Lex Machina Report on ANDA Litigation

Methodology:

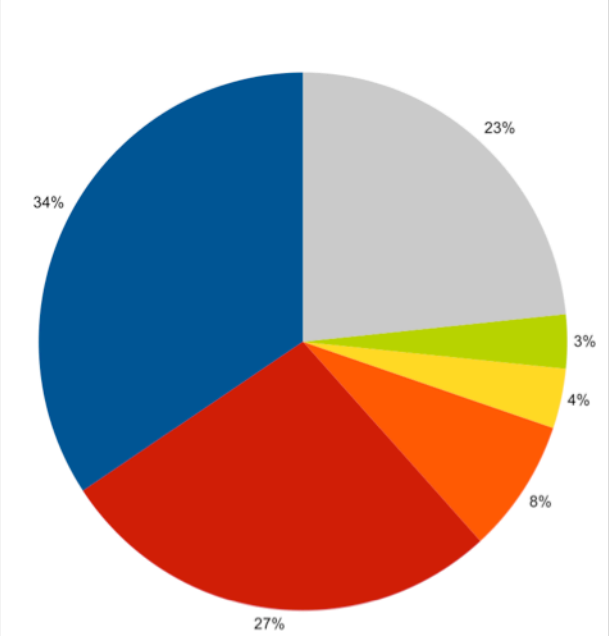
Our first task is to identify all of the relevant ANDA cases in the dataset. To do this, we begin by retrieving the entire world of ANDA cases within my time frame. Instead of trying to do an exhaustive search through all cases filed, we use Lex Machina's robust patents cited data and match it with the FDA's own patent data. The FDA's Electronic Orange Book database includes files with a list of all patents cited across all filed NDAs, updated frequently[1]. We posit that this will cover the entire world of patents that can be cited across all ANDA cases. We confirm that this method of recovering ANDA cases is proper by comparing the set of cases retrieved in this manner against both a set of already tagged ANDA cases and a set of cases retrieved through broad queries through the Lex Machina database. After extensive quality control and data pruning, we find that there are 1421 unique ANDA patent cases within our dataset.

Results:

From just looking at the data generally, we can already see interesting trends and confirm some widespread anecdotes about pharmaceuticals patent litigation. For example, the District of New Jersey is home to some of the biggest pharmaceutical drug companies in the world, including Johnson and Johnson, Sanofi-Aventis, Pfizer, Schering-Plough, and Novartis. So, it should not be a surprise that the District of New Jersey federal court ranks at the top of the list for popular ANDA litigation venues. Similarly, Delaware is both known for being a popular place for corporations to incorporate and also houses large players in the chemical and pharmaceutical industries, such as AstraZeneca. As such, the District of Delaware court also processes a large number of ANDA cases. These two districts, New Jersey and Delaware, combined account for 61% of the total ANDA cases filed. Other significant venues include Southern New York, Eastern Pennsylvania, and Southern Indiana.

[1] Data at: http://www.fda.gov/Drugs/InformationOnDrugs/ucm129689.htm

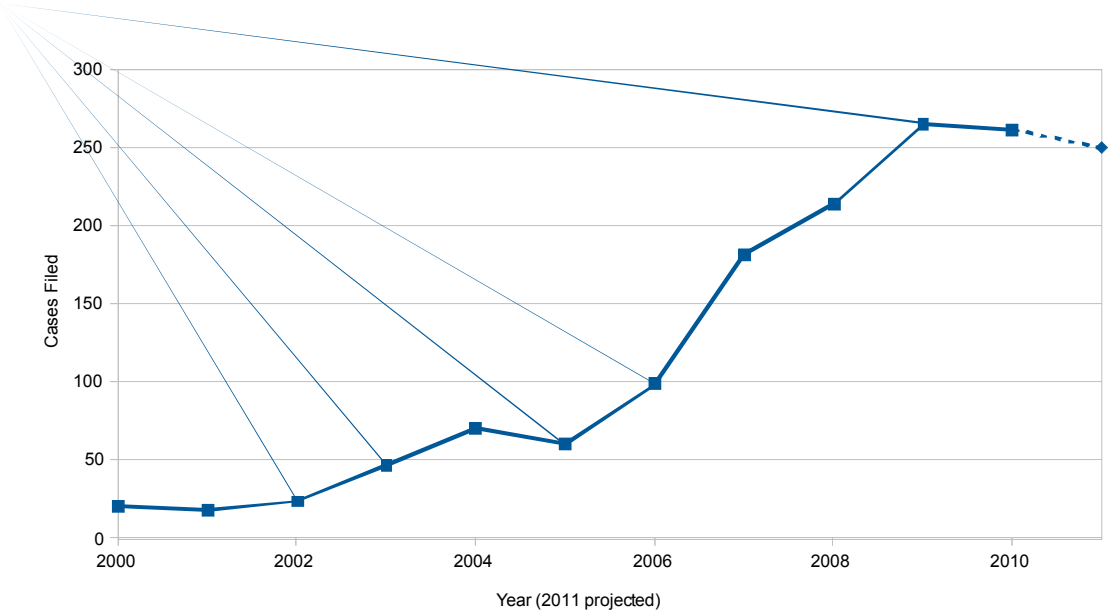
Figure 1: Top five venues for ANDA litigation



