venues for ANDA litigation. Similarly, Delaware is known as both a popular state for corporations to incorporate and also houses some large players in the chemical and pharmaceutical industries, including AstraZeneca. We then would also expect that the District of Delaware court processes a large number of ANDA cases. Indeed, the data suggest that these widely held beliefs are true.

Table 1—Most Popular ANDA Litigation Venues

Rank	Venue	ANDA Cases
1	New Jersey	390
2	Delaware	356
3	New York, Southern	80
4	Indiana, Southern	38
5	Maryland	33

Note: Table 1 shows the top five districts ranked by the total number of ANDA cases filed. There were 31 districts in total that included at least one ANDA case.

According to Table 1, New Jersey and Delaware far outpace the other districts in the number of cases filed within our time frame. In fact, combined, the two districts account for 68.13 percent of all ANDA cases in the dataset. However, some of this distinction can be attributed to the fact that New Jersey and Delaware are popular jurisdictions to file any patent case, not just ANDA cases. We can look at the data in a different way by finding the percentage of the total number of patent cases filed in a particular district that are ANDA cases.

Table 2—Most Popular ANDA Litigation Venues by Share of Total Patent Cases

Rank	Venue	ANDA Cases	Total Cases	ANDA Share
1	W. Virginia, Northern	18	31	58.06%
2	New Jersey	390	895	43.58%
3	Delaware	356	1135	31.37%
4	Indiana, Southern	38	157	24.20%
5	Maryland	33	135	24.44%

Note: Table 2 shows the top five districts ranked by the proportion of total patent cases that are ANDA cases. There is a slight difference between this ranking and the ranking in Table 1, as West Virginia, Northern has an incredibly high percentage of ANDA cases despite seeing very few patent cases as a whole.

Incredibly, in the Northern District of West Virginia, a district that was not even on our radar previously, 58.06 percent of the patent cases filed were ANDA cases (See Table 2). Of course, the district court is not very active in the first place and only heard 31 patent cases total over the five and a half year period. These data also confirm that New Jersey

and Delaware do seem fairly unique in their desirability as an ANDA litigation jurisdiction with 43.58 percent and 31.37 percent ANDA case rates, respectively. The Southern District of New York court, which was in the top five venues for ANDA litigation by pure counts, dropped off the list with only a 13.16 percent ANDA case rate.

Cases Filed

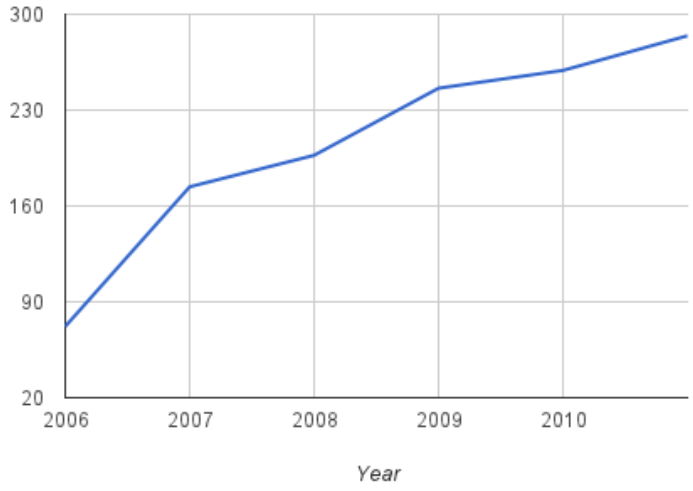
Experts have also commented on a sharp rise in ANDA litigation over the last several years. Again, the data can confirm this colloquially cited evidence. As with ANDA litigation venues, we can examine both the raw counts of ANDA cases per year as well as the percentage of total patent litigation ANDA cases accounted for over the year.

Looking at raw counts (Figure 1), we see the expected steady upward trend of ANDA patent litigation. In particular, we see that over the time of the dataset, ANDA litigation grew at a massive rate, with estimated 2011 totals[5] four times larger than just five years prior. Again, we can observe ANDA case numbers as a percentage of total patent cases.

Interestingly, we see a slightly different trend if we observe the share of patent litigation that is comprised of ANDA cases instead of raw counts (Figure 2). Though an upward trend is evident from 2006 to 2009, the proportion falls in the last couple of years. This suggests that other types of patent cases (for example, those involving mobile phone technologies) may now be out-pacing ANDA cases.

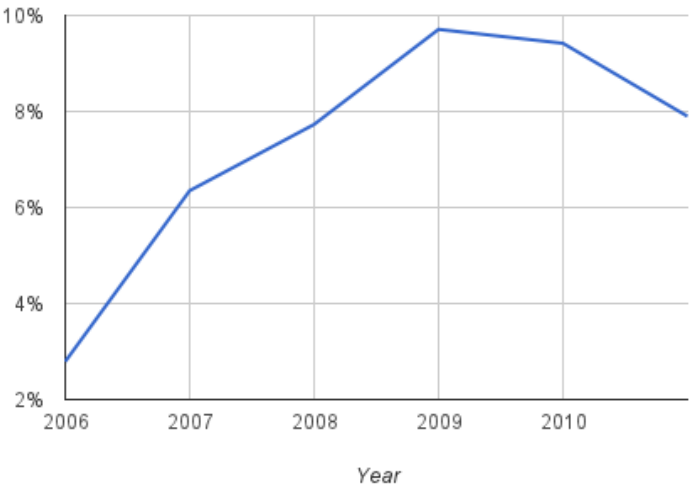
[5]The 2011 total counts are estimated by assuming that the proportion of ANDA cases out of total cases from January 1, 2011 to August 1, 2011 is equal to the proportion from August 1, 2011 to the end of the year.

FIGURE 1. ANDA CASES FILED OVER TIME, RAW COUNTS



Note: Figure 1 shows the raw count for ANDA cases filed from 2006 through 2011. The 2011 total number is estimated based on the total patent cases filed in 2011 multiplied by the 2011 proportion of ANDA cases in from January to August.

FIGURE 2. ANDA CASES FILED OVER TIME, PERCENTAGE



Note: Figure 2 shows the proportion of total patent cases that ANDA cases account for from 2006 to August 2011. The 2011 number is just the percentage of ANDA cases filed in January-August compared against the total patent cases filed in January-August.

Litigants

Next, the data can also give us an idea of which drug companies, both brand-name and generic, are most often parties to ANDA litigation suits. First, we can look at the most litigious brand-name drug companies in my dataset. I rank the companies based on the count of ANDA cases these companies participated in as either the patent infringement claimant or the declaratory judgment defendant. Prior to ranking, I use a mixture of internet searching, Wikipedia, and corporate websites to resolve parent company to subsidiary relationships and mergers[6]. For example, I've included in the Johnson & Johnson numbers all cases involving its subsidiary Ortho-McNeil-Janssen.

Table 3—Most Litigious Pioneer Companies

Rank	Pioneer	Cases	FT Global 500 Rank	2011 Market Value ($m)
1	Pfizer	95	26	162301.4
2	Sanofi-Aventis	90	59	92044.4
3	Novartis	75	32	143633
4	AstraZeneca	70	111	63514.2
5	Abbott	64	88	75908.8
6	Teva	57	169	47235.7
7	Eli Lilly	57	197	40715.1
8	Merck	49	51	101772.4
9	Roche	41	40	127055.6
10	Johnson & Johnson	35	25	162361.8

Note: Table 3 shows the ranking of the top ten companies that appeared as the pioneer drug company in all ANDA cases from 2006-2011. It also includes the 2011 FT Global 500 ranking for each of these companies to illustrate their size and wealth.

As we can see from Table 3, it is the large brand-name drug companies that are most involved in ANDA cases. All of the companies listed in the table are in the top 200 of

[6]See Appendix A1 for a full list of resolved entities.

the 2011 Financial Times Global 500[7] and have incredibly large market values. They also represent some of the most recognizable names in the pharmaceuticals industry. Because ANDA cases are triggered by paragraph IV certifications, this data also provides us with some insight as to which brand-name companies are most often the targets of paragraph IV certifications. Another interesting measure, which is not reported here, would be a litigiousness score based on the number of lawsuits per billion dollars in revenue for each pioneer.

Similarly, we can look at the most litigious generic drug companies. First, it's important to note that multiple defendants often appear in the same case. In many cases, a plaintiff will name both a parent company and some set of its subsidiaries in a lawsuit, so resolving these relationships gives us a clearer picture of the actual number of defendants in a case. After resolving parent-subsidiary relationships in the same manner as with pioneer companies, I find that each case has an average of 1.17 unique defendants. Table 4 shows the most litigious generic companies.

The case counts for generic companies are higher compared to pioneer companies in part due to the fact that multiple defendants appeared in several cases. However, the top generic litigants do appear in a very high share of the cases. Teva alone is a defendant in 16.8 percent of all the ANDA cases in the dataset. Interestingly, several of the top pioneers are also top generics. This is due to the fact that pioneers often acquire generic manufacturers and bring them in-house. In the case of Teva, for instance, Teva Women's Health is a subsidiary of Teva that creates new drugs, even though Teva as a whole is a generic drug manufacturer.

