

Lex Machina *Hatch-Waxman / ANDA* *Litigation Report 2017*



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a LexisNexis® Company

by Brian C. Howard J.D./M.A
Associate General Counsel & Legal Data Scientist

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Executive Summary

Lex Machina's third Hatch-Waxman / ANDA Litigation Report demonstrates the power of Legal Analytics by revealing trends and insights into pharmaceutical patent litigation. With large amounts of money riding on litigation decisions, knowing the data landscape is essential to assessing risk and making informed cost/benefit decisions.

This report covers the 2,646 cases filed in U.S. district courts filed between January 1, 2009, and March 31, 2017, related to new drug applications before the U.S. Food and Drug Administration (FDA) pursuant to the Hatch-Waxman Act. These cases involve the assertion of 1,879 unique patents and about 600 applications. Of these cases, fewer than 3% were based on paper new drug applications under 505(b)(2) (often called "paper NDAs"); the vast majority were based on Abbreviated New Drug Applications (ANDAs).

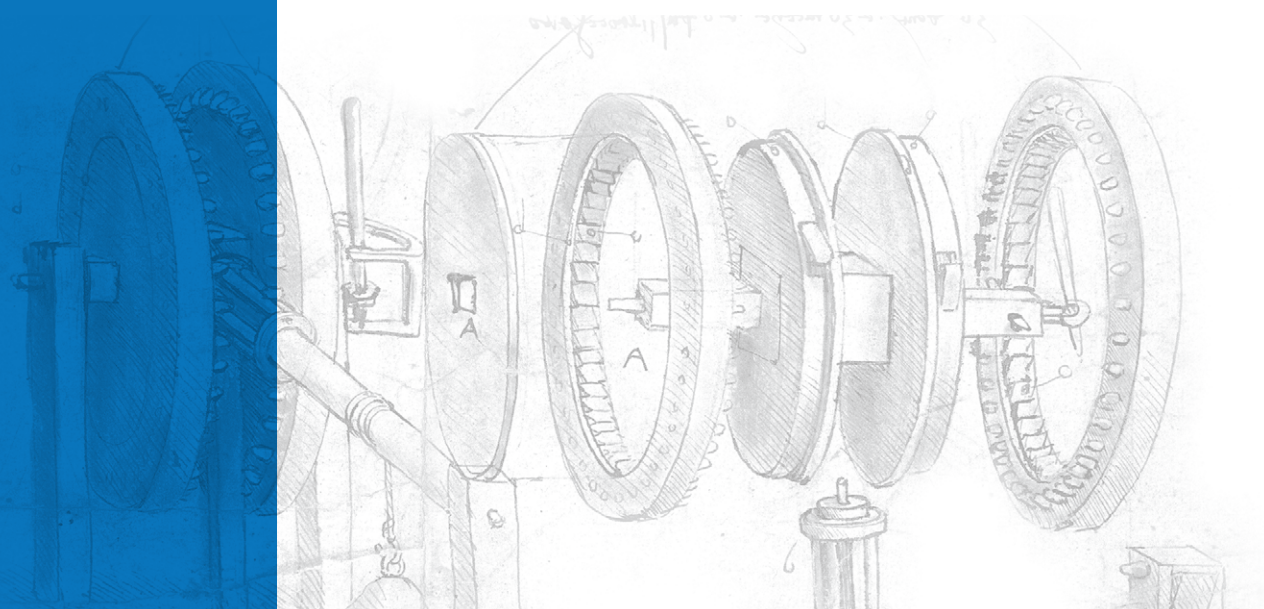
Drawing on a combination of litigation data from Lex Machina's platform and data published by the FDA on ANDA applications and related patents in the Orange Book, this report analyzes various aspects of ANDA litigation to provide data-driven insights. Together with traditional research and intuition gained from experience, these insights can provide practitioners, whether in-house or at a law firm, an edge over the competition.

From knowing where to file a case, to understanding exposure to damage awards, Legal Analytics helps practitioners make more informed decisions, leading to better litigation strategy. For example, the timing charts below provide a framework for estimating budgets based on how long previous cases have taken. Using our groundbreaking platform, it's easy to narrow down the dataset to analyze only the most relevant cases (in a particular jurisdiction, for example, or involving a certain party).

This report surveys the landscape of patent litigation related to Abbreviated New Drug Applications (ANDAs) submitted to the FDA under the Hatch-Waxman Act.

The ANDA process expedites the FDA approval process for generic drugs, and allows drug companies to litigate any patent claims implicated by a new drug, often before the drug even gains FDA approval or reaches the market.

Integrating patent and drug information from the FDA's Orange Book with Lex Machina's intellectual property litigation database, this report provides insight into current trends in ANDA litigation and shows the ways in which ANDA litigation differs significantly from other, non-ANDA patent litigation.



Key findings from this report include:**Filing Trends:**

- In 2016, 316 ANDA cases were filed - the first decline in 3 years.
- Litigation in 2016 remained higher than the average in 2009-2013 of about 269 cases per year.

Top Districts

- Since 2009, the District of Delaware (1,114 cases) and the District of New Jersey (850 cases) have more cases than all the other districts combined.
- The Southern District of New York, third by number of cases filed since 2009 (159 cases total), has seen a dramatic decline from a peak of 41 cases in 2011 to only a single case filed in the last five quarters.

Top Parties and Firms

- Since 2009, Actavis (including Allergan and Watson Laboratories) has participated in the most ANDA cases (427 cases), followed by Mylan (290 cases), and then by Teva Pharmaceutical Industries (232 cases).
- Among the top parties since 2009, Astrazeneca (156 cases), Pfizer (143 cases), and Novartis (144 cases) have the largest number of cases as claimant (i.e., where the party is asserting the patent, regardless of whether plaintiff or declaratory judgment defendant). Many other top claimants are exclusively claimants including Takeda, Cephalon, Roche, Abbott Labs, Genzyme, and Wyeth.
- In more recent cases filed since 2015, the top parties remain the same: Actavis (138 cases), Mylan (85 cases) and Teva (67 cases). Actavis remains the top claimant in the more recent cases, but Sanofi-Aventis is second (56 cases) and Horizon (41 cases) third.
- McCarter English is the leading plaintiff-side firm with 391 cases since 2009 and 150 since 2015. Other top plaintiff firms include Finnegan, Henderson, Farabow Garrett & Dunner (363 cases since 2009, 125 since 2015), and Fitzpatrick, Cella, Harper & Scinto (310 cases since 2009, 81 since 2015). Saul Ewing appears to be catching up though, with 80 cases since 2015.
- The leading firm representing plaintiffs overall is the Delaware firm of Morris, Nichols, Arsht & Tunnell, with 251 cases in that role during 2015-2017Q1, and an astounding 707 cases in that role since 2009.
- On the defense side, Winston & Strawn leads with 187 cases since 2009, followed by Chicago boutique Rakoczy Molino Mazzochi Siwik (136 cases), Goodwin Procter (127 cases), and Knobbe Martens (108 cases). Among the more recent cases, Winston & Strawn still leads (56 cases), followed by Goodwin Procter (39 cases) and Budd Lamar (35 cases).

ANDA vs Other Patent Litigation

- ANDA litigation is only about 10% of all patent litigation.
- ANDA cases are significantly more likely to involve injunctive relief (12.4% of ANDA cases vs 4.2% of other cases).
- ANDA cases are much less likely to end as a result of settlement (56.5%) than other patent litigation (77.8%), and more likely to be won by the claimant (15.9% in ANDA cases vs 4.4% in other litigation).
- 35 U.S.C. § 103 (obviousness) is the most frequent basis for invalidity in ANDA cases, appearing in 68.8% of the ANDA cases where invalidity has been found.

Orange Book Data

- Abilify (an antipsychotic, 63 cases since 2009) has overtaken Oxycontin (a pain relief medication, 59 cases) as the most litigated tradename by number of cases. Vascepa (a cholesterol medication) leads by number of asserted patents.
- In more recent cases since 2015, Pennsaid (29 cases, 17 patents), Vimovo (25 cases, 13 patents), and Xyrem (17 cases, 17 patents) have also been heavily litigated.
- The vast majority (97.5%) of applications are for prescription drugs; over-the-counter and discontinued drugs are a tiny minority.
- Most applications do not indicate any Therapeutic Equivalence (TE) code (67.9%), but the most popular code when indicated is the “AB” code, representing “products in conventional dosage forms not presenting bioequivalence problems.”

Timing and Injunctions

- The median time to a Markman hearing was 453 days (about a year and three months) from the case filing date.
- When a permanent injunction issues, the median time to its issuance is 591 days (just over a year and a half).
- Time from case filing to summary judgment is 662 days (about 1 year and 9 months) on median while time to trial is 761 days (just over 2 years) on median.

Damages

- Only six ANDA cases filed since 2000 have resulted in damages.

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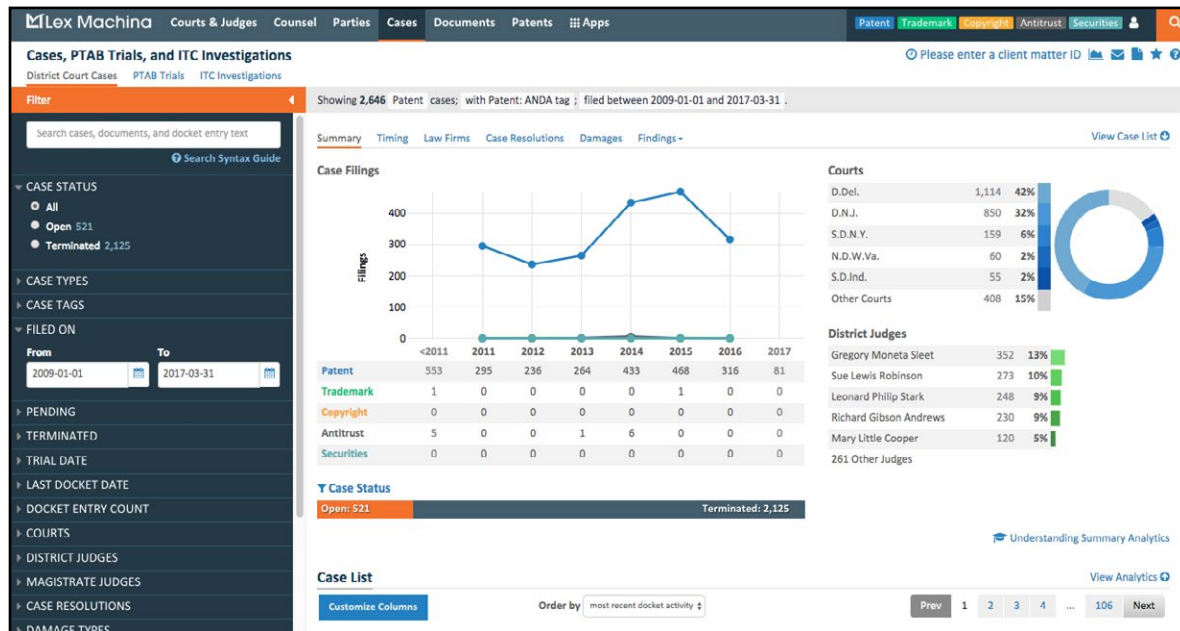
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New Feature: Viewing products and ingredients in Lex Machina