District	Cases Filed
New Jersey	488
Delaware	389
Southern New York	115
Eastern Pennsylvania	51
Southern Indiana	46
All Others	332

Significantly, we can also confirm the colloquially cited evidence of a sharp rise in ANDA cases filed in recent years. This simultaneously confirms the FTC's own findings of such an increase.

Figure 2: ANDA Cases Filed by Year

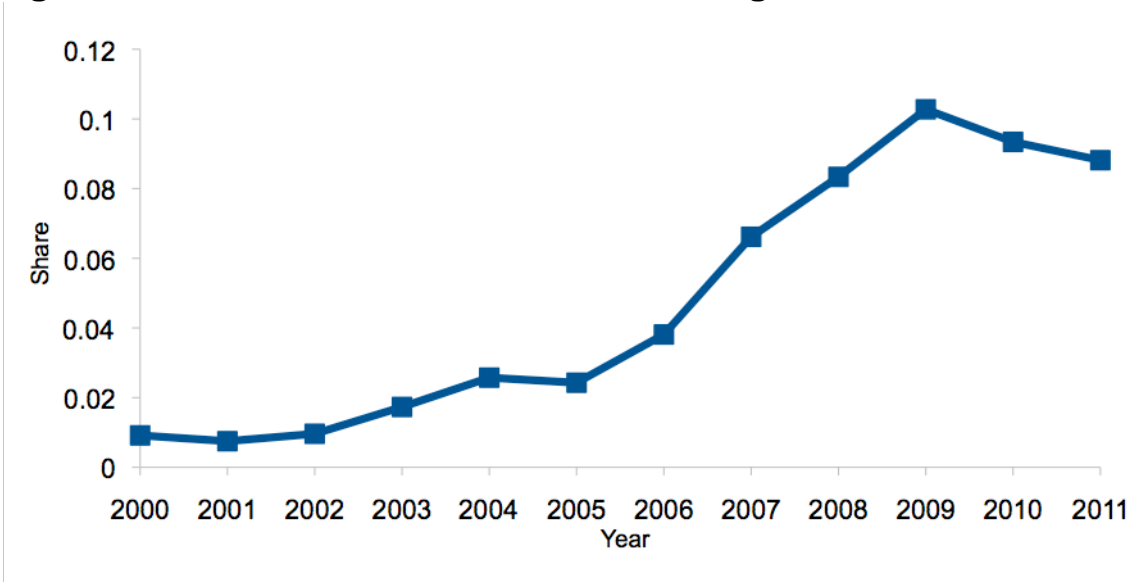


and may be influenced by a number of factors. One such important biasing affect is that there is missing data in the earlier years of the dataset. Specifically, the Lex

Machina data we use is somewhat dependant on court electronic filing records. Because not all of the courts were on electronic filing for the first couple years of the data, the actual counts of cases may be lower than the actual number of cases litigated at the time. That said, we consider any data after 2004 and especially after 2006 to be highly accurate, as electronic filing saw almost universal adoption.

Another potentially biasing factor is that the trend of patent litigation has also gone up sharply in the recent years. This increase in all of patent litigation could explain the rise in ANDA cases, as well. To address these issues, we also measure the share of patent litigation that is comprised of ANDA cases. We simply look at what percentage of all patent litigation is ANDA litigation. If the trend disappears, we can hypothesize that ANDA litigation remained steady and only grew as patent litigation grew. Instead, we see that the upward trend is most certainly still present. This also will partially account for the bias of missing data. If we assume that the distribution of cases in the set of data that is missing is the same as in the set that is visible, we can assume that the share of total patent cases belonging to ANDA cases will be the same. Thus, the data seems to support the conjecture that ANDA cases are a massively growing area of patent litigation.