[7]FT Global 500 ranking published June 24, 2011, found at: `http://www.ft.com/`

Table 4—Most Litigious Generic Companies

Rank	Generic	Cases
1	Teva	184
2	Mylan	120
3	Novartis	119
4	Watson	90
5	Apotex	79
6	Sun	69
7	Lupin	69
8	Par	62
9	Actavis	46
10	Impax	38

Note: Table 4 shows the ranking of the top ten companies that appeared as the generic drug company in all ANDA cases from 2006 to August of 2011. Some cases included multiple defendants.

Finally, we can look at the most common litigant pairs. First, I split the dataset into causes of action. A cause of action is a patent claim that is asserted between a single pioneer and a single generic litigant. So, each plaintiff will have a different cause of action with each defendant in the case. For example, if Pfizer sues Mylan and Teva, there is a cause of action between Pfizer and Mylan, as well as, a cause of action between Pfizer and Teva. There are 1283 unique causes of action and 477 unique litigant pairs in the data. Of these pairs, only 272 or roughly 57 percent of these were repeat litigants. The remaining set of 205 litigant pairs were only involved in one case together. Table 5 shows the most common litigant pairs.

Table 5—Most Common Pioneer-Generic Litigant Pairs

Rank	Pioneer	Generic	Cases
1	Sanofi-Aventis	Novartis	20
2	Novartis	Teva	20
3	Pfizer	Novartis	18
4	Pfizer	Mylan	15
5	Teva	Mylan	14
6	Teva	Watson	13
7	Sanofi-Aventis	Sun	13

Note: Table 5 shows the most common pairs of pioneer and generic litigants in ANDA cases in my timeframe.

Sanofi-Aventis as the pioneer and Novartis as the generic have been involved in 20 cases (1.8 percent of total cases) together in only the five and a half years available in my dataset. The remainder of the list includes many of the biggest players in the ANDA litigation space. In line with these data, Hemphill (2007) reports that the emergence of repeat litigants was one of the key emerging trends of ANDA litigation. Future analysis could look at the relationship between repeat litigants and outcomes.

Pioneer Drug Products

With data on which drugs are litigated, we can uncover interesting information about commonly litigated drugs. For instance, Bae (1997) previously found that generic drug companies most often target high-revenue brand-name drugs and drugs treating chronic diseases. We can first analyze the latter claim by breaking out the data by drug treatment class, which describes the general ailment or condition the litigated drug is intended to alleviate. This was determined in part by consulting the drug classes listed on Drugs.com[8], an independent website with consumer and approval information on over 24,000 drugs on the market.

The most litigated treatment class happens to be drugs dealing with high cholesterol. ANDA cases involving a cholesterol drug make up 11.07 percent of the total ANDA cases from 2006 to August of 2011. Unsurprisingly, allergy medication, drugs dealing with attention deficit and related disorders, as well as, anti-depressants are also amongst the most litigated drug classes. These types of drugs are heavily marketed and often include some of the most

[8]Drugs.com is a continually updated information source which uses data from Micromedex, Cerner Multum, Wolters Kluwer, and others.

TABLE 6—MOST LITIGATED DRUG TREATMENT CLASSES

Rank	Drug Treatment Class	Cases
1	Cholesterol	123
2	Cancer	70
3	Allergy	69
4	Pain Reliever	60
5	ADD/ADHD	53
6	Anxiety/Depression	53
7	Skin Conditions	53

Note: Table 6 shows the top seven drug treatment classes ranked by ANDA case count.

well known drugs sold and distributed around the world. We often see these drug classes advertised in television commercials. Other widely marketed drug classes like contraceptives and erectile dysfunction medication don't quite make the cut, appearing in 38 and ten cases respectively. While Bae's claim that drugs treating chronic illnesses are targeted seems to be generally correct, analgesics that treat non-chronic pain do account for roughly 5.4 percent of total ANDA cases.

We can partially assess Bae's first claim (that high revenue drugs are challenged more) by looking more specifically at the actual drug products being litigated. In Table 7, I present the most litigated drug products along with their associated companies, drug treatment classes, NDA approval years, and peak sales data. The peak sales data is determined from the Drugs.com list of top 200 drugs by sales.

The individual drug products listed in Table 7 are some of the most well known drugs on the market. While this doesn't prove that high revenue drugs are disproportionately challenged (as in Bae's analysis), the data do show several high profile drugs topping the most litigated list.

Table 7—Most Litigated Drug Treatment Classes

Rank	Product	Cases	Class	Peak Year	Peak Rank
1	Crestor	28	Cholesterol	2010	9
2	Boniva	27	Osteoporosis	2009	71
3	Clarinex	24	Allergy	2006	106
4	Eloxatin	22	Cancer	Never Ranked	N/A
5	Antara	19	Cholesterol	Never Ranked	N/A
6	Lyrica	19	Seizure	2010	17
7	Opana	18	Pain Reliever	2010	92
8	Focalin	17	ADD/ADHD	2010	85
9	Seroquel	17	Anti-psychotic	2009	5
10	Cymbalta	17	Anxiety/Depression	2010	10

Note: Table 7 shows the most litigated individual drug products in the dataset. Peak sales year and peak sales rank are assessed just in the 2006-2010 timeframe. Some drugs never appeared in the Drugs.com top 200. These include some of the most well known drugs currently on the market.

Outcomes

One of the most interesting aspects of an ANDA case to analyze is its outcome. With district court data, we can see how ANDA cases are ultimately terminated. Determining the final outcome of an ANDA case can be fairly complicated, so I will first review the methodology I used to code case outcomes consistently.

To begin, there are three very similar outcomes that are often difficult to distinguish. I make clear distinctions between consolidations out, general transfers out, and Multi-District Litigation (MDL) transfers out.

A consolidation commonly occurs when a plaintiff sues several defendants on the same patents. Because it is more efficient to simply settle the facts of the case once, several of these cases may be consolidated into one already existing case. For consolidations, I code the outcomes of each consolidated case as the final outcome in the main case as to the particular defendants in the original cases. A consolidation simply groups cases together and does not

necessarily end the original case. In fact, often times, in cases that are consolidated, the final outcome is also docketed in the original case as well as the consolidated case. If there is no final outcome in the main case, I code a consolidation as a procedural outcome.

A transfer is a similar outcome to a consolidation. A case is transferred when it leaves one district court and goes to another. Unlike consolidations, I treat transfers out as a final outcome. This is because there is a one-to-one correspondence from the transferred out case and the new case it becomes. Essentially, the case is simply moved over to another district, even though the parties, patents in suit, and other facts remain the same. MDL Transfers are slightly different from general transfers. An MDL transfer involves several cases all transferring into the same case. However, it is different from a consolidation in that a brand new case, generally an "In re" case, is created (e.g. *In re: Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*). Thus, I code all the MDL transfers as final outcomes, and I code separate outcome for the newly created MDL case if it was resolved.

The outcomes I use are coded as follows:

- **Consent Judgment for Pioneer:** Any case that goes to final judgment on the stipulation or consent of the parties in suit is coded as a consent judgment. A consent judgment for the pioneer will often include a stipulation that the patents-in-suit are infringed, valid, and enforceable as well as an injunction until the patents expire, delaying generic entry.

- **Consent Judgment for Generic:** A consent judgment for the generic will often include a stipulation that the patents-in-suit are invalid, not infringed, or not enforceable. Generally, the ANDA is approved after the consent judgment.

- **Pioneer Win:** If the pioneer patent holder wins the case, it is coded as a pioneer win, regardless of whether or not the patent holder was actually the plaintiff in the case (e.g. declaratory judgment cases). The pioneer win classification is agnostic as to how the pioneer won and includes cases that were won on bench trial, jury trial, and summary judgment.

- **Generic Win:** I use the the same general principle for coding generic wins as pioneer wins.

- **Likely Settlement:** I code any case that ends in a stipulation of dismissal that does not include a final judgment as likely settlement, regardless of whether a settlement is confirmed or not. I specifically note confirmed settlements within this bucket. Unfortunately, in many cases, it is very hard to confirm a settlement in a case because the court record does not necessarily record these in the case docket. Similarly, it is very difficult to get information about the terms of the settlement even when confirmed.

- **Transfer/MDL Transfer:** As explained above, transfers are considered final outcomes. Any case that is transferred to another district and closes the original case is coded as a transfer.

- **Administrative/Procedural:** If a given case is consolidated out, stayed indefinitely, or terminated in any other way that is not on the merits and is not listed above, it is considered an administrative outcome.

- **On-going:** Any case that has not reached some final outcome is coded as on-going. I exclude any cases that are pending appeal from this designation. For example, if a

case was decided on the merits and now is stayed pending appeal, I code that case by its appealed district court outcome and not as on-going or administrative, even though there is a possibility that the district court decision could be reversed or remanded..