1. Start with any case list
2. Click on Customize Columns
3. Select OrangeBook Product(s) and OrangeBook Ingredient(s) at bottom

Case List

Customize Columns Order by: most recent docket activity

Title	Civil Action #	Case Type	Court	Filed On
Galderma Laboratories LP v Actavis Laboratories UT Inc et al	3:17-cv-00903	Patent	N.D.Tex.	2017-03-30
Salix Pharmaceuticals, Inc. et al v. Teva Pharmaceuticals USA, Inc.	1:17-cv-00329	Patent	D.Del.	2017-03-27
UCB, Inc. et al v. Mylan Technologies, Inc. et al	1:17-cv-00322	Patent	D.Del.	2017-03-24
ViiV Healthcare Company et al v. Lupin Limited et al	1:17-cv-00315	Patent	D.Del.	2017-03-23
BioDelivery Sciences International, Inc. et al v. Teva Pharmaceuticals USA, Inc. et al	1:17-cv-00282	Patent	D.Del.	2017-03-16

Case List

Customize Columns

Save Custom Column View

My Custom Column Views

- ★ Title/Civil Action #/Case Type/Court/Filed On/Last Docket/Terminated
- ★ ☺ Title/Civil Action #/Case Type/Court/Filed On/Last Docket/Terminated/Damages

☑ Orange Book Product(s)

☑ Orange Book Ingredient(s)

★ = Default View

Court	Filed On	Terminated	Orange Book Product(s)	Orange Book Ingredient(s)
N.D.Tex.	2017-03-30	—	EPIDUO FORTE EPIDUO	adapalene; benzoyl peroxide
D.Del.	2017-03-27	—	APRISO	mesalamine
D.Del.	2017-03-24	—	NEUPRO	rotigotine
D.Del.	2017-03-23	—	LEXIVA	fosamprenavir calcium
D.Del.	2017-03-16	—	ONSOLIS BUNAVAIL BELBUCA	buprenorphine hydrochloride fentanyl citrate buprenorphine hydrochloride; naloxone hydrochloride
D.N.J.	2017-03-15	—	ONEXTON	benzoyl peroxide; clindamycin phosphate
D.Del.	2017-03-07	—	BOSULIF	bosutinib monohydrate
D.N.J.	2017-02-03	—	ONEXTON ACANYA	benzoyl peroxide; clindamycin phosphate
D.N.J.	2017-01-19	—	ABILIFY	aripiprazole
D.Del.	2017-01-11	—	AUBAGIO	teriflunomide
D.Del.	2017-01-10	—	AUBAGIO	teriflunomide

Lex Machina's Data, Methodology, and Terminology

This report considers the last 7 years of patent litigation related to Abbreviated New Drug Applications (ANDA) and paper New Drug Applications (paper NDAs), focusing on cases filed from January 2009 through the end of March 2017, except where otherwise noted. Data derived from the Orange Book is current through March 2017.

What is an ANDA case?

The sale of new drugs in the United States is controlled by the Food and Drug Administration (FDA). Pharmaceutical companies launching new, branded drugs must file NDAs (New Drug Applications). For all approved NDAs, the FDA lists patent data in the Approved Drug Products with Therapeutic Equivalence Determinations publication (known as the Orange Book).

The FDA also approves applications for new generic drugs, and makers may file abbreviated applications, either an ANDA or paper NDA (hybrid of a full NDA and an ANDA, also known as a “Section 505(b)(2)” application). These abbreviated applications assert that the generic is a duplicate of a branded drug (ANDA) or differs from a branded drug but meets safety and efficacy standards based on published studies (paper NDA). Although ANDA and paper NDA cases differ in some important respects, this report considers them together as “ANDA cases” as paper NDAs represent less than 3% of Hatch-Waxman litigation.

The Hatch-Waxman Act put in place the expedited approval processes for generics and in doing so launched a new type of patent litigation — cases with accused infringing products that are not yet on the market or even approved by the FDA at the time the lawsuit is filed. These cases are often tried by a judge and the generic maker frequently stipulates to infringement. The remedies sought often include injunctions with specific date bounds.

A prospective generic maker's filing with the FDA may include a Paragraph IV certification, which states the patents in the branded drug NDA that are invalid or will not be infringed by the generic version. The generic applicant must give the NDA holder and the patentee a notice letter regarding their application. Then, if the patentee sues within 45-days the FDA stays the generic's application for 30 months. First-filers for an ANDA with a Paragraph IV certification may receive a 180-day exclusivity period wherein the FDA will not approve any other ANDAs; first-filers for paper NDAs with a Paragraph IV certification are entitled to exclusivity periods relating to an orphan drug, a new chemical entity, a new clinical study or a pediatric exclusivity.

Lex Machina identifies as ANDA cases those patent infringement cases prompted by the filing of an ANDA or paper NDA by a prospective generic maker. This definition, however, does not include cases involving investigational new drugs, over-the-counter drugs or any process or product not requiring FDA approval, therapeutic biologic applications (biosimilars), or generics authorized by the branded drug maker.

Lex Machina's Data

Lex Machina maintains a specialized database containing information about intellectual property litigation in U.S. District Courts, the U.S. Patent and Trademark Office's Patent Trial and Appeal Board (PTAB) and the U.S. International Trade Commission (ITC). On a daily basis, Lex Machina requests and receives data from the various district courts' PACER systems on new cases and docket entries filed. Lex Machina's automated systems ensure the completeness and consistency of this data, before analyzing it in conjunction with other data sources, such as the FDA's Orange Book data (<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm>).

Overview

Figure 1: ANDA cases filed 2009-2016, by year

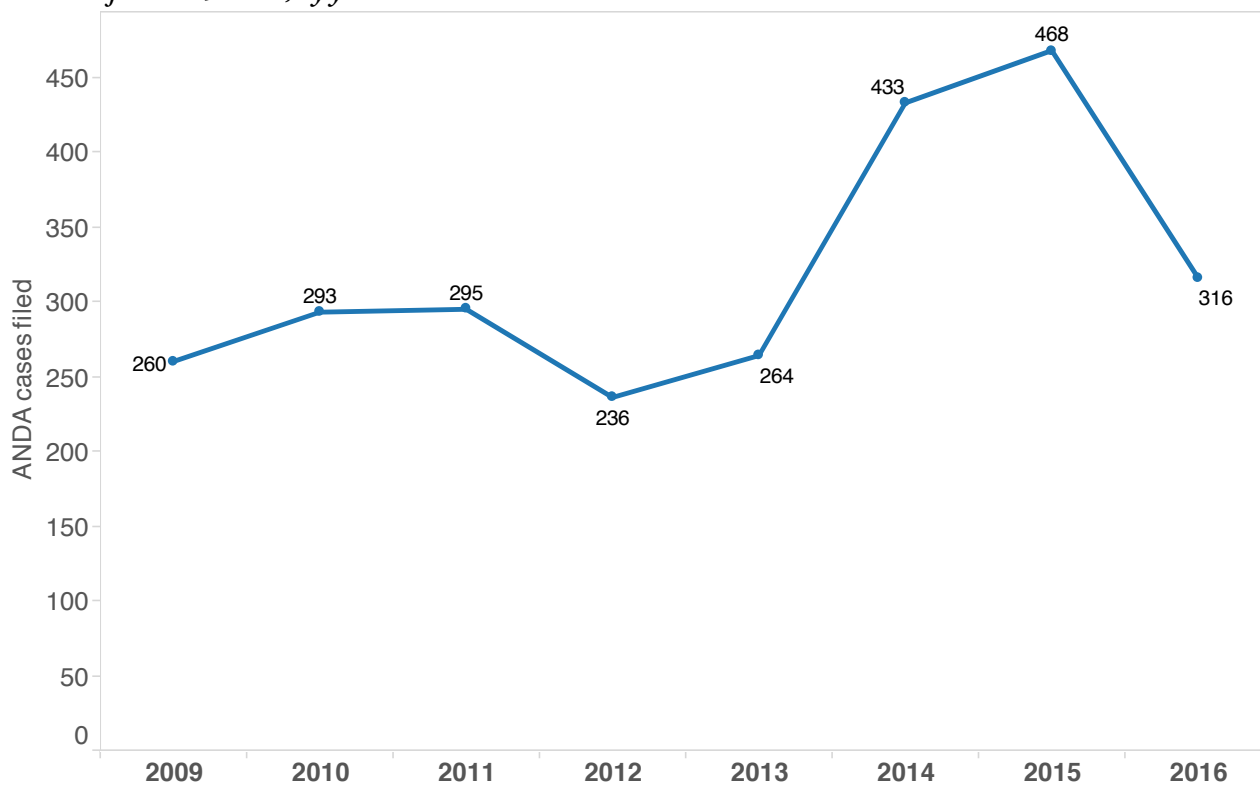
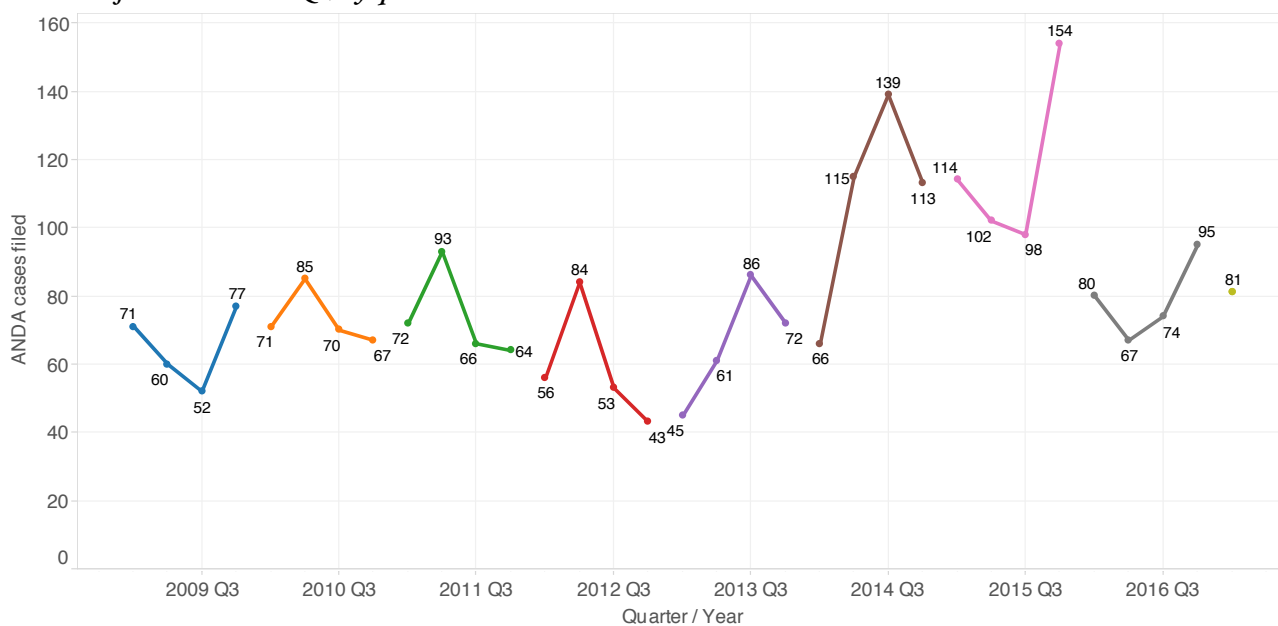


Figure 2: ANDA cases filed 2009-2017Q1, by quarter



Note: All charts reflect patent litigation in the U.S. District Courts except where otherwise stated.