Figure 3: ANDA Cases as a Share of Total Patent Litigation



Finally, we can put together a chart showing the five most litigated patents across the entire ANDA litigation dataset. We can see that the original NDA applicants are all brand-name pharmaceuticals giants. However, the nature or purpose of the drugs varies extensively. We can see, though, that the drug categories match with some of the most lucrative markets including analgesics, narcolepsy medications, cancer treatments, and others. Also, not that, interestingly, there is no repeat brand-name applicant in the top five list. This shows that the field of pharmaceutical drugs is a wide industry incorporating many possible types of drugs and many potential parties.

Figure 4: Top five litigation patents in ANDA cases

Patent Number	Asserted Cases	Expiration Date	NDA Number	Applicant	Drug	Purpose
5508042	34	04/16/13	22272	Purdue	Oxycotin	Analgesic
RE37516	30	10/06/14	21875	Cephalon	Nuvigil	Excessive Sleepiness
			20717		Provigil	
6054482	28	04/25/17	20882	Pfizer	Neurontin	Anticonvulsant
5338874	22	04/07/13	21759	Sanofi Aventis	Eloxatin	Cancer
6166043	20	06/19/16	21073	Takeda	Actos	Diabetes
			21842		Actoplus Met	
			22024		Actoplus Met XR	

We discerned all of the preceding observations just from looking at the data broadly. We can learn much more about the nature of ANDA litigation by collecting more specific data from each case. So, next, we drill down into the cases and collect additional data on the drug products in each lawsuit, the specific outcomes, and the confirmed settlements. Attempting to do this analysis for every ANDA case in our dataset would be a very time-intensive and labor-intensive project. Thus, for the purposes of this report, we take a simple random sample of 70 patents from the set of all unique cited patents in our data. With this smaller set of cases, we can investigate further and assume that many of the results can generalize to the whole set.

One of the most interesting pieces of information we can extract from this analysis relates to outcomes. By tagging specific outcomes in this set of cases, we can see an overview of how ANDA cases are ultimately terminated. First, we noticed that outcomes in ANDA cases can be fairly complicated, potentially involving multiple consolidated cases, Multi-District Litigation cases, and transfers. Thus, we defined general buckets for outcomes and used a consistent method to pipe outcomes into these buckets.

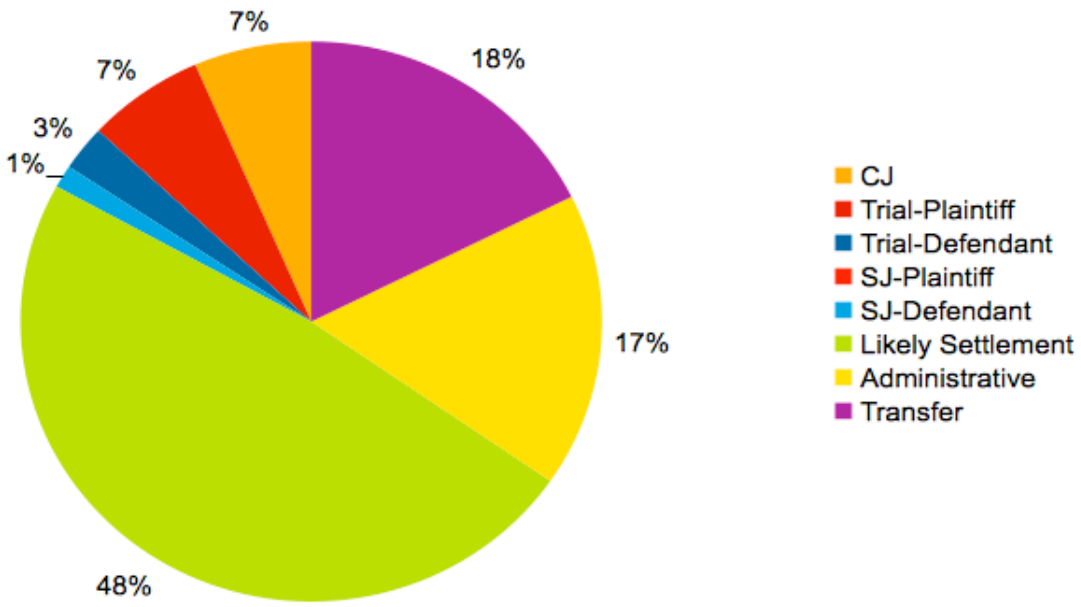
Consolidations and transfers, in particular, are difficult to code consistently. For consolidations, we code the outcomes of each consolidated case as the final outcome in the main case as to the particular defendants in the original case. We justify this by assuming that a consolidation simply groups cases together and does not necessarily end the original case. This is confirmed by the fact that often times in cases that are consolidated out, the final outcome is docketed in the original case as well as the consolidated case. We treat transfers out as a final outcome, however. 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 stationary facts all stay the same. If we did not code transfers as final outcomes, we would be duplicating a case outcome whenever it was transferred.

The outcomes and descriptions are as follows:

- **Consent Judgment:** We code any case that goes to final judgment on the stipulation or consent of the parties in suit as consent judgments. These are coded as either favoring the plaintiff or the defendant.
- **Trial-Plaintiff/Trial-Defendant**: We code any case where the pioneer patent holder wins the case on trial as Trial-Plaintiff, regardless of whether the patent holder was actually the plaintiff in the case. The same general principle is true for Trial-Defendant tags. We also include information on whether the trial is a bench or jury trial.
- **SJ-Plaintiff/SJ-Defendant**: We code any case where the pioneer patent holder wins the case on summary judgment as SJ-Plaintiff, regardless of whether the patent holder was actually the plaintiff in the case. The same general principle is true for SJ-Defendant tags.
- **Likely Settlement**: We 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. We specifically code confirmed settlements within this bucket.
- **Transfer**: We code any case that is transferred out and not consolidated out as Transfer.
- **Administrative**: We code any case that is consolidated out, stayed indefinitely, or terminated in any other way that is not on the merits and is not listed above as Administrative.
- **On-going**: We code any case that has not reached some outcome as on-going. We 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, we code this as a merits outcome and not as On-going or Administrative.

From the sample, we can get a good idea of the distribution of outcomes in ANDA cases. First, we know that because out data set features cases from recent years, there are many cases in our set that have not yet reached an outcome. Specifically, we discovered that 30% of the cases in the sample are correctly categorized as On-going and have never reached an outcome. This leaves 153 terminated cases in the sample that did reach an outcome. The distribution of these terminated cases is shown below.

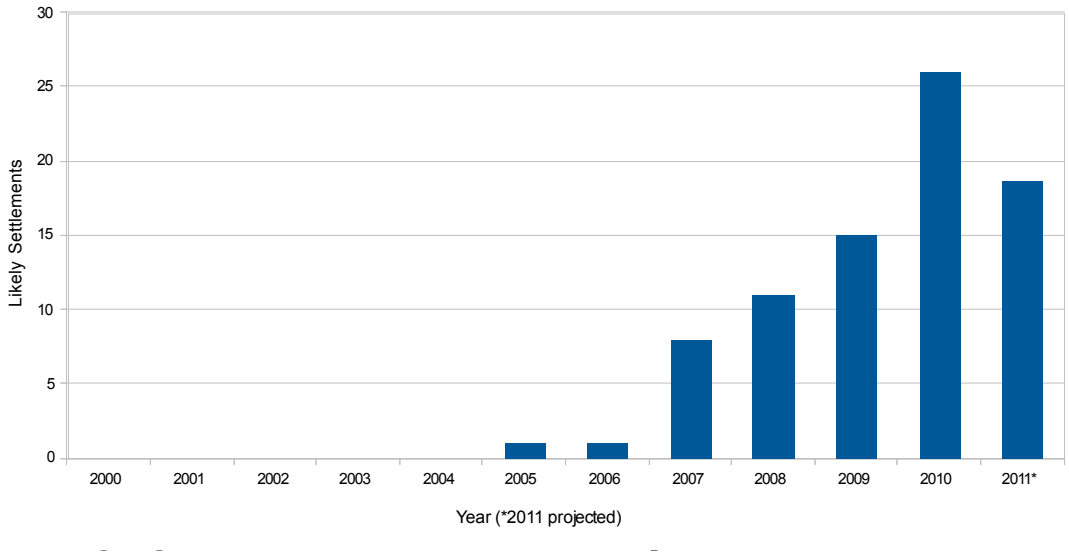
Figure 5: Sample distribution of outcomes in terminated ANDA cases



Right away, we can see that the most common outcome from the sample is Likely Settlement. This is not a surprise, as we know that patent cases are often settled before the court reaches a judgment. This data confirms widespread anecdotal evidence that settlements are the most likely outcomes in ANDA cases and also explains why the Federal Trade Commission has taken a particular interest in these types of settlements in recent years.

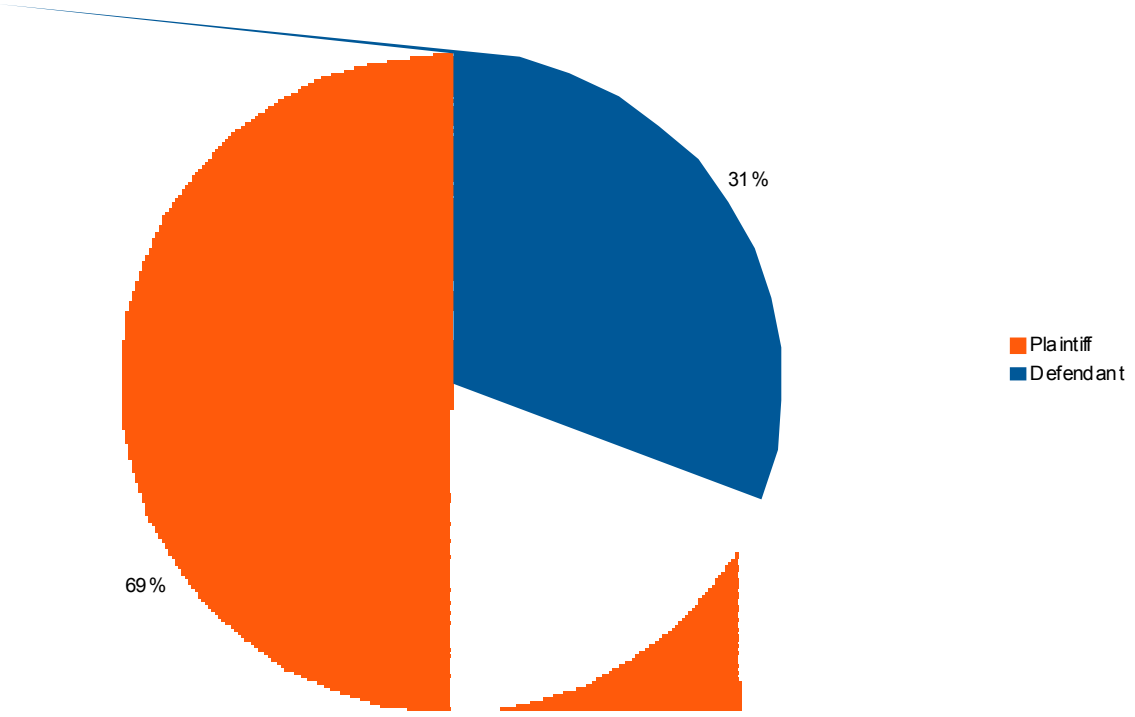
Looking more closely at settlements, we can confirm that the number of settlements have actually risen steadily over the years. This mirrors the FTC's own data showing evidence of the growth of reverse payments in ANDA cases over the years. Figure 6 shows this sharp increase in ANDA settlements after 2005. Again, our data may suffer from some downward bias in earlier years. Because courts were not on electronic filing, we may be missing some key data between 2000 and 2004. Additionally, because we only look at cases filed after 1 January 2000, conceivably, we may be missing settlements in earlier years if those cases were filed before the scope of our data begins. For example, if a case was filed in 1998 but finally settled in 2002, we likely will not see this case in the data. Nonetheless, the trend is quite large and would be unlikely to disappear even with the potentially missing data.

Figure 6: Settlements in ANDA cases by year



according to the random sample data.

Figure 7: Plaintiff win rate in ANDA cases



To determine the number of plaintiff wins, we added all of the plaintiff victories on trial and judgment, summary judgment, and consent judgment. We did the same summing for defendant wins as well. Again, we assume through this report that plaintiff actually refers to the patent holder. Thus, for example, a declaratory

judgment case where the generic plaintiff wins and a patent is found to be invalid will be coded as a defendant win.

It may seem odd to add in consent judgments into the calculation, but upon deeper analysis of the consent judgments, we find that they always have a polarity in our sample data. That means that despite the fact that they are stipulated agreements, there is always a clear winner. For example, some consent judgments included stipulations that the patents in suit were valid and that the generic company would not enter the market until after the patents expired. These were coded as plaintiff wins. In the sample data, there were ten consent judgments, two going for the defendant and eight going for the plaintiff.

We can see from Figure 7 that when a case comes to some resolution on the merits or by consent judgment, the plaintiff wins more often than the defendant. According to our sample, they exclusively win on trial or consent judgment, with trials making up the slightly larger share. This makes sense, as plaintiff victories on summary judgment are very rare. Defendant wins on summary judgment are more common, accounting for only 25% of total wins. Consent judgments also make up 25% of the total wins for defendants. The bulk of defendant victories occur from trial judgments. All of the trial outcomes, for both plaintiffs and defendants, came from bench trials instead of jury trials.