I find that 34.3 percent of cases in my data set were still on-going and didn't reached an outcome as of August 1, 2011. The longest running such case was filed on Febuary 22, 2006. This leaves 720 cases in the data that did reach an outcome. The outcome distribution of the terminated cases is shown in Table 8.

Table 8—Outcomes in ANDA Litigation

Outcome	Cases	Percentage
Consent Judgment for Pioneer	86	11.9%
Consent Judgment for Generic	7	0.9%
Pioneer Win	27	3.8%
Generic Win	42	5.8%
Likely Settlement	374	51.9%
Transfer/MDL Transfer	67	9.3%
Administrative/Procedural	116	16.1%

Note: Table 8 shows the counts and the shares of total ANDA cases that each outcome accounts for after removing on-going cases.

Right away, we can see that the most common outcome across all ANDA cases is the likely settlement. This is not a surprise. Patent cases are often settled before the court reaches a judgment. In fact, courts often promote and encourage settlement as a good alternative to continuing litigation. Settlement frees up the court to try other cases, and the process can be cheaper on the whole for both parties compared to going to trial. These data confirm widespread anecdotal evidence that settlements are the most likely outcomes in ANDA cases and also helps explain why the FTC has taken a particular interest in these types of settlements in recent years. We can see this even more clearly in Table 9 after

removing transfers and procedural outcomes to retain only the most important outcomes.

Table 9—Outcomes in ANDA Litigation

Outcome	Cases	Percentage
Consent Judgment	93	17.4%
Pioneer Win	27	5.0%
Generic Win	42	7.8%
Likely Settlement	374	69.8%

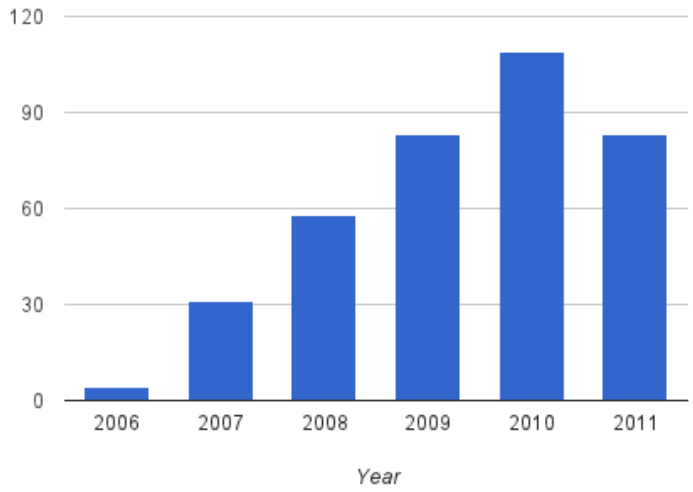
Note: Table 9 shows the counts and the shares of total ANDA cases that each outcome accounts for after removing on-going, transferred, and procedural cases.

Looking more closely at settlements, I can confirm that the number of settlements has actually risen steadily over the years. This mirrors the FTC's own data showing evidence of the growth of reverse payments in ANDA cases over the years (see FTC 2010). Figure 3 shows this sharp increase in ANDA settlements after 2006. According to my data, by the end of the time period of this thesis on August 1, there were already 83 settlements in 2011. This can be compared to 59 settlements from January to August of 2010. So, 2011 was likely to be another record breaking year for settlements. While these settlements are not necessarily all reverse payment settlements, Hemphill (2009) suggests that almost all settlements in paragraph IV ANDA cases include some form of reverse payment[9].

Besides settlements, we can also look at cases that came to some outcome favoring the pioneer or generic litigant. I sum together the cases that the pioneer won including consent judgments favoring the pioneer, and I do the same for cases that the generic won. Table 10 shows that the pioneer wins more than twice as often as the generic, though most of this is accounted for by the number of consent judgments for the pioneer. Nearly 70 percent of the 162 cases were in favor of the pioneer company. Consent judgments for the pioneer

[9]Hemphill (2009) surveyed 143 settlements in his study.

FIGURE 3. SETTLEMENTS OVER TIME, TOTAL COUNTS



Note: Figure 3 shows settlements over time during the time period of my dataset. The 2011 case count is only through August. In 2010, there were only 59 settlements from January to August.

company make up an incredible 53.1 percent of all the merits outcomes. Excluding consent judgments, pioneer companies only win 39.14 percent of the time.

The FTC (2002) previously found that between 1992 and June of 2002, generic companies won 73 percent of patent suits. We can see in Table 11 that by excluding consent judgments, I reach a similar win rate for generics as the FTC does in its study. This suggests that consent judgments are a particularly interesting brand of outcome, and may deserve special treatment in the econometric analysis.

5 Econometric Specifications

Finally, I will present some simple econometric specifications to model ANDA case outcomes as a function of several case features. I begin by looking at the determinants of

Table 10—Merits Outcomes in ANDA Litigation

Outcome	Cases	Percentage
Generic Win: Appeal	1	0.62%
Generic Win: Dismissal	20	12.35%
Generic Win: SJ	7	4.32%
Generic Win: Trial	14	8.64%
Consent Judgment: Generic	7	4.32%
Generic	**49**	**30.25%**
Pioneer Win: Dismissal	2	1.23%
Pioneer Win: SJ	3	1.85%
Pioneer Win: Trial	22	13.58%
Consent Judgment: Pioneer	86	53.09%
Pioneer	**113**	**69.75%**

Note: Table 10 compares outcomes for pioneer drug companies and generic drug companies. Pioneer litigants win over twice as often as generic litigants if we include consent judgments.

Table 11—Merits Outcomes in ANDA Litigation Without Consent Judgment

Outcome	Cases	Percentage
Generic Win: Appeal	1	1.45%
Generic Win: Dismissal	20	28.99%
Generic Win: SJ	7	10.14%
Generic Win: Trial	14	20.29%
Generic	**42**	**60.87%**
Pioneer Win: Dismissal	2	2.90%
Pioneer Win: SJ	3	4.35%
Pioneer Win: Trial	22	31.88%
Pioneer	**27**	**39.13%**

Note: Table 11 compares outcomes for pioneer drug companies and generic drug companies, excluding consent judgments. After removing consent judgments, generics appear to win significantly more than pioneers.

settlement using the linear probability model. Then, I will proceed to model pioneer and generic wins. These econometric models are not meant to be interpreted strictly and are not meant to be used to model the precise effect of case variables on settlement and pioneer wins. In many cases, I have not accounted for heteroskedasticity in the error terms, possible endogeniety in the independent variables, or possible omitted variable bias. However, these models can be used as an interesting indicator for some of the features that may influence settlement rates and pioneer win rates. Future work could use these models as a starting point to conduct a more rigorous analysis of the factors that play a role in case outcomes. All of the models and regression tables as presented in Appendix A2.

Modeling Settlement

To model settlements, I drop any cases from the dataset that are on-going, end in procedural outcomes, or end in transfers. This leaves 533 cases to work with, including consent judgments, outcomes on the merits, and settlements. My dependent variable for these settlement regressions is a dummy for if the case settled (1) or did not settle (0). For this analysis, I do not include consent judgments as settlements.

There are a number of independent variables that may impact settlement rates in a case. First, I look at if the nature of the suit matters for settlement. Specifically, I see if declaratory judgment actions affect settlement in ANDA cases. A declaratory judgment case is one where the generic brings suit against a pioneer in an attempt to invalidate a pioneer's patent. Defendants may be less likely to agree to a settlement if they brought suit to begin with.

Next, I look to variables that will likely impact how aggressively a generic will attempt to

challenge a pioneer company. Based on the insights from Hemphill and Sampat (2011b), I will look at the strength of patent protection covering the drug-in-suit. A general proxy for the scope of patent protection is simply the number of patents-in-suit. I assume that more patents means a greater scope of patent protection. This is certainly not always the case, but Hemphill and Sampat do claim that the addition of any patents (weak or otherwise) will result in an increase in patent protection. However, Hemphill and Sampat place special significance on the number of non-active-ingredient patents that cover a particular drug, finding that this has an effect on decisions to challenge pioneer drugs with ANDAs. Thus, I proceed by coding both the number of patents-in-suit and the number of non-AI patents in suit. This is a potentially significant factor because weaker patent protection may lead a generic to believe it has a good chance in court to invalidate the patent.

Additionally, I look at variables that proxy the economic value of the drug. Bae (1997) and many others found that the economic value of a drug was important to generic drug companies' decisions to challenge a drug. It seems reasonable that these factors could impact the outcome of the case, as well. I start with a dummy variable for if the drug is a top 200 drug by sales[10] on the year preceding the case termination year(1 if the drug is in the top 200 and 0 otherwise). I use the year preceding the termination year because I want to avoid capturing any possible effects the case outcome may have had on the drug's sales after the fact. Clearly, a lot can change in a year for a drug's sales numbers, but the previous year's data should be a reasonable approximation of the drug's commercial success near the time of termination. Again using the Drugs.com database, I also record a particular drug's rank for

[10]Source: Drugs.com

the year and total sales in billions of dollars to complement the dummy variable. Because I only have data on the top 200 drugs in a particular year, only 318 of the 533 total cases have this more detailed sales information. I predict that the more lucrative a drug is, the more likely a generic will want to aggressively enter the market, potentially decreasing the rate of settlement.

Another factor related to drugs that I test is the impact of the number of other cases in my dataset that a particular drug has been litigated in. This is a variable that represents the extent to which a drug has been challenged via ANDA paragraph IV certifications. We might guess that a drug that has been challenged many times previously might be less likely to settle because many generics want to enter the market on this drug.

The size of the pioneer company may also matter. If the pioneer company is large, they may be more willing to settle a case to avoid the possibility of early market entry by the generic. Or, in the reverse payment settlement scenario, where the plaintiff pays off the defendant to settle a case, a larger company may have the resources to pay off defendants in settlement agreements. I again start with a dummy variable for if the pioneer company is listed in the Forbes 2000[11] list of largest public companies in the year preceding its case termination date. Like with drug sales, settlements and other outcomes could have a major impact on a companies market value or sales, so I use the data for the year prior to the termination year. I also collect sales and rank data for these companies, as well. The Forbes 2000 is compiled by Forbes magazine and weights features like sales, profits, assets, and market value in its determination of the top 2000 companies. Every year, this includes many

[11]Source: `http://www.forbes.com`

pharmaceutical companies. Unfortunately, the data is only for public companies, and it will exclude large private pharmaceutical companies such as Boehringer Ingelheim. However, the Forbes 2000 is still a valuable tool because it includes many of the companies in the dataset. 409 out of the 533 cases have Forbes 2000 data associated with them.

I also want to model settlement on temporal data. In particular, I code the time to the expiration of the latest expiring patent-in-suit and the time from beginning to end of the case. The time to patent expiration is crucial because it partially represents the value of the patent protection. If a patent is about to expire, a pioneer may not care as much about generic entry compared to if there are ten years left to a patent's lifetime. I collect this data by going through the listed patents-in-suit and finding the latest expiration data of all the patents-in-suit for a particular case. I then take the number of days from the termination date of the case to the expiration date and divide by 30 to get an approximation for the number of months to expiration. Time to termination may also be important. We may guess that as a case drags on, the litigants may be more willing to settle as the lawyer's fees grow.

Finally, I include a proxy for the political affiliation of the judge. Because all district court judges are federal judges, they are all nominated by the President. I simply look at the judge that issued the outcome and code which president nominated the judge to the court. Then, I include as a dummy variable whether this president was a Democrat (1) or a Republican (0). Political affiliation may have some unknown consequences on the outcome of the litigation.

Linear Probability Models

Table 12 shows three different linear probability model specifications. The linear probability model is used for predicting the effects of certain independent variables on a binary rather than continuous dependent variable. The model predicts the probability that an event will occur, and the coefficient estimates on the explanatory variables represents the effect of the variable on that probability. Thus, in the case at hand, we are testing the effects of variables on settlement rates.

LPM1 is run on all 533 observations in the dataset and includes the independent variables for number of patents, number of patents squared, the number of months to the expiration of the last patent, the number of months the case lasted, the number of other cases the drug is litigated in, and dummy variables for declaratory judgments, Forbes 2000 pioneer companies, top 200 drugs, and judges who were nominated by a Democrat. I include the number of patents squared because I predict there may be a diminishing effect of each additional patent-in-suit. LPM2 meanwhile drops 215 observations to focus on high sales drugs (top 200 drugs only) and uses sales data to model settlement. Finally, LPM3 uses sales data for the 409 cases with a Fortune 2000 pioneer company to model settlement for top public pioneer companies.

First, we see that declaratory judgment cases in LPM1 are significant and are 17.9 percent less likely to settle than non-declaratory judgment cases according to the model. When we look at settlement rates for top 200 drugs (LPM2) and Fortune 2000 companies (LPM3) in turn, we find that the relationship disappears, though it does remain negatively correlated. A generic litigant who files a declaratory judgment action against a pioneer is probably

seeking certainty over the level of patent protection before entering the market, so they may be unlikely to settle.

Next, LPM1 shows that top public pioneer companies listed in the Forbes 2000 increase the probability of settlement by 12.8 percent. Following the reverse payment story, we can hypothesize that large companies have the resources to settle the case and pay off a generic instead of litigating it through to the end and risking the possible invalidation of their patents. This trend continues in LPM2. For cases with a top 200 drug, a large pioneer company increases the chance of settlement by 16.2 percent. Finally, LPM3 shows that for each additional billion dollars in sales for a Fortune 2000 company the settlement probability increases by roughly 0.33 percent.

The number of patents-in-suit also seem to be significant. Each additional patent in LPM1 decreases the probability of settlement starting at 11.5 percent. However, we can also see that the number of patents squared has a positive coefficient, showing that the number of patents decreases the probability of settlement at a decreasing rate. We can see the same is true for the number of non-AI patents in LPM2 and LPM3. If non-AI patents are considered weaker than AI patents, our intuition tells us that generics may be less likely to settle the case and simply try to invalidate the patents instead. This relationship is especially pronounced in LPM3, where the the generic is litigating against a Forbes 2000 pioneer company. In this case, each additional non-AI patent decreases the rate of settlement starting at 12.5 percent.

The time from the case termination date to the expiration date of the last patent is quite significant in all three LPM models. LPM1 shows that for each additional month of patent exclusivity remaining on the date of a case's final outcome, the probability that the case will

settle increases by 4.93 percent. Likewise, LPM2 predicts that for top 200 drugs, the effect is roughly the same. For LPM3's Fortune 2000 pioneer cases, this probability of settlement rises by as much as 7.65 percent. This means that the more time there is left on a patent's lifetime, the more the parties will settle, especially for large pioneer companies. Again, this may fit into the reverse payment story. The more exclusivity time remains for a particular patent, the more valuable the patents are to the pioneer. Large pioneer companies would presumably be incentivized to settle cases rather than risk having their patents invalidated.

In a similar vein, the time from the start to the end of a case may be strongly correlated with a slightly decreased chance of settlement. LPM1 shows that for each additional month the case continues, the probability of settlement decreases by 0.89 percent. The coefficient remains roughly the same for both LPM2 and LPM3. This is probably accounted for by the large number of settlements that occur in the first few months of the case and the settlements that occur before trials. Thus, this effect may be endogenous as a case cannot go to trial in one day. So, this relationship is un-surprising.

Finally, the impact of a Democrat nominated judge and of the number of other cases a drug has been litigated in have unclear effects on settlement probability. For LPM1, we see that for each additional case a drug is being litigated in, the settlement probability increases slightly by about 0.50 percent. However, when we narrow in on cases with Fortune 2000 pioneer companies as litigants, the trend reverses and an additional case results in a 0.90 percent smaller probability of settlement. Only in cases involving a top 200 drug is a Democrat nominated judge significant, increasing the probability of settlement by 9.41 percent.

The linear probability model has several key drawbacks: the regression line is not well-fitted and R-squared values aren't reliable, the residuals are heteroskedastic and are not normally distributed, and the model is not bounded at 0 and 1 as probability estimates should be. The linear probability model can only be seen as a linear approximation of a model with a continuous dependent variable that is the probability of settlement. Due to these limitations, econometricians often use the logit or probit models, which account for some of the problems with the linear probability model.

Probit Model

The probit model does not assume a linear relationship between the dependent and independent variables. Instead of using ordinary least squares, the probit model uses the cumulative distribution function of the normal curve to model the relationship between variables. For the purposes of the econometric analysis in this paper, I can check if the linear probability approximations from LPM1-3 are reasonable by comparing them with the probit model specifications. Table 13 shows that we get similar results when we use the probit model. Importantly, the signs are all the same, the comparative magnitudes of the coefficients are similar to the LPM estimates, and the same estimates as significant in both models. Looking at the marginal effects in the probit model, Probit MFX shows that the effect of each of the variables on settlement, all else constant, is almost exactly the same for both the linear probability and the probit estimates. Thus, the linear approximations from Table 12 are probably a reasonable way to model settlements.

Fixed Effects

Finally, we can re-run our linear probability models with firm, year, and drug fixed effects. Each of these will help control for unobserved heterogeneity across years and entities by accounting for variation across those variables. By including dummy variables for unique years and entitites, in turn, I can get estimates for the effect of the explanatory variables on settlement rate absent the effect of across group variation. Fixed effects can correct for some of the omitted variable bias. Table 17 shows the results of running individual fixed effects with pioneer drug companies, the year of lawsuit termination, and the specific drug product.