Top Districts and Judges

Figure 4: Top districts by cases filed 2009-2017Q1

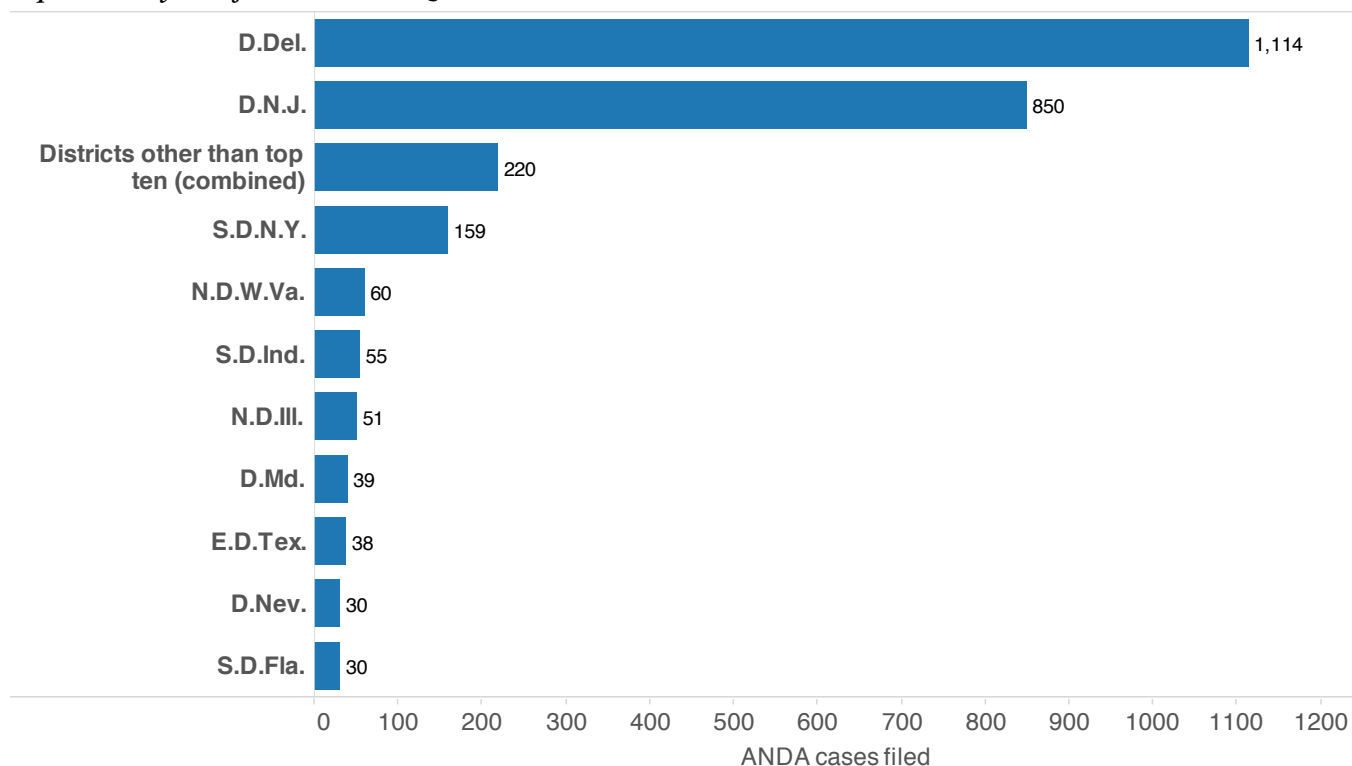
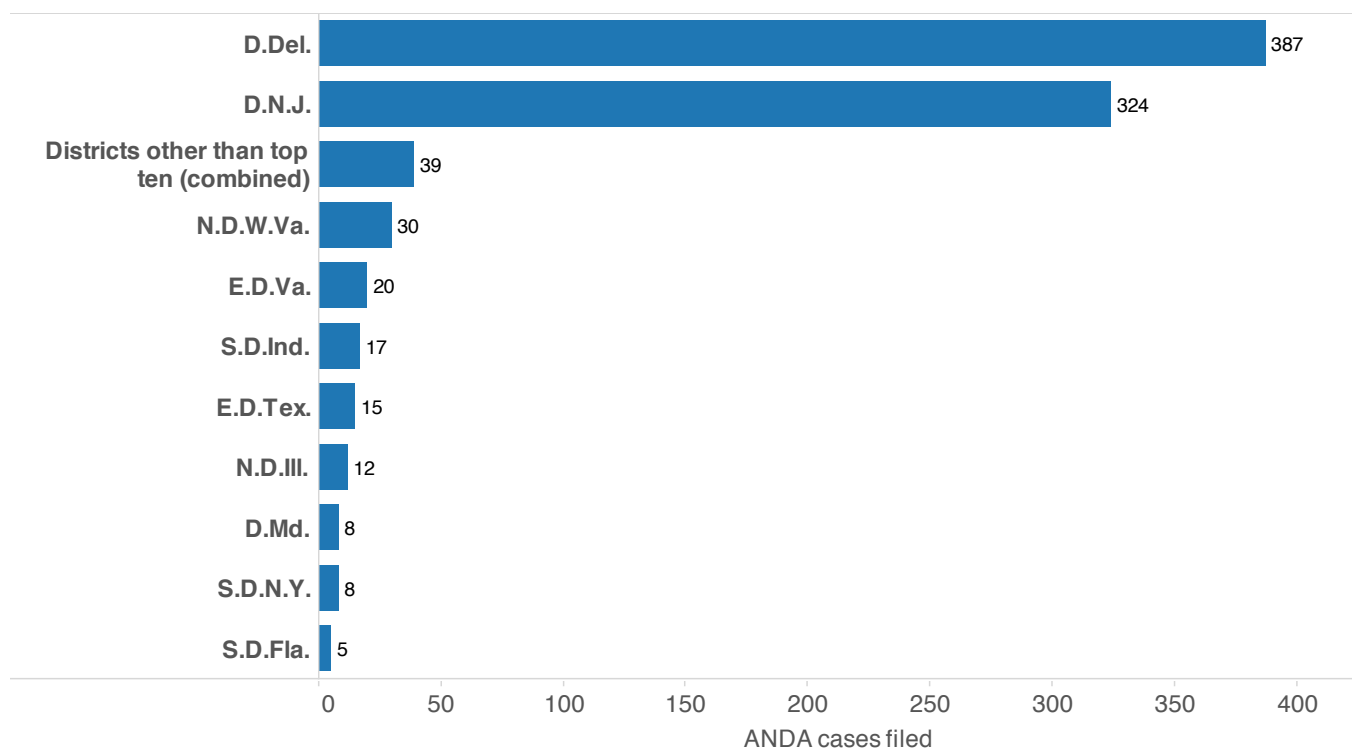


Figure 5: Top districts by cases filed 2015-2017Q1



ANDA litigation is heavily concentrated in the top districts: the District of Delaware (1,114 cases since 2009) and the District of New Jersey (850 cases) each easily have more cases than all the other districts combined (a combined total of 220 cases). Since 2009, a total of 2,646 ANDA cases have been filed.

The District of Delaware has historically been the most popular district for ANDA litigation and it remains so today. The District of New Jersey held the lead for much of 2015, but since then has been second to the District of Delaware by a fair margin.

Unsurprisingly, the top judges for ANDA cases all hail from these two districts.

The Southern District of New York, third by number of cases filed since 2009 (159 cases total), has seen a dramatic decline from a peak of 41 cases in 2011 to only a single case filed in the last five quarters.

Figure 6: Districts of Delaware and New Jersey, cases filed 2009-2017Q1, by year

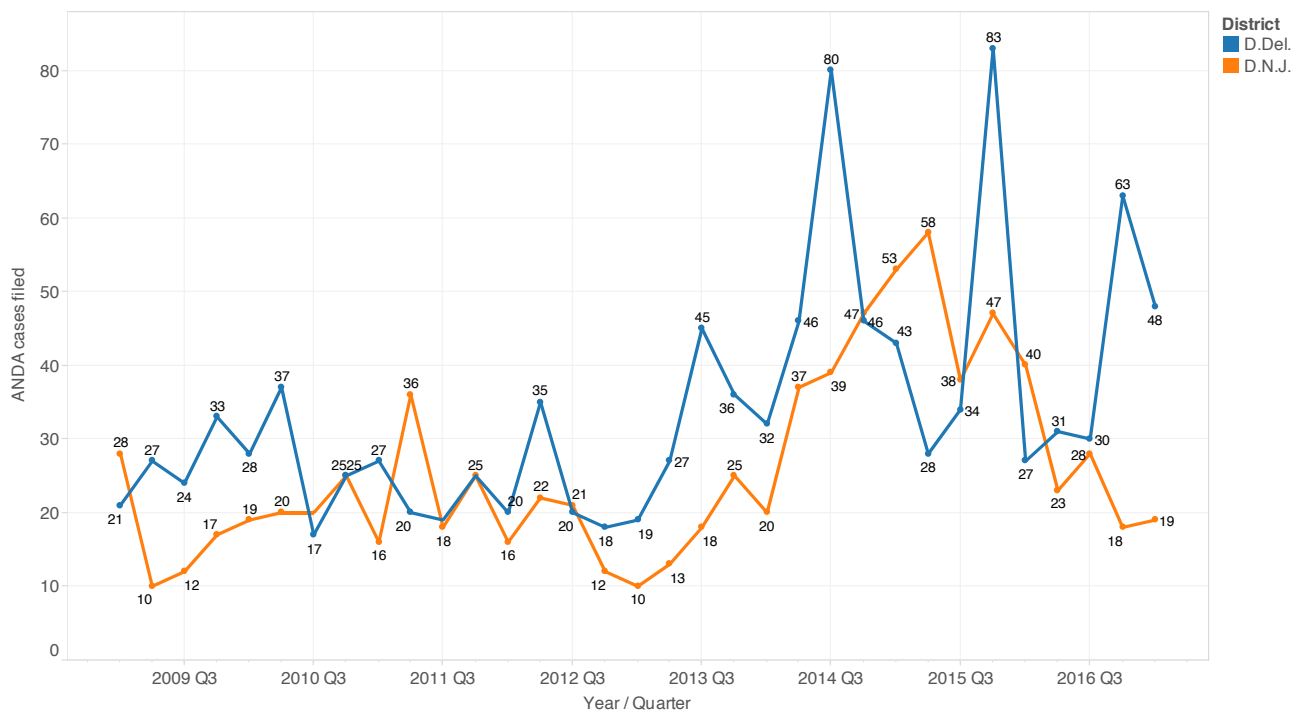


Figure 7: Other top districts, cases filed in 2009-2016, by year

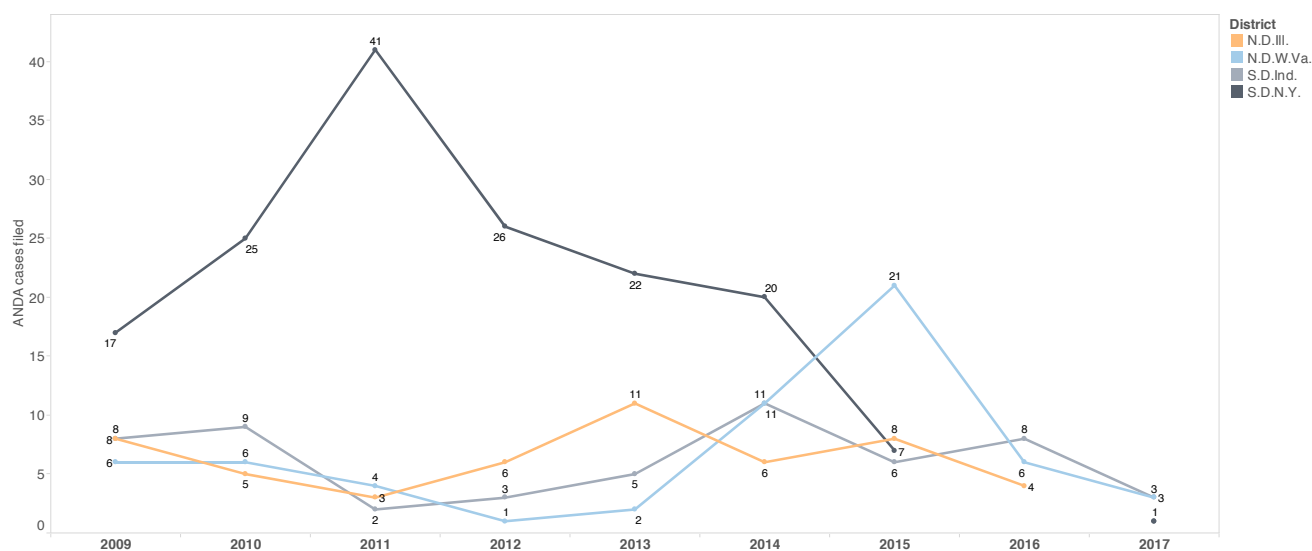
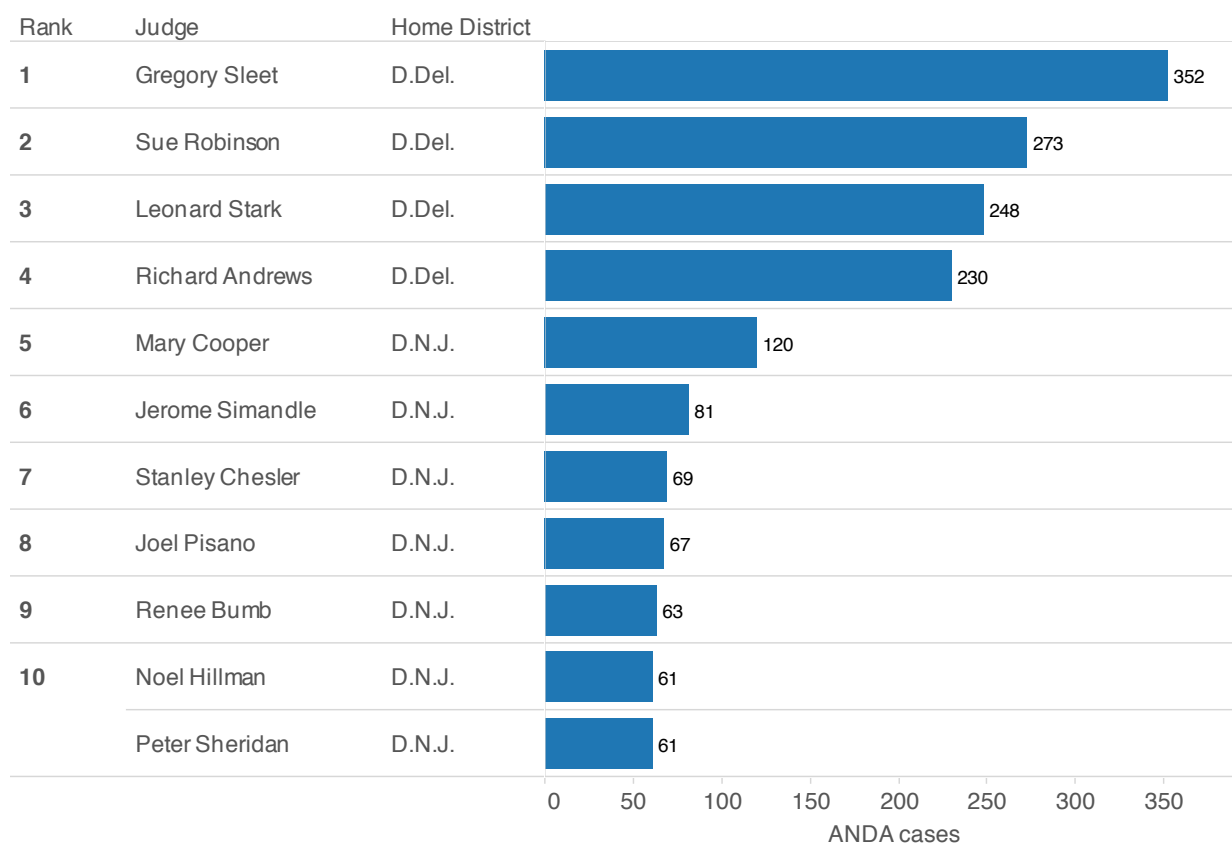
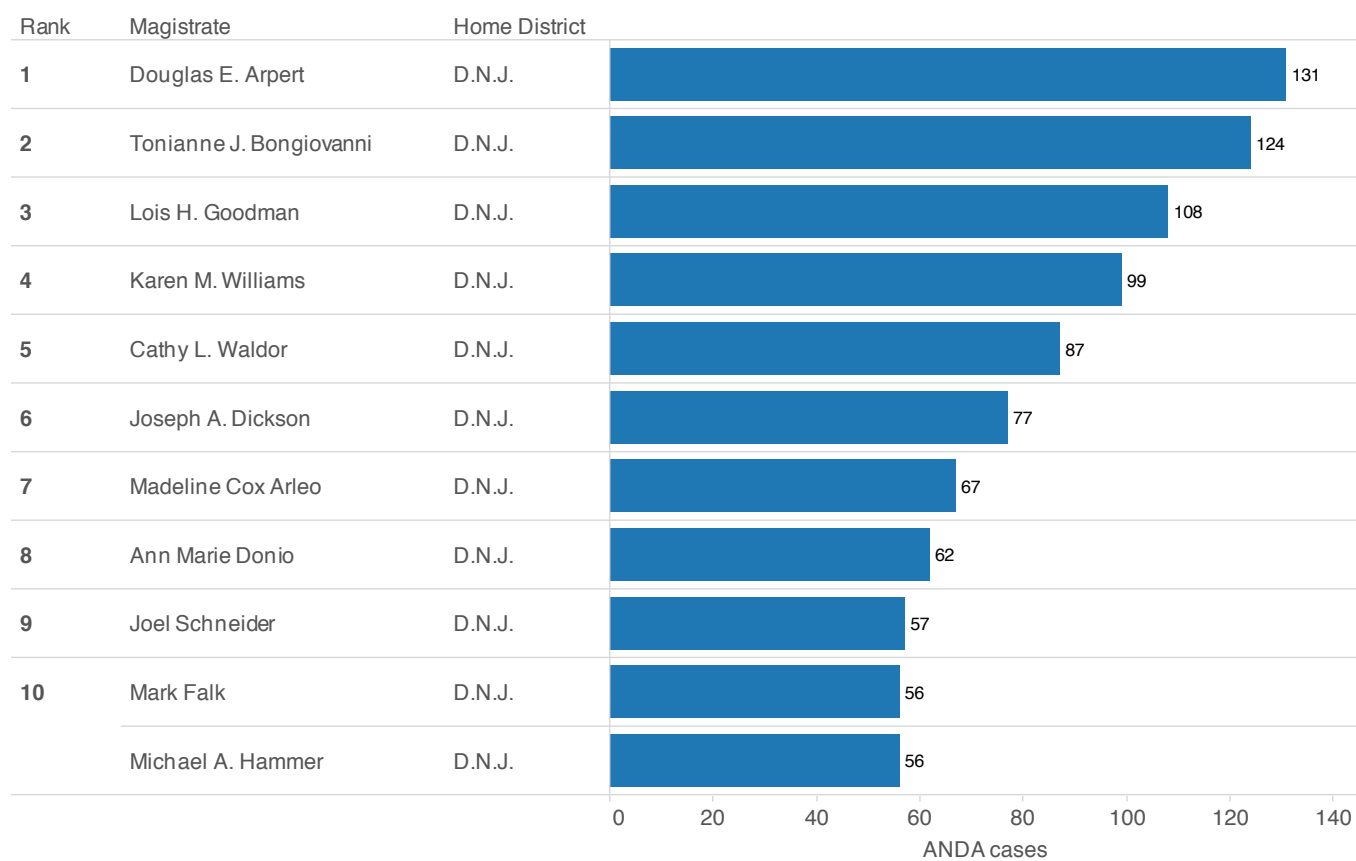


Figure 8: Top judges, by cases filed 2009-2017Q1



Note: Judges shown with home district, but case counts may include cases in other jurisdictions when sitting by designation.

Figure 9: Top magistrate judges, by cases filed 2009-2017Q1

Parties and Law Firms

Figure 10: Top parties by cases filed 2009-2017Q1

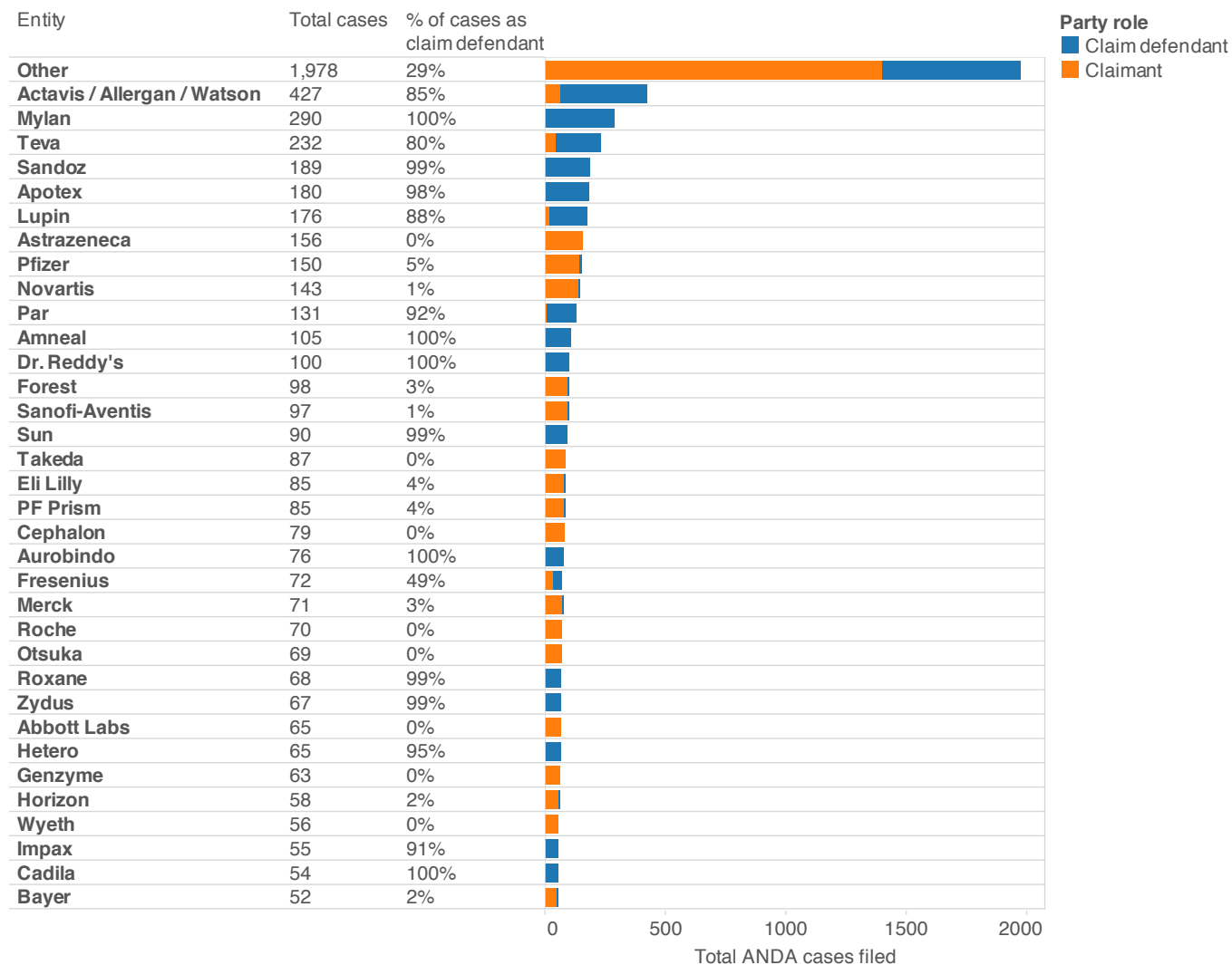
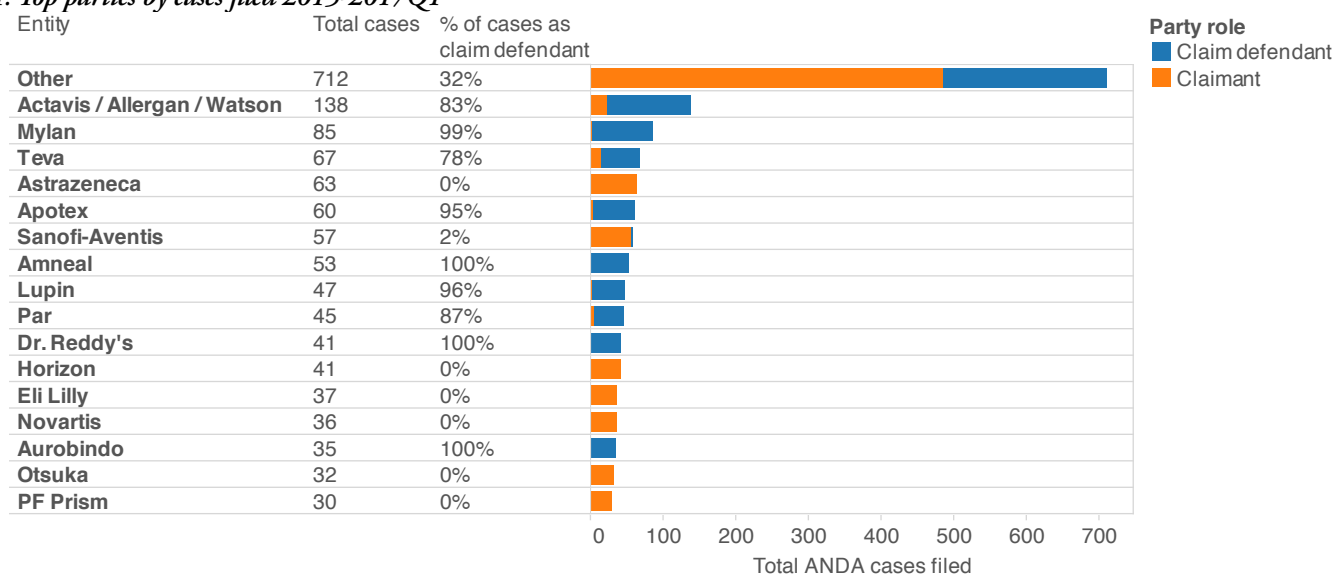


Figure 11: Top parties by cases filed 2015-2017Q1

Since 2009, Actavis (including Allergan and Watson Laboratories) has participated in the most ANDA cases (427 cases), followed by Mylan (290 cases), and then by Teva Pharmaceutical Industries (232 cases). The top parties most of the time appear in the role of a claim defendant (i.e. a defendant or declaratory judgment plaintiff), although Actavis is an exception in large part due to its Allergan cases.

Among the top parties since 2009, Astrazeneca (156 cases), Pfizer (143 cases), and Novartis (144 cases) have the largest number of cases as claimant (i.e., where the party is asserting the patent, regardless of whether plaintiff or declaratory judgment defendant). Many other top claimants are exclusively claimants including Takeda, Cephalon, Roche, Abbott Labs, Genzyme, and Wyeth.

In more recent cases filed since 2015, the top parties remain the same: Actavis (138 cases), Mylan (85 cases) and Teva (67 cases). Actavis remains the top claimant in the more recent cases, but Sanofi-Aventis is second (56 cases) and Horizon (41 cases) third.

Figure 12: Top claimants by cases filed 2009-2017Q1

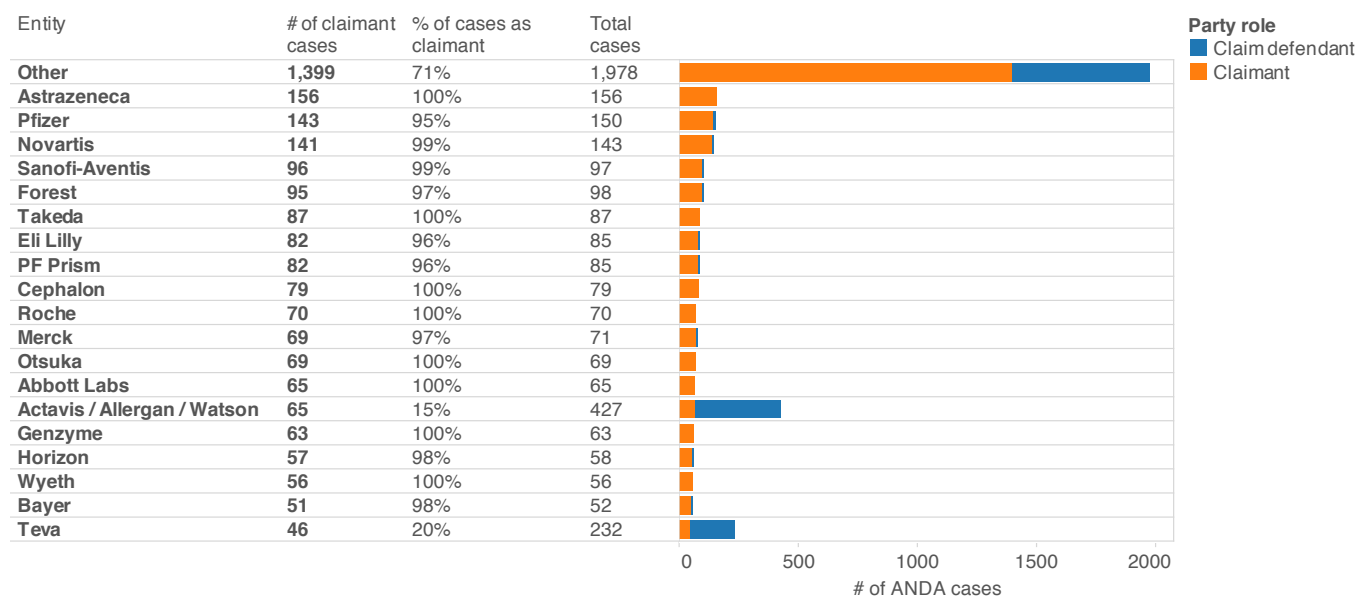
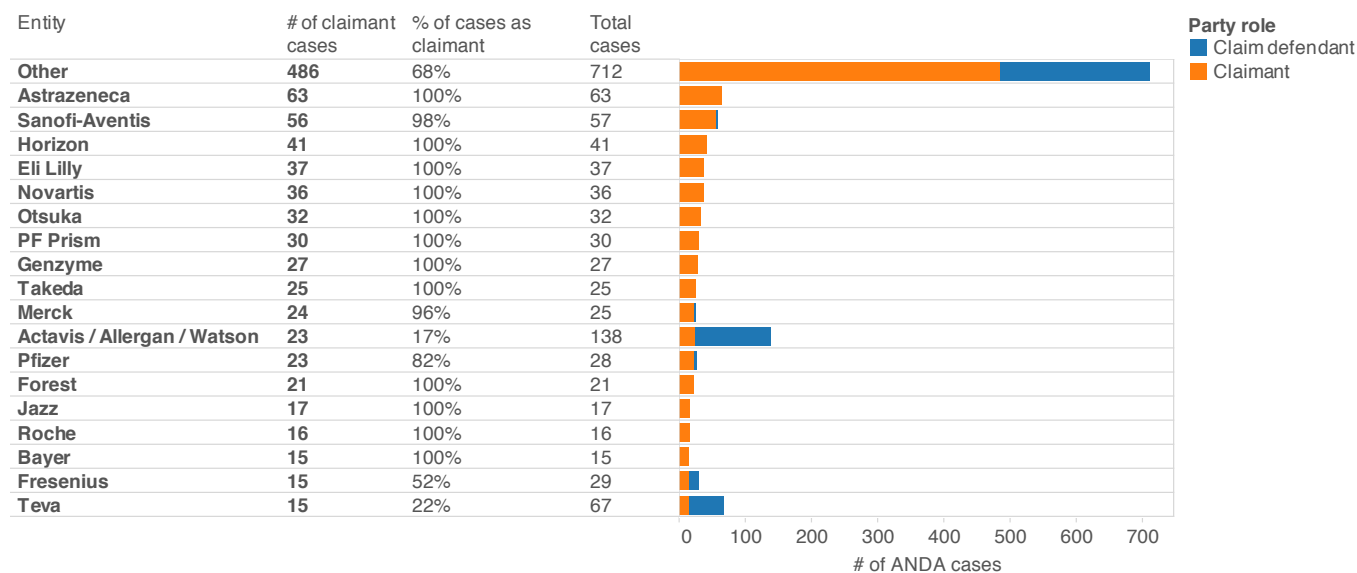


Figure 13: Top claimants by cases filed 2015-2017Q1



Note: Judges shown with home district, but case counts may include cases in other jurisdictions when sitting by designation.

Figure 14: Top law firms by cases filed 2009-2017Q1 representing plaintiffs

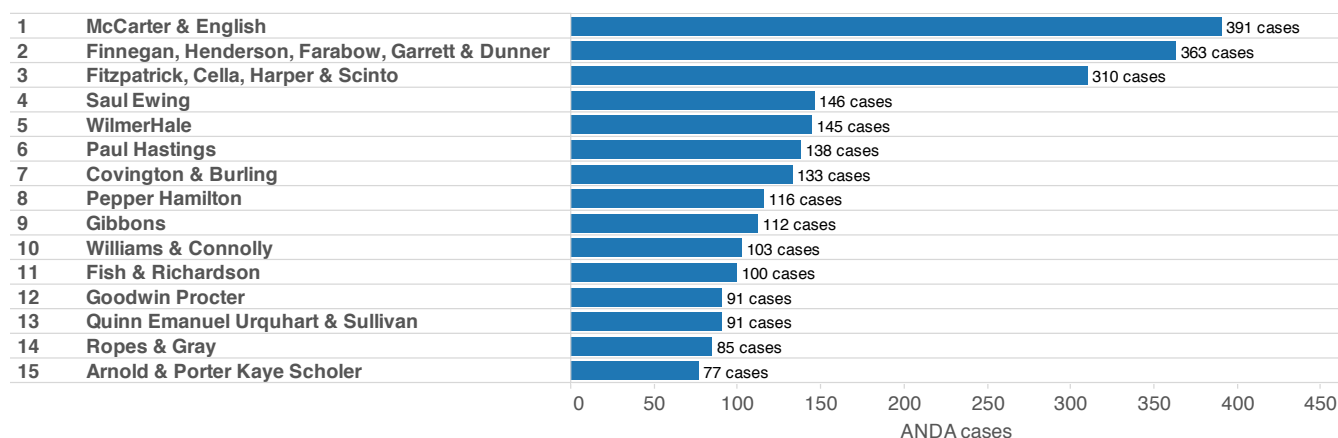
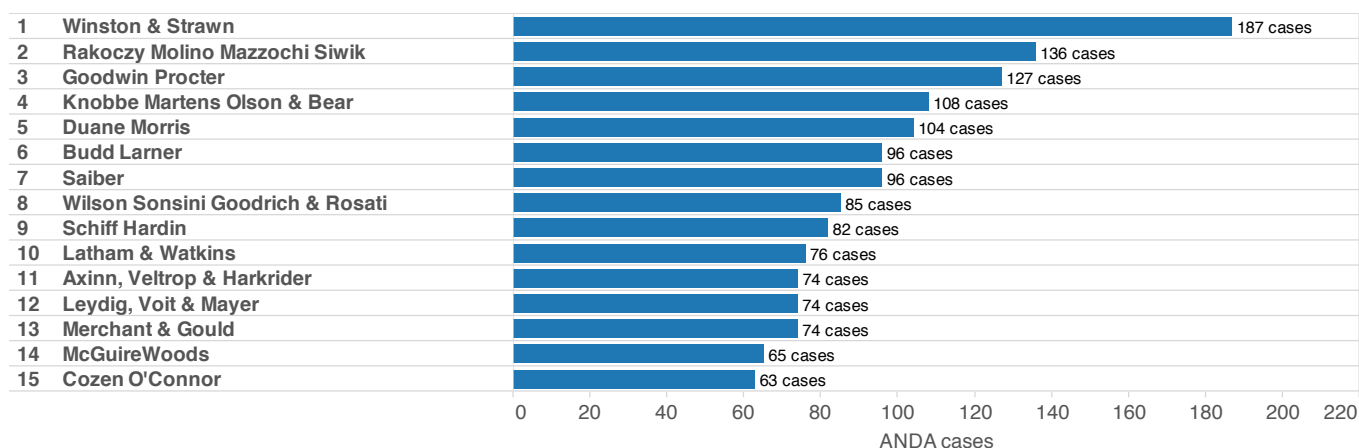


Figure 15: Top law firms by cases filed 2009-2017Q1 representing defendants



Note: These charts exclude Delaware local counsel law firms - see box on next page.

Solid data on law firm representation helps law firms communicate their experience to clients, and enables companies to choose the right firm for the job. Although this section only examines top firms overall, Lex Machina allows users to narrow in on the top law firms by particular districts, or that have achieved certain results (e.g. trial).

The top law firms for representing plaintiffs in ANDA cases have been relatively stable. McCarter English is the leading plaintiff-side firm with 391 cases since 2009 and 150 since 2015. Other top plaintiff firms include Finnegan, Henderson, Farabow Garrett & Dunner (363 cases since 2009, 125 since 2015), and Fitzpatrick, Cella, Harper & Scinto (310 cases since 2009, 81 since 2015). Saul Ewing appears to be catching up though, with 80 cases since 2015.

On the defense side, Winston & Strawn leads with 187 cases since 2009, followed by Chicago boutique Rakoczy Molino Mazzochi Siwik (136 cases), Goodwin Procter (127 cases), and Knobbe Martens (108 cases).

Among the more recent cases, Winston & Strawn still leads (56 cases), followed by Goodwin Procter (39 cases) and Budd Lamar (35 cases).

Figure 16: Top law firms by cases filed 2015-2017Q1 representing plaintiffs

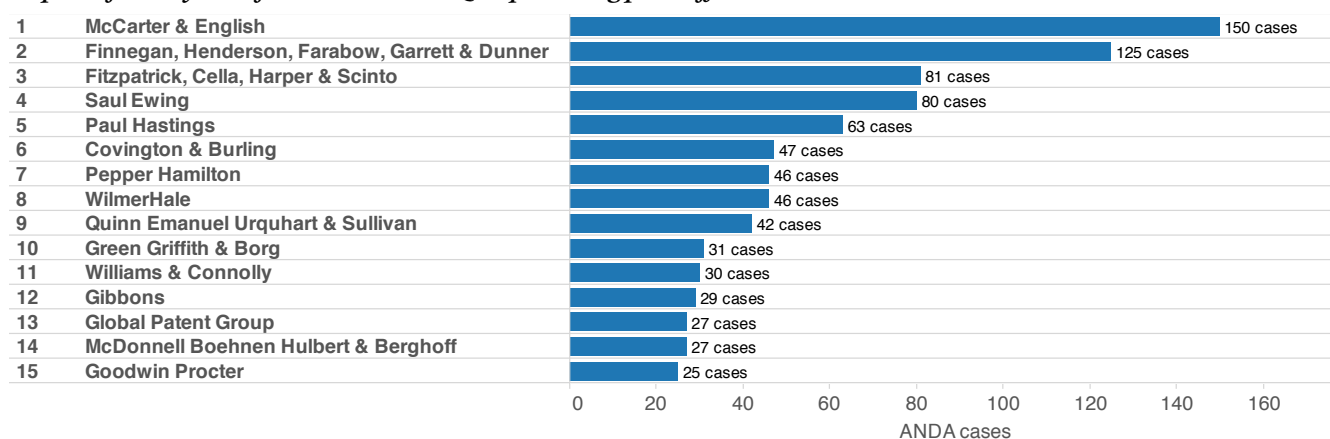
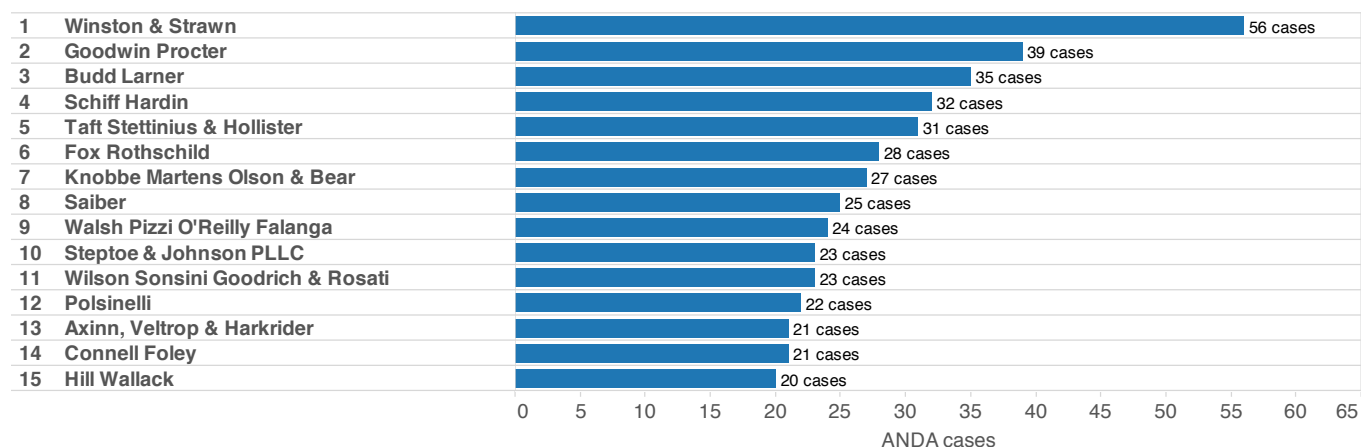


Figure 17: Top law firms by cases filed 2015-2017Q1 representing defendants

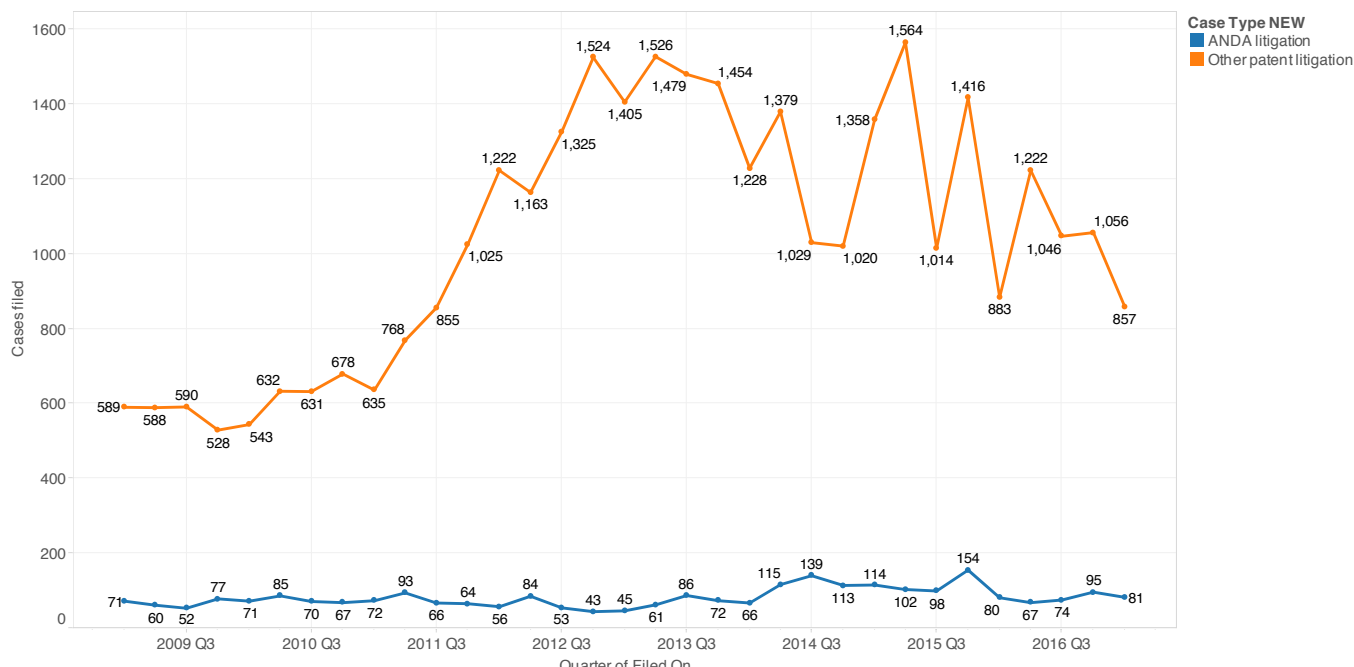


Of course, the leading firm representing plaintiffs overall is the Delaware firm of Morris, Nichols, Arsht & Tunnell, with 251 cases in that role during 2015-2017Q1, and an astounding 707 cases in that role since 2009.

Also notable, on the defense side, are the Delaware firms of Young Conaway Stargatt & Taylor (with 161 cases in that role since 2009, and 55 cases during 2015-2017Q1) as well as Philips, Goldman, McLaughlin & Hall (100 cases in that role since 2009, and 62 during 2015-2017Q1).

ANDA vs Other Patent Litigation

Figure 18: Cases filed 2009-2017Q1, by quarter



ANDA litigation differs from other patent litigation in several key aspects. By examining and comparing filing rates, remedies, and case resolutions between these two kinds of cases, practitioners can ensure they are supported by data relevant to the specific kind of case at hand.

Although ANDA filings constitute only about 10% of all patent litigation in the U.S. district courts in recent years, it has remained more steady than filing rates for other patent litigation. While other patent litigation has risen and fallen dramatically, ANDA litigation has been comparatively stable with only a moderate rise in 2014 to 2015.

ANDA cases also differ significantly in the likelihood of gaining injunctive relief: while an injunction has issued in 12.4% of ANDA cases, the percentage for other patent litigation is only 4.2% (see below for more on injunctive relief in ANDA cases).

ANDA cases are much less likely to end as a result of settlement (56.5%) than other patent litigation (77.8%), and more likely to be won by the claimant (15.9% in ANDA cases vs 4.4% in other litigation). Procedural outcomes (such as transfer or consolidation) also account for a larger percentage of ANDA case resolutions (23.9%) than in other patent litigation (14.6%).

In ANDA cases, consent judgment is the most frequent vehicle for getting a patent finding (accounting for a finding in 229 cases) followed by trial (89 cases). In contrast, other patent litigation is more likely to result in a patent finding from summary judgment, or on default judgment.

When patents are found invalid, ANDA cases differ from other litigation in the bases for the invalidity. Among ANDA cases, 35 U.S.C. § 103 (obviousness) is the most frequent basis for invalidity, appearing in 68.8% of the ANDA cases where invalidity has been found. In contrast, other patent cases tend to rely more on § 102 (anticipation/novelty, 55.9% of invalid patents in non-ANDA cases).

Figure 19: Injunctions granted in cases filed 2009-2017Q1, ANDA vs other patent litigation

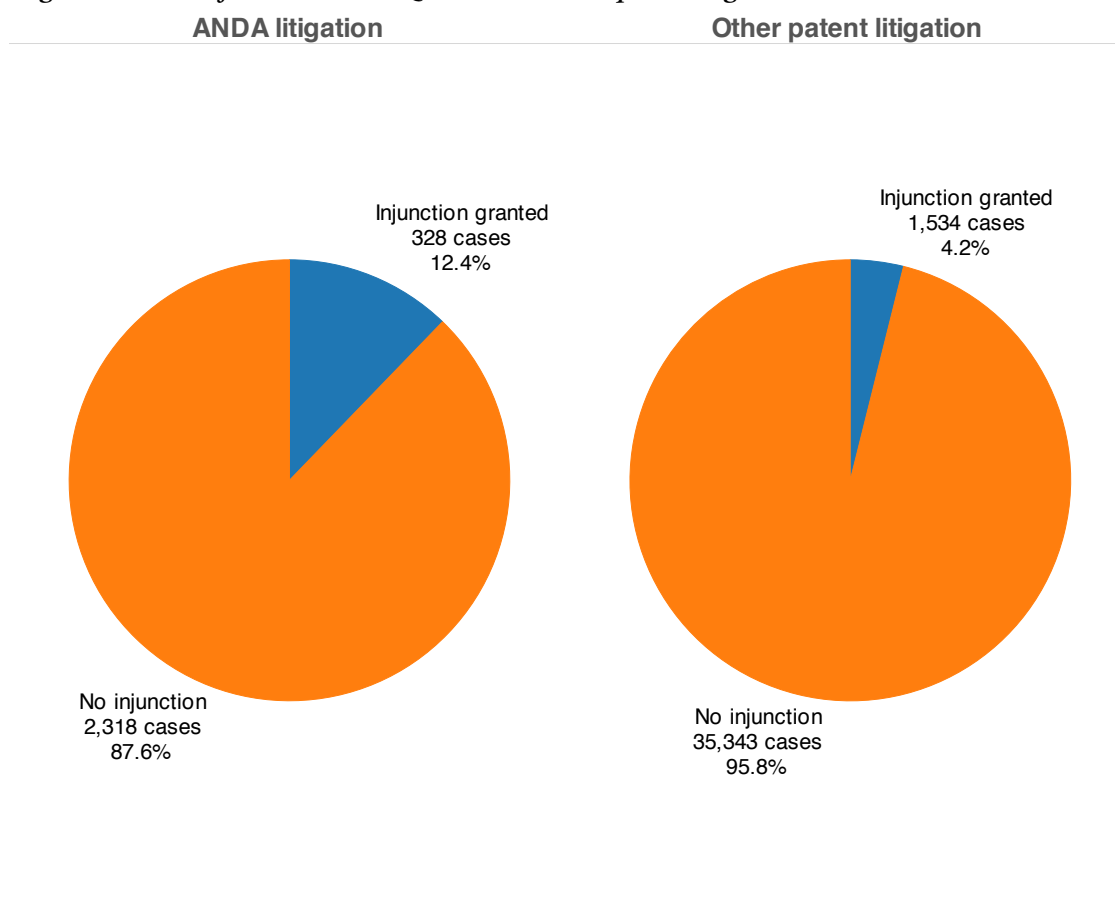
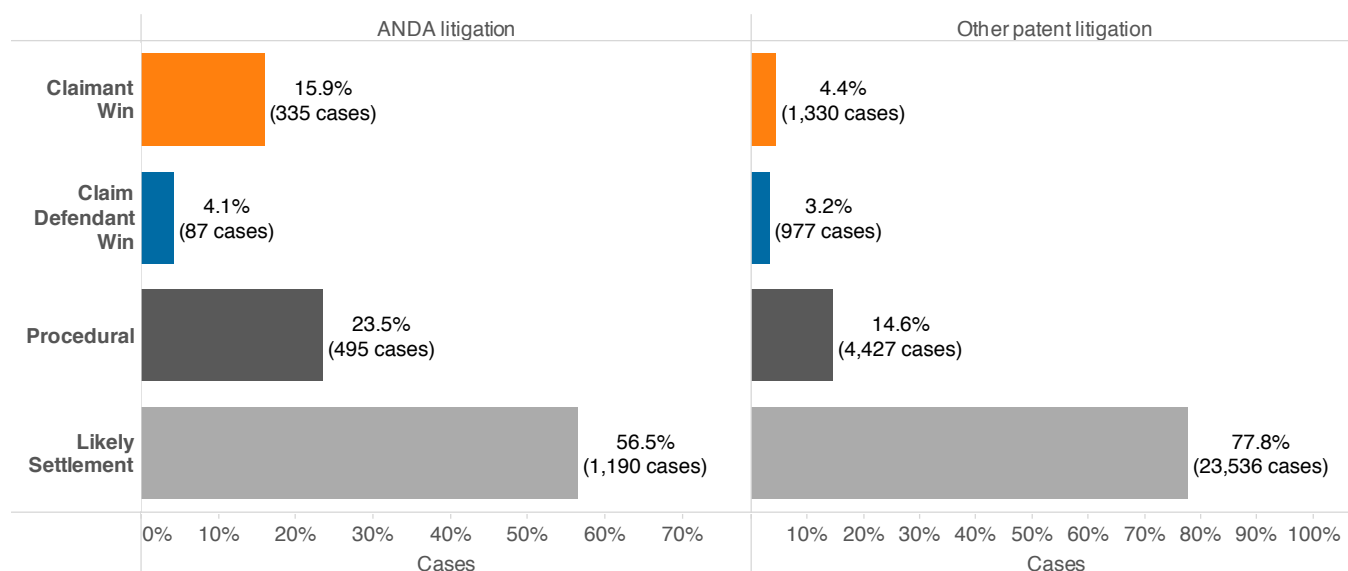
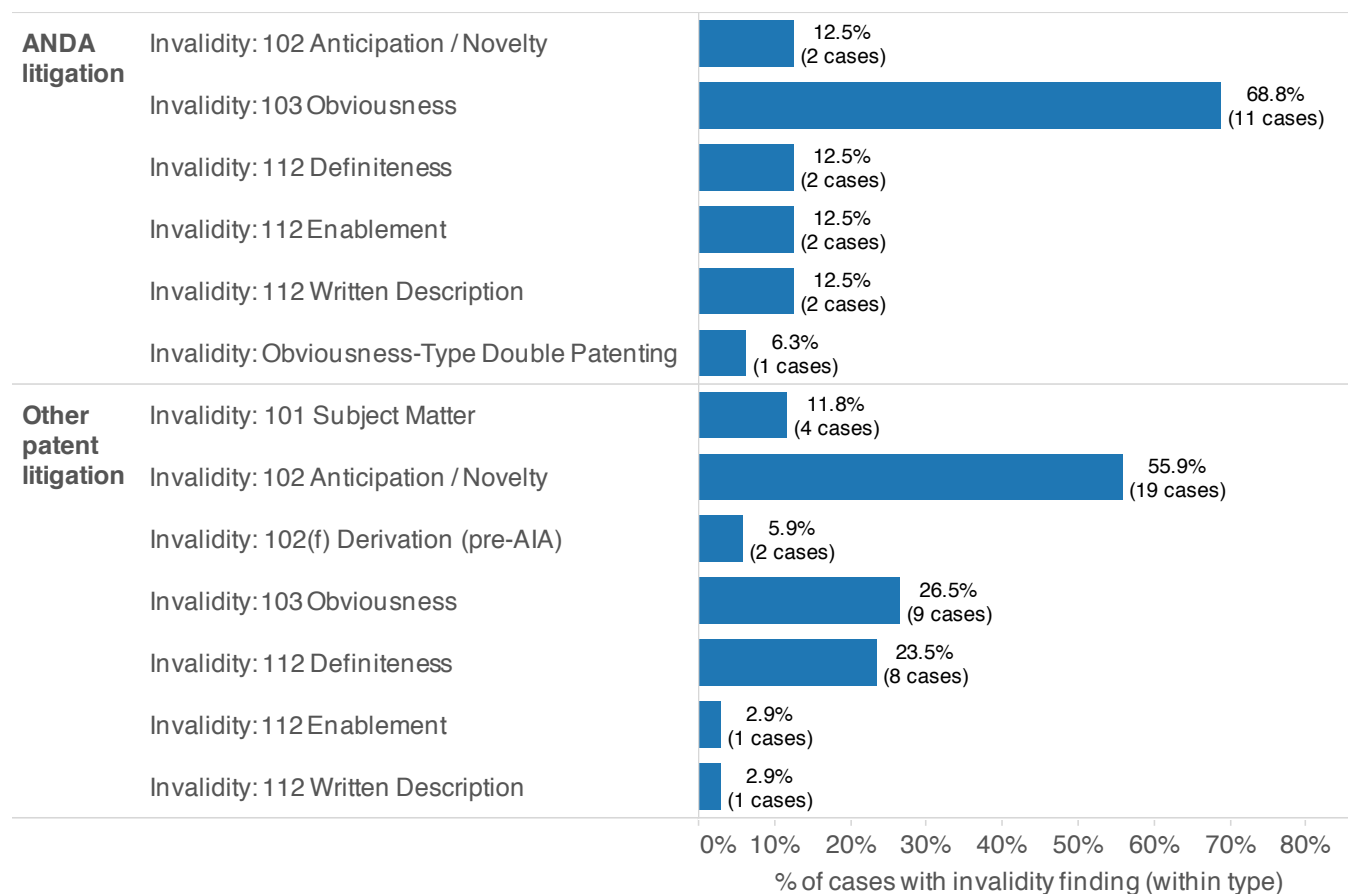


Figure 20: Resolutions of cases filed and terminated 2009-2017Q1



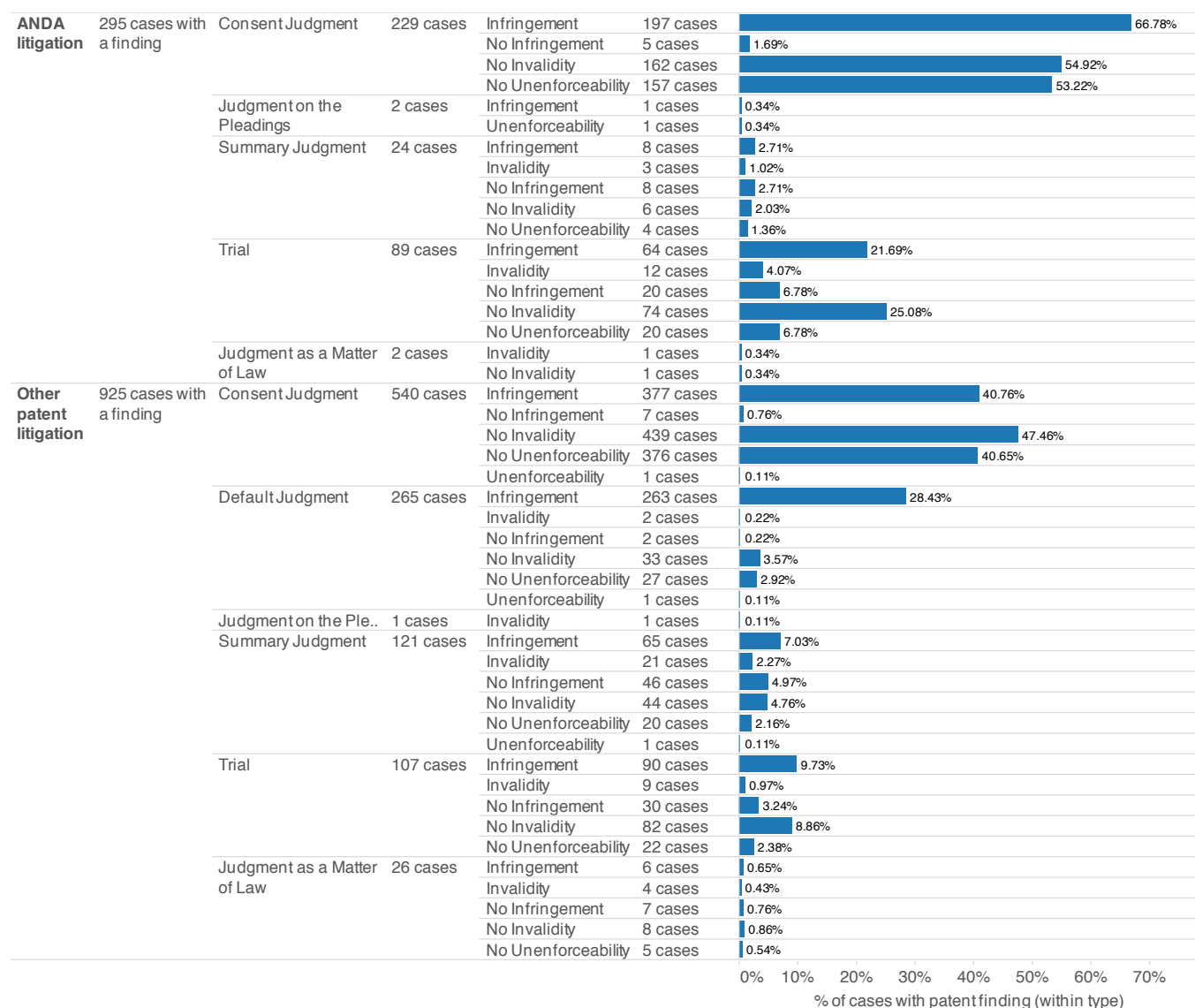
Note: “Claimant win” refers to the rights-holder - the plaintiff, or declaratory judgment defendant - winning over an accused infringer (the “claim defendant”).

Figure 21: Invalidity bases, by findings of invalidity in cases filed and terminated 2009-2017Q1



Note: Cases may include multiple findings of invalidity.

Figure 22: Findings in cases filed and terminated 2009-2017Q1



Orange Book Data

The U.S. Food and Drug Administration (FDA) publishes data on new drug applications in the “Orange Book.” Integrating that data into Lex Machina’s platform enables insight into how different parts of the application affect ANDA litigation.

Abilify (an antipsychotic, 63 cases since 2009) has overtaken Oxycontin (a pain relief medication, 59 cases) as the most litigated tradename by number of cases. Vascepa (a cholesterol medication) leads by number of asserted patents. In more recent cases since 2015, Pennsaid (29 cases, 17 patents), Vimovo (25 cases, 13 patents), and Xyrem (17 cases, 17 patents) have also been heavily litigated.

By constituent ingredients, oxycodone hydrochloride (the primary ingredient of Oxycontin) has the most cases, followed by aripiprazole (an anti-psychotic), although testosterone has been asserted in the most patents.

Prescription drugs are more common than over-the-counter or discontinued drugs by cases (97.5% of cases are prescription). Therapeutic Equivalence (TE) codes indicate information about bioequivalence and FDA testing. Most applications do not indicate any TE code (67.9%). The most popular TE code among applications indicating one is the “AB” code, representing “products in conventional dosage forms not presenting bioequivalence problems.” 538 patents, or just over one quarter of ANDA litigated patents bear this code.

Drug substance/product flags indicate whether the patent underlying the ANDA application claims the drug substance or the drug product. Most applications have only the product flag (applications linked to litigated 1,527 patents) followed by those with no flag (those linked to 1,436 litigated patents).

Figure 23: Word cloud of tradenames (colored by number of cases and sized by number of asserted patents) in cases filed 2009-2017Q1



Figure 24: Word cloud of tradenames (colored by number of cases and sized by number of asserted patents) in cases filed 2015-2017Q1



Figure 25: Word cloud of ingredients (colored by number of cases and sized by number of asserted patents) in cases filed 2009-2017Q1



Figure 26: Application type, by cases filed 2009-2017Q1

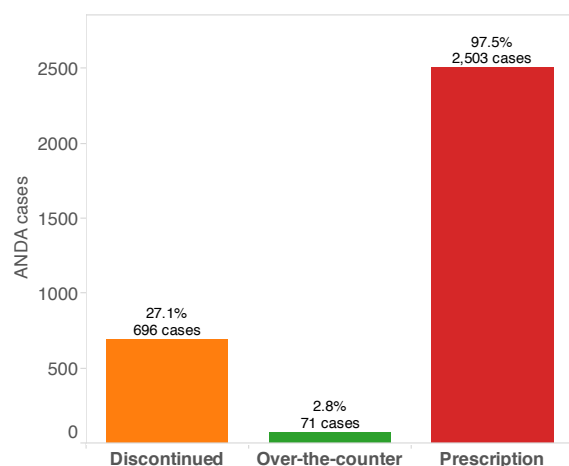


Figure 27: Therapeutic equivalence codes, by patents asserted 2009-2017Q1

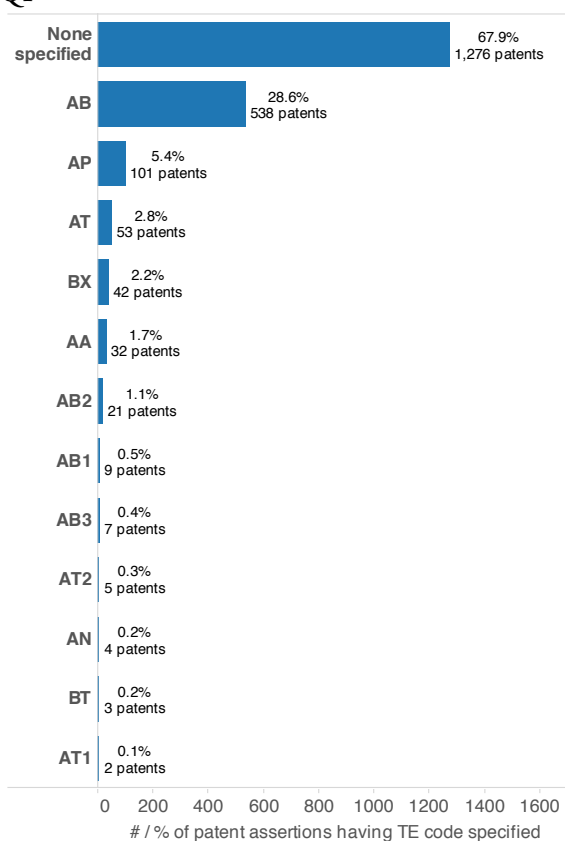


Figure 28: Therapeutic equivalence codes, by patents asserted 2009-2017Q1

Therapeutic equivalence code	
None specified	1,276 patents
AA	1,694 cases 32 patents
AB	85 cases 538 patents
AB1	1,145 cases 9 patents
AB2	39 cases 21 patents
AB3	21 cases 7 patents
AN	10 cases 4 patents
AP	6 cases 101 patents
AT	275 cases 53 patents
AT1	106 cases 2 patents
AT2	7 cases 5 patents
BT	11 cases 3 patents
BX	6 cases 42 patents
	64 cases

- AA Products in conventional dosage forms not presenting bioequivalence problems
- AB, AB1, AB2, AB3... Products meeting necessary bioequivalence requirements
- AN Solutions and powders for aerosolization
- AO Injectable oil solutions
- AP Injectable aqueous solutions and, in certain instances, intravenous non-aqueous solutions
- AT Topical products
- B* Drug products requiring further FDA investigation and review to determine therapeutic equivalence
- BT Topical products with bioequivalence issues
- BX Drug products for which the data are insufficient to determine therapeutic equivalence

The Orange Book allows for multiple entries in some data fields, like ingredients, Therapeutic Equivalence (TE) codes, or drug/product flags. When a case or patent corresponds to multiple Orange Book entries (e.g. one application contains a “AB” TE code, but the other contains a “BT” code) the case and patent count towards each TE code.

Figure 29: Top Ingredients (relