



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

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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.

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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.

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.

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.

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.

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.

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.

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	Clarinet	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.

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.

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.

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%

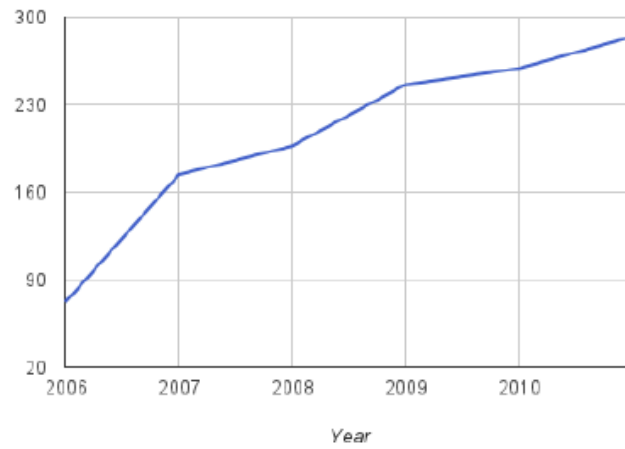
Note: Table 10 compares outcomes for pioneer drug companies and generic drug companies. Pioneer litigants win over twice as often as generic litigants if we include consent judgments.

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%

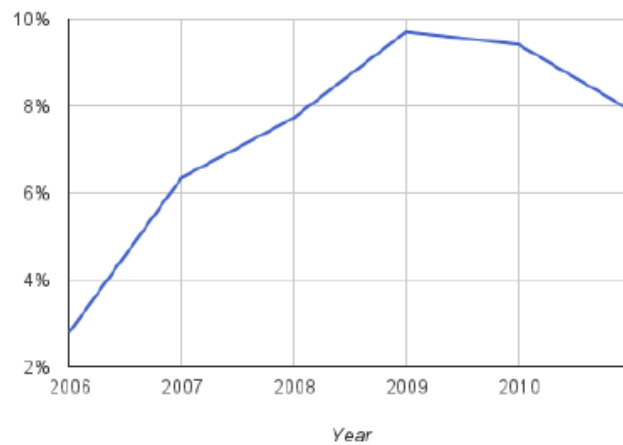
Note: Table 11 compares outcomes for pioneer drug companies and generic drug companies, excluding consent judgments. After removing consent judgments, generics appear to win significantly more than pioneers.

FIGURE 1. ANDA CASES FILED OVER TIME, RAW COUNTS



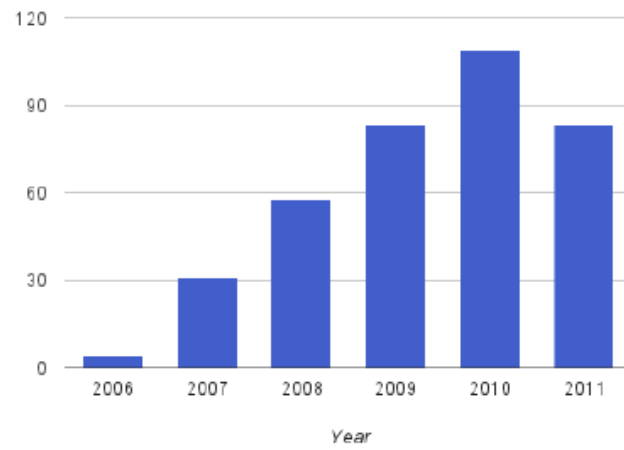
Note: Figure 1 shows the raw count for ANDA cases filed from 2006 through 2011. The 2011 total number is estimated based on the total patent cases filed in 2011 multiplied by the 2011 proportion of ANDA cases in from January to August.

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.

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.