Controlling for these fixed effects, we again see that the results match generally with what we expect from LPM1. However, there are a few interesting observations to make. First, controlling for pioneer company, we can see that the effect of the number of patents on settlement rate is reduced, though it still remains negative. This could suggest that some variation across pioneer companies helps to account for the high negative correlation between number of patents and non-settled cases. We can also see that with fixed effects, there is a slight increase in the effect of patent lifetime on settlement rate. Finally, an interesting difference pertains to the number of other cases a drug is litigated in. Under all three fixed effects models, we see a slightly negative coefficient, adding stock to the idea that a drug that is commonly litigated is less likely to settle.

Again, these models are not meant to accurately predict the actual settlement rate given a set of factors. Instead, they are basic models that are presented as a starting point to more rigorous analysis. While these regression models may not account for all possible errors and biases, they can be instructive on the direction and magnitude of the effect of

an explanatory variable on settlement rate. From these models, we can see that declaratory judgment cases are less likely to settle than non-declaratory judgment cases. Similarly, each additional patent-in-suit (a proxy for the level of patent protection) has a negative effect on settlement, though it is likely at a decreasing rate. Shorter cases also tend to settle more often than longer cases, with each additional month the case continues having a negative effect on settlement rate, though the factor is endogenous. Meanwhile, large pioneer companies (proxied by the Forbes 2000 list) tend to have an increasing effect on the probability of settlement. The remaining patent life for a drug also seems to impact settlement, with each additional month of protection resulting in an increased chance of settlement. Finally, the full impact of high revenue drugs (top 200 drugs), a Democrat nominated judge, and the number of other cases a drug is litigated in is still unclear.

Modeling Merits Outcomes

We can do a similar analysis with the merits outcomes as the dependent variable. I drop all the settlements in my data and retain just the 162 outcomes that were found in favor of the pioneer or the generic. I construct a dummy variable for the outcome with pioneer wins as 1 and generic wins as 0. This set includes all of the consent judgments. Again, we can take the same approach as with settlements, using the same set of independent variables and models. Table 15 includes the details for LPM4-6.

Linear Probability Models

Beginning again with declaratory judgment cases, the models show that they have a very large negative effect on pioneer win rates. LPM 4, for instance, predicts that a declaratory

judgment case can decrease the probability that the pioneer company wins by as much as 39.4 percent. The effect remains, for the most part, unchanged when looking at top 200 drugs and Forbes 2000 pioneer companies, though its significance disappears in LPM6.

In each of LPM4-6, a top pioneer company from the Forbes 2000 list leads to a decrease in the pioneer win rate. LPM4 shows specifically that a top pioneer has a 17.6 percent lower probability of winning. LPM6 shows an interesting tension within top pioneer companies. For each additional billion dollars in sales, the pioneer win rate decreases by 1.5 percent, while for each additional billion dollars in pioneer market value, the pioneer win rate increases by 0.55 percent.

Drug sales seems to be only significant for top drugs and top pioneer companies. In LPM5, for top 200 drugs, each additional billion dollars of drug sales corresponds to a decrease of 9.17 percent in pioneer wins. For top pioneers in LPM6, a top drug decreases the pioneer win rate by 20.3 percent. A generic may be more aggressive in challenging a pioneer's patent if the sales are especially high.

Months to termination is the last variable that is significant for each of LPM4-6. Each additional month has an effect of between 0.5 and just over 1 percent increase in the probability of a pioneer win, depending on specification. This shows that as a litigation continues, the probability that the pioneer wins increases slightly.

Interestingly, neither number of patents (a proxy for patent scope) nor time to patent expiration (a measure for time of patent exclusion) are significant. The effects of months to expiration are clearly mixed and not even close to significant, but number of patents is closer to being significant and is across the board positive. This suggests that the greater

the patent protection, the higher the probability of pioneer win, which is a reasonable story. That said, the greater the patent scope, the larger the target for generic companies' patent invalidity arguments. Thus, it is reasonable that the coefficients on number of patents are not significant. A Democrat nominated judge also does not seem to have any close to a significant effect on pioneer wins. Finally, the number of other cases a patent is litigated in has mixed significance. Only in LPM5, with top 200 drugs, each additional case a drug is litigated in leads to a decrease of nearly 2 percent in the probability of pioneer wins. A lucrative drug may be a large enough reward to break down some of the collective action problems associated with invalidating pioneer patents. The large potential pay-off of market entry incentivizes generics to actually follow through with the litigation instead of settling. Thus, when there are more cases, there are more generic challengers seeking to invalidate the patents, and when one generic succeeds, all the others can win their cases.

Probit Model

Again, as with settlements, the drawbacks of the linear probability model merit comparisons with the equivalent probit models. Looking at the comparison in Table 16, we can see that the probit model matches the linear probability model in terms of sign and significance for the same coefficients. Looking at the marginal effects for the probit model with Probit MFX, we can see that they match very well with its linear probability model counterpart (LPM4). Thus, as with settlements, I proceed assuming that the linear probability model is a reasonable approximation of the correct model.

Fixed Effects

Finally, I again look at individual fixed effects for pioneer company, termination year, and drug product. After accounting for these across group effects, declaratory judgment remains significant and negative. Though the magnitude of the negative effect of declaratory judgments on pioneer wins declines from nearly 40 percent to between 25.7 and 36.4 percent, it is still clear that declaratory judgments do decrease the probability of pioneer wins. Similarly, the months to termination are also significant across the board. Under all three specifications, the months to termination have a slight positive effect on pioneer wins, just as with LPM4. Finally, the remaining factors have mixed results. Forbes 2000 pioneer companies are significant with year and drug fixed effects but have different signs depending on specification. The same is true for the number of patents-in-suit, which is significant and negative when accounting for pioneer variation and significant and positive when accounting for drug variation. The number of months to patent expiration is close to being consistent across all three fixed effects specifications, generally being significant and negative. This matches with LPM4 in magnitude, but is now significant under the fixed effects models. This seems to make sense. As the exclusivity period shrinks, generics have fewer and fewer incentives to invalidate the patent as the potential pay-off is lower. Finally, the dummy for top 200 drugs, the dummy for a Democrat nominated judge, and the number of other cases are also mixed or fairly insignificant.

The results of the specifications for pioneer wins are less clear than for settlements. I can generally state that declaratory judgment cases are significantly less likely to result in a pioneer win. Top pioneer drug companies are likely a significant contributor to pioneer win

probabilities, as well. While it seems that they have a negative impact on pioneer wins, when accounting for drug fixed effects, the sign switches, so the total effect is unclear. Another unclear but potentially important variable is the months to patent expiration. Though this factor is not significant in the linear probability models, they do become significant under the pioneer and drug fixed effects models. Finally, the length of the case seems to be an important contributor to pioneer win probabilities. Each additional month the case continues, the probability of pioneer wins increase by between roughly 0.5 to 1.7 percent. Again, as with settlement, these models are useful mostly as instruments to explore the factors that matter in determining pioneer wins and are not meant to actually predict the true probability of a pioneer win.

Removing Consent Judgments from Merits Outcomes

Finally, as mentioned earlier, consent judgments are a special case of settlements because they generally have a polarity (either the pioneer or the generic wins). A consent judgment differs from an outcome on the merits in that the court itself doesn't have to make a determination as to the merits of the case; it is simply an outcome that is reached by the consent of the parties (as with a settlement). As reported in the previous section, this distinction is particularly important due to the number of consent judgments found in favor of the pioneer, which skewed the win rate. While this thesis has so far treated consent judgments as non-settlement outcomes, this final section of econometric specifications will exclude consent judgments when modeling merits outcomes to see if this changes our findings. The results are reported in Table 18.

First of all, we can see that the results are different enough to suggest that consent judgments did have some impact on our modeling of pioneer wins. The second regression shows that the same independent variables used in LPM4 don't provide significant results, though some of the signs do match. The third regression in Table 18 shows a slightly different specification than LPM4, which provides more significant results.

For instance, we can see that declaratory judgment cases for true merits outcomes still have a negative impact on pioneer win rate, but this impact is even greater than in LPM4. According to this model, a declaratory judgment case decreases the chance of a pioneer win by 57.7 percent. Another important observation is that the dummy variable for a large pioneer company (listed in the Forbes 2000) becomes insignificant. This suggests that for these true merits outcomes, the wealth of the pioneer doesn't matter at all. We also observe that the number of AI patents (generally considered the strongest patents covering a drug) has a big impact on pioneer win rate, increasing it by 36.9 percent for each patent. The significant and negative coefficient in front of the number of AI patents squared suggests that this increasing win rate occurs at a decreasing rate. This finding suggests that if a pioneer sues a defendant based on stronger AI patents and the case reaches a merits outcome, then the pioneer has a much better chance of winning for each AI patent-in-suit. The third model also shows that for each additional other case a drug has been litigated in, the pioneer win rate drops by about 1.39 percent. This finding also makes sense. The more cases a drug is involved in, the more defendants have the chance to attack the patents in an attempt to invalidate them. Interestingly, though the coefficient for the dummy variable for a Democrat nominated judge is not significant at the 10 percent level, it is significant at the 13 percent

level. If the coefficient were significant, it would suggest that a Democrat nominated judge actually increases the pioneer win rate by an incredible 18.1 percent. This set of regressions provides some added insight into how these true merits outcomes (outcomes determined by the court) can be modeled.

6 Conclusion

This thesis and future work can have important implications for drug approval and competition policy. By examining ANDA cases in the district courts, this work can contribute to our understanding of the generic drug development process and its relation to patent litigation. Primarily, this thesis seeks to investigate the current trends in ANDA litigation and the factors that may have led to some of the outcomes revealed by these trends. In particular, I present data revealing that a growing number of ANDA cases have been filed in recent years. But, along with this growth in cases, there has also been a growing number of generic and pioneer settlements. This trend may be troubling because according to the FTC (2002, 2010) and other sources (e.g., Hemphill 2009), most of these settlements ultimately result in reverse payment agreements, which delay generic entry and contribute to the increasing cost of prescription medications for consumers. In fact, testifying before the U.S. House of Representatives Committee on the Judiciary's Subcommittee on Courts and Competition Policy, the FTC asserted that these deals cost consumers as much as $3.5 billion a year due to high drug prices and has called stopping these pay-for-delay settlements a top competition priority. However, Hemphill (2009) writes that antitrust analysis on drug settlements suffers from what he calls "aggregation deficit," or a "troubling lack of informa-

tion about the frequency and costliness of anticompetitive activity." This thesis was written to help alleviate this deficit by expanding on existing knowledge to deepen our collective understanding of ANDA litigation.

To determine how some of these outcomes have developed, I model the determinants of settlement and pioneer wins in ANDA litigation. The econometric analysis presented in this paper is a starting point for determining the factors that are important in drug litigation settlements and merits outcomes. While the methodology used in this thesis does not present conclusive causal relationships between the independent variables and the outcomes they attempt to predict, the results of the analysis do reveal interesting connections that lend themselves to further research and study. For instance, using basic linear probability models, this paper found that declaratory judgment cases tend to settle less. Along those lines, cases with more patents-in-suit (or cases with expanded patent scope) also appear to settle less. Some factors appear to lead to a higher likelihood of settlement. In particular, larger pioneer companies seem to settle more, which may support the FTC's reverse payment story. Larger companies may be able to afford to pay off generics because they already have large revenues from previously successful drugs. The more time of exclusivity remaining also seems to increase the rate of settlement. Again, this could support the reverse payment story. The longer the time of exclusivity, the more valuable the patents may be to a pioneer. Thus, a pioneer would be more incentivized to protect this exclusivity through settlement and pay-for-delay agreements. Interestingly, it doesn't appear that high revenue drugs have a clear impact on settlement.

The thesis also explored the determinants of pioneer wins in ANDA cases. This was

done both with and without consent judgments included as merits outcomes. In the models with consent judgments, the analysis showed some unclear results. However, it does appear that factors like declaratory judgments, the time of patent exclusivity, and top pioneer litigants do have some impact on pioneer win rates. The thesis did not come up with a conclusive answer as to what direction these factors could swing the case. Finally, running similar models without including consent judgments, the models show some clearer findings. Specifically, the number of AI patents (the strongest patents covering drugs) appears to have a strong positive effect on the likelihood of a pioneer win. Essentially, as the patent protection becomes stronger, pioneers have a higher chance of victory. In the same vein, drugs that were litigated more had a lower probability of a pioneer win. These cases have more of a history for defendants to draw upon, and they may have more information on the patents-in-suit. Thus, drugs that have been highly litigated could reasonably be easier to defeat or invalidate.

The econometric work presented in this thesis can be used for further research in several important ways. For one, it lends itself to additional qualitative analysis. There are opportunities to look into some of the significant trends revealed in this thesis and present individual case studies for certain archetypical cases. Future work could seek to explain why some of these relationships and trends exist. This thesis also can contribute to further quantitative research on the subject of ANDA case outcomes. There are clearly many more variables that contribute to settlement and pioneer win rates. For example, important factors I didn't include in my analysis include litigiousness by cases per billion in revenue, the existence of authorized generics by the pioneer company, and if the generic was the first ANDA filer. All

of these factors could ultimately prove significant. The analysis presented in this paper also does not do much error correction for endogeniety or heteroskedasticity in the data. Future work could improve the basic methodology used in this paper to more accurately model settlement and other outcomes.

Future research and extensions to this thesis can hopefully expand the depth and breadth of knowledge about the important intersection of public health and patent policy. This thesis can also spur additional research on the relationship between competition policy and intellectual property. Further work can even aid the FTC in determining which cases to pursue antitrust claims against. Finally, by continuing to explore trends in ANDA litigation and analyzing the factors that contribute to the high settlement and high reverse payment rate, scholars and policymakers can find ways to reduce some of the adverse incentives that pioneers and generics face in light of the Hatch-Waxman Act. Maintaining generic entry to promote lower drug prices while keeping the incentives to innovate alive will improve both consumer welfare and health.

REFERENCES

Christopher P. Adams and Van V. Brantner. Estimating the cost of new drug development: Is it really $802 million? *Health Affairs*, 25(2):420–428, 2006. doi: 10.1377/hlthaff.25.2.420. URL http://content.healthaffairs.org/content/25/2/420.abstract.

M. Aitken, E.R. Berndt, and D.M. Cutler. Prescription drug spending trends in the united states: looking beyond the turning point. *Health Affairs*, 28(1):151–160, 2009.

J.P. Bae. Drug patent expirations and the speed of generic entry. *Health Services Research*, 32(1):87, 1997.

E.R. Berndt, R. Mortimer, A. Bhattacharjya, A. Parece, and E. Tuttle. Authorized generic drugs, price competition, and consumers welfare. *Health Affairs*, 26(3):790–799, 2007.

Ernst R. Berndt. Pharmaceuticals in u.s. health care: Determinants of quantity and price. *The Journal of Economic Perspectives*, 16(4):45–66, 2002. ISSN 08953309. URL http://www.jstor.org/stable/3216914.

Centers for Medicare & Medicaid Services. National health expenditure accounts, historical., 2012. URL http://www.cms.gov/NationalHealthExpendData/. Last checked: May 10, 2012.

Congressional Budget Office. Effects of using generic drugs on medicare's prescription drug spending., 2010. URL http://www.cbo.gov/publication/21800. Last checked: Dec 3, 2011.

11th Circuit Court of Appeals. Valley drug co. v. geneva pharmaceuticals, inc. *F. 3d*, 350: 1181, 2003a.

2nd Circuit Court of Appeals. In re tamoxifen citrate antitrust litigation. *F. 3d*, 466:187, 2006.

6th Circuit Court of Appeals. In re cardizem cd antitrust litigation. *F. 3d*, 332:896, 2003b.

Joseph A DiMasi, Ronald W Hansen, and Henry G Grabowski. The price of innovation: new estimates of drug development costs. *Journal of Health Economics*, 22 (2):151 – 185, 2003. ISSN 0167-6296. doi: 10.1016/S0167-6296(02)00126-1. URL http://www.sciencedirect.com/science/article/pii/S0167629602001261.

Federal Trade Commission. Generic drug entry prior to patent expiration: An ftc study. *Washington (DC): Federal Trade Commission*, 2002a.

Federal Trade Commission. Pay-for-delay: How drug company pay-offs cost consumers billions. *Washington (DC): Federal Trade Commission*, 2010b.

Richard G. Frank. The ongoing regulation of generic drugs. *New England Journal of Medicine*, 357(20):1993–1996, 2007. doi: 10.1056/NEJMp078193. URL http://www.nejm.org/doi/full/10.1056/NEJMp078193.

Lara J. Glasglow. Stretching the limits of intellectual property rights: Has the pharmaceutical industry gone too far? *IDEA-Journal of Law and Technology*, 41(227):229–230, 2007.

H. Grabowski and J. Vernon. Longer patents for increased generic competition in the us. the waxman-hatch act after one decade. *PharmacoEconomics*, 10:110, 1996.

Henry Grabowski and John Vernon. Longer patents for lower imitation barriers: The 1984 drug act. *The American Economic Review*, 76(2):pp. 195–198, 1986. ISSN 00028282. URL http://www.jstor.org/stable/1818763.

Henry G. Grabowski and Margaret Kyle. Generic competition and market exclusivity periods in pharmaceuticals. *Managerial and Decision Economics*, 28(4-5):491–502, 2007. ISSN 1099-1468. doi: 10.1002/mde.1356. URL http://dx.doi.org/10.1002/mde.1356.

C. Scott Hemphill. Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem. *New York University Law Review*, 81:1553, 2006. URL http://ssrn.com/paper=925919.

C. Scott Hemphill. Drug Patent Settlements Between Rivals: A Survey. *SSRN eLibrary*, 2007. doi: 10.2139/ssrn.969492.

C. Scott Hemphill. An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition. *Columbia Law Review*, page 1905, 2009.

C. Scott Hemphill and Bhaven N. Sampat. When do generics challenge drug patents? *Journal of Empirical Legal Studies*, 2011a. URL http://ssrn.com/paper=1640512.

C. Scott Hemphill and Bhaven N. Sampat. Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals. *SSRN eLibrary*, 2011b. URL http://ssrn.com/paper=1830404.

C.S. Hemphill and M. Lemley. Earning exclusivity: Generic drug incentives and the hatch-waxman act. *Antitrust Law Journal*, 77(3):947–989, 2011.

IMS Institute for Healthcare Informatics. The use of medicines in the united states: Review of 2010, 2011. URL `http://www.imshealth.com/imshealth/Global/Content/IMS\%20Institute/Documents/IHII_UseOfMed_report\%20.pdf`. Last checked: May 14, 2011.

Kaiser Family Foundation. Prescription drug trends, 2010. URL `http://www.kff.org/rxdrugs/upload/3057-08.pdf`. Last checked: Nov 12, 2011.

J.L. Miller. Drug price competition and patent term restoration act: The elimination of competition between drug manufacturers. *DePaul J. Health Care L.*, 5:91, 2002.

Fiona M. Scott Morton. Entry decisions in the generic pharmaceutical industry. *The RAND Journal of Economics*, 30(3):pp. 421–440, 1999. ISSN 07416261. URL `http://www.jstor.org/stable/2556056`.

L.E. Panattoni. The effect of paragraph iv decisions and generic entry before patent expiration on brand pharmaceutical firms. *Journal of health economics*, 30(1):126–145, 2011.

H. Soehnge. Drug price competition and patent term restoration act of 1984: Fine-tuning the balance between the interests of pioneer and generic drug manufacturers, the. *Food & Drug LJ*, 58:51, 2003.

J.J. Wheaton. Generic competition and pharmaceutical innovation: The drug price competition and patent term restoration act of 1984. *Cath. UL Rev.*, 35:433, 1985.

Appendix

A1 Parent and Subsidiary Relationships

- Novartis: Ciba, Sandoz, Alcon, Chiron
- Sandoz: Ebewe
- Johnson & Johnson: Ortho-McNeil-Janssen
- Merck: Schering-Plough
- Pfizer: Wyeth, King
- Valeant: Biovail
- Dainippon Sumitomo: Sunovion
- Jazz: Azur
- Teva: Zenith, Ivax, Pliva, Sicor, Gate, Barr
- Barr: Duramed
- Reckitt Benckiser: Adams
- Fougera: Nycomed
- GlaxoSmithKline: Stiefel
- Stiefel: Connetics
- Watson: Andrx, Cobalt, Breath
- UCB: Schwarz
- Fresenius: APP
- Mylan: Dey, Matrix, Alphapharm, Bioniche
- Bayer: Intendis

- Takeda: Millenium
- Astellas: OSI
- Celgene: Abraxis
- Cephalon: Anesta, Lafon, CIMA
- Sun: Taro, Caraco
- Boehringer Ingelheim: Roxane, Ben Venue
- Orchid: Orgenus
- Hospira: Mayne
- Zydus Cadila: Zydus, Cadila
- UCB: Kudco, Kremers
- Mutual: United Research Labs
- Par: Kali, Anchen, Edict
- Daiichi Sankyo: Ranbaxy
- Pentech: Cobrek
- Enem Nostrum: Enem, Nostrum
- Actavis: Abrika
- DFB: DTP

A2 Regression Models

LPM1: Settlement = $\beta_0 + \beta_1$DJ + β_2Forbes 2000 + β_3Top 200 Drugs + β_4Num Patents + β_5Num Patents^2 + β_6Mo to Patent Exp + β_7Mo to Term + β_8Democrat Nom Judge + β_9Other Cases

LPM2: Settlement = β_0+β_1DJ + β_2Forbes 2000 + β_3Top 200 Drug Sales + β_4Num Non-AI Patents + β_5Num Non-AI Patents^2 + β_6Mo to Patent Exp + β_7Mo to Term + β_8Democrat Nom Judge + β_9Other Cases

LPM3: Settlement = β_0 + β_1DJ + β_2Pioneer Sales + β_3Top 200 Drug Sales + β_4Num Non-AI Patents + β_5Num Non-AI Patents^2 + β_6Mo to Patent Exp + β_7Mo to Term + β_8Other Cases

LPM with Pioneer FE: Settlement = β_0 + β_1DJ + β_2Top 200 Drugs + β_3Num Patents + β_4Num Patents^2 + β_5Mo to Patent Exp + β_6Mo to Term + β_7Democrat Nom Judge + β_8Other Cases + Pioneer FE

LPM with Year FE: Settlement = β_0 + β_1DJ + β_2Forbes 2000 + β_3Top 200 Drugs + β_4Num Patents + β_5Num Patents^2 + β_6Mo to Patent Exp + β_7Mo to Term + β_8Democrat Nom Judge + β_9Other Cases + Year FE

LPM with Drug FE: Settlement = β_0 + β_1DJ + β_2Forbes 2000 + β_3Num Patents + β_4Num Patents^2 + β_5Mo to Patent Exp + β_6Mo to Term + β_7Democrat Nom Judge + β_8Other Cases + Drug FE

LPM4: Pioneer Win = β_0 + β_1DJ + β_2Forbes 2000 + β_3Top 200 Drugs + β_4Num Patents + β_5Mo to Patent Exp + β_6Mo to Term + β_7Democrat Nom Judge

LPM5: Pioneer Win = β_0 + β_1DJ + β_2Forbes 2000 + β_3Top 200 Drug Sales + β_4Num Patents + β_5Mo to Term + β_6Democrat Nom Judge + β_7Other Cases

LPM6: Pioneer Win = β_0 + β_1DJ + β_2Pioneer Sales + β_3Pioneer Market Value + β_4Top 200 Drug + β_5Num Patents + β_6Mo to Patent Exp + β_7Mo to Term + β_8Other Cases

LPM with Pioneer FE: Pioneer Win = β_0 + β_1DJ + β_2Top 200 Drugs + β_3Num Patents

+ β_4Mo to Patent Exp + β_5Mo to Term + β_6Democrat Nom Judge + β_7Other Cases + Pioneer FE

LPM with Year FE: Pioneer Win = β_0 + β_1DJ + β_2Forbes 2000 + β_3Top 200 Drugs + β_4Num Patents + β_5Mo to Patent Exp + β_6Mo to Term + β_7Democrat Nom Judge + β_8Other Cases + Year FE

LPM with Drug FE: Pioneer Win = β_0 + β_1DJ + β_2Forbes 2000 + β_3Num Patents + β_4Mo to Patent Exp + β_5Mo to Term + β_6Democrat Nom Judge + β_7Other Cases + Drug FE

Pioneer Win without CJ: Pioneer Win = β_0 + β_1DJ + β_2Forbes 2000 + β_3Top 200 Drugs + β_4Num AI Patents + β_5Num AI Patents^2 + β_6Mo to Patent Exp + β_7Democrat Nom Judge + β_8Other Cases

TABLE 12—LINEAR PROBABILITY ESTIMATES FOR SETTLEMENT

	(1) LPM1	(2) LPM2	(3) LPM3
(Intercept)	0.742***	0.645***	0.690***
	(0.083)	(0.093)	0.078)
DJ (0,1)	-0.179**	-0.101	-0.125
	(0.088)	(0.12)	(0.10)
Forbes 2000 (0,1)	0.128***	0.162**	
	(0.046)	(0.066)	
Pioneer Sales ($ bil)			0.00332**
			(0.0014)
Top 200 Drug (0,1)	0.0339		0.0423
	(0.040)		(0.045)
Top 200 Drug Sales ($ bil)		-0.0833***	
		(0.022)	
Number of Patents	-0.115***		
	(0.041)		
Number of Patents^2	0.0151***		
	(0.0052)		
Number of Non-AI Patents		-0.0679*	-0.125***
		(0.039)	(0.033)
Number of Non-AI Patents^2		0.00980	0.0176***
		(0.0061)	(0.0050)
Months to Patent Expiration	0.0493***	0.0420**	0.0765***
	(0.013)	(0.019)	(0.016)
Months to Termination	-0.00891***	-0.00820***	-0.00862***
	(0.0016)	(0.0020)	(0.0017)
Democrat Nominated Judge (0,1)	0.0352	0.0941*	
	(0.040)	(0.051)	
Other Cases	0.00501*	0.00364	-0.00900***
	(0.0029)	(0.0036)	(0.0030)
Observations	533	318	409

Note: * Significant at 10% level ** Significant at 5% level *** Significant at 1% level
Table 12 shows the regression results for modeling settlement on various independent variables. Each of these regressions was run using ordinary least squares to predict a linear probability model.

Table 13—LPM1 and Probit Model Estimates for Settlement

	(1) LPM	(2) Probit	(3) Probit MFX
(Intercept)	0.742***	0.697***	
	(0.083)	(0.26)	
DJ (0,1)	-0.179**	-0.552**	-0.171**
	(0.088)	(0.27)	(0.098)
Forbes 2000 (0,1)	0.128***	0.405***	0.125**
	(0.046)	(0.14)	(0.057)
Top 200 Drug (0,1)	0.0339	0.107	0.0333
	(0.040)	(0.13)	(0.042)
Number of Patents	-0.115***	-0.377***	-0.117**
	(0.041)	(0.14)	(0.053)
Number of Patents^2	0.0151***	0.0492***	0.0152**
	(0.0052)	(0.019)	(0.0070)
Months to Patent Expiration	0.0493***	0.159***	0.495***
	(0.013)	(0.043)	(0.018)
Months to Termination	-0.00891***	-0.0268***	-0.00831***
	(0.0016)	(0.0050)	(0.0026)
Democrat Nominated Judge (0,1)	0.0352	0.133	0.0412
	(0.040)	(0.13)	(0.041)
Other Cases	0.00501*	0.0154*	0.00477*
	(0.0029)	(0.0091)	(0.0033)
Observations	533	533	533

Note: * Significant at 10% level ** Significant at 5% level *** Significant at 1% level
Table 13 compares the results of LPM1 model with a probit model using the same independent variables. We observe that the signs and the significance levels are the same.

TABLE 14—LINEAR PROBABILITY ESTIMATES WITH INDIVIDUAL FIXED EFFECTS FOR SETTLEMENT

	(1) Pioneer FE	(2) Year FE	(3) Drug FE
(Intercept)	1.10***	0.934***	1.24***
	(0.11)	(0.23)	0.44)
DJ (0,1)	-0.143*	-0.178**	-0.224**
	(0.083)	(0.089)	(0.087)
Forbes 2000 (0,1)		0.128***	0.157
		(0.046)	(0.17)
Top 200 Drug (0,1)	-0.00695	0.0426	
	(0.042)	(0.041)	
Number of Patents	-0.0787*	-0.123***	-0.122**
	(0.043)	(0.041)	(0.058)
Number of Patents^2	0.00942*	0.0156***	0.00855
	(0.0056)	(0.0053)	(0.0076)
Months to Patent Expiration	0.0592***	0.0511***	0.0541*
	(0.014)	(0.013)	(0.028)
Months to Termination	-0.00869***	-0.00967***	-0.00622***
	(0.0015)	(0.0017)	(0.0016)
Democrat Nominated Judge (0,1)	0.00101	0.0347	-0.0133
	(0.039)	(0.040)	(0.046)
Other Cases	-0.00731**	-0.00452	-0.0901**
	(0.0032)	(0.0029)	(0.042)
Observations	530	530	530

Note: * Significant at 10% level ** Significant at 5% level *** Significant at 1% level
Table 14 shows the regression results for linear probability models with pioneer firm fixed effects, terminated year fixed effects, and drug product fixed effects. Some of the independent variables remain significant after fixing each of these factors in turn.

TABLE 15—LINEAR PROBABILITY ESTIMATES FOR PIONEER WINS

	(1) LPM4	(2) LPM5	(3) LPM6
(Intercept)	0.787***	0.834***	0.407**
	(0.12)	(0.14)	(0.19)
DJ (0,1)	-0.394***	-0.361*	-0.315
	(0.15)	(0.21)	(0.20)
Forbes 2000 (0,1)	-0.176**	-0.257**	
	(0.080)	(0.11)	
Pioneer Sales ($ bil)			-0.0153*
			(0.0081)
Pioneer Market Value ($ bil)			0.00550**
			(0.0025)
Top 200 Drug (0,1)	-0.0820		-0.203**
	(0.072)		(0.094)
Top 200 Drug Sales ($ bil)		-0.0917**	
		(0.039)	
Number of Patents	0.0345	0.0120	0.0363
	(0.028)	(0.032)	(0.033)
Months to Patent Expiration	-0.0192		0.00812
	(0.026)		(0.041)
Months to Termination	0.00562*	0.00679*	0.0102***
	(0.0029)	(0.0038)	(0.0037)
Democrat Nominated Judge	-0.0754	-0.100	
	(0.078)	(0.11)	
Other Cases		-0.0197***	0.00659
		(0.0072)	(0.0066)
Observations	162	88	112

Note: * Significant at 10% level ** Significant at 5% level *** Significant at 1% level
Table 15 shows the regression results for modeling a dummy for pioneer wins on various independent variables. Each of these regressions was run using ordinary least squares to predict a linear probability model.

Table 16—LPM4 and Probit Estimates for Pioneer Wins

	(1) LPM4	(2) Probit	(3) Probit MFX
(Intercept)	0.787***	0.863**	
	(0.12)	(0.39)	
DJ (0,1)	-0.394***	-1.10**	-0.350**
	(0.15)	(0.45)	(0.16)
Forbes 2000 (0,1)	-0.176**	-0.560**	-0.178**
	(0.080)	(0.26)	(0.092)
Top 200 Drug (0,1)	-0.0820	-0.251	-0.0797
	(0.072)	(0.22)	(0.075)
Number of Patents	0.0345	0.103	0.0327
	(0.028)	(0.089)	(0.030)
Months to Patent Expiration	-0.0192	-0.0636	-0.0202
	(0.026)	(0.081)	(0.026)
Months to Termination	0.00562*	0.0171*	0.00543**
	(0.0029)	(0.0090)	(0.0031)
Democrat Nominated Judge	-0.0754	-0.251	-0.0799
	(0.078)	(0.24)	(0.080)
Observations	162	162	162

Note: * Significant at 10% level ** Significant at 5% level *** Significant at 1% level
Table 16 compares the results of LPM4 model with a probit model using the same independent variables. We observe that the signs and the significance levels are the same.

TABLE 17—LINEAR PROBABILITY ESTIMATES WITH INDIVIDUAL FIXED EFFECTS FOR PIONEER WIN

	(1) Pioneer FE	(2) Year FE	(3) Drug FE
(Intercept)	-0.151	1.111***	-0.505
	(0.37)	(0.23)	0.34)
DJ (0,1)	-0.286**	-0.364**	-0.257***
	(0.14)	(0.14)	(0.096)
Forbes 2000 (0,1)		-0.165***	0.834***
		(0.083)	(0.22)
Top 200 Drug (0,1)	-0.0510	-0.100	
	(0.085)	(0.041)	
Number of Patents	0.0524**	0.0188	0.127***
	(0.026)	(0.028)	(0.033)
Months to Patent Expiration	-0.0601**	-0.0257	-0.130***
	(0.028)	(0.026)	(0.046)
Months to Termination	0.00717***	0.00649**	0.00584***
	(0.0026)	(0.00314)	(0.0019)
Democrat Nominated Judge (0,1)	0.0119	-0.102	-0.0628
	(0.071)	(0.077)	(0.057)
Other Cases	0.00829	-0.00166	0.0830***
	(0.0055)	(0.0053)	(0.030)
Observations	162	162	162

Note: * Significant at 10% level ** Significant at 5% level *** Significant at 1% level
Table 17 shows the regression results for linear probability models with pioneer firm fixed effects, terminated year fixed effects, and drug product fixed effects. Some of the independent variables remain significant after fixing each of these factors in turn.

Table 18—LPM4 and Models that Exclude Consent Judgments

	(1) Pioneer Win (LPM4)	(2) Pioneer Win (without CJ)	(3) Pioneer Win (without CJ)
(Intercept)	0.787***	-0.0885	0.170
	(0.12)	(0.26)	(0.23)
DJ (0,1)	-0.394***	-0.358*	-0.577***
	(0.15)	(0.21)	(0.19)
Forbes 2000 (0,1)	-0.176**	-0.0798**	-0.0593
	(0.080)	(0.16)	(0.15)
Top 200 Drug (0,1)	-0.0820	0.0923	0.0766
	(0.072)	(0.12)	(0.11)
Number of Patents	0.0345	0.0413	
	(0.028)	(0.037)	
Number of AI Patents			0.369***
			(0.106)
number of AI Patents^2			-0.0606***
			(0.019)
Months to Patent Expiration	-0.0192	-0.000495	0.00206
	(0.026)	(0.0015)	(0.0014)
Months to Termination	0.00562*	0.0138***	
	(0.0029)	(0.0044)	
Democrat Nominated Judge	-0.0754	0.199	0.181
	(0.078)	(0.12)	(0.11)
Other Cases			-0.0139**
			(0.0068)
Observations	162	69	69

Note: * Significant at 10% level ** Significant at 5% level *** Significant at 1% level

Table 18 compares the results of the LPM4 model with models that exclude consent judgments as merits outcomes. The results are slightly different, which suggest that consent judgments for the generic or pioneer are fairly different from other outcomes for a particular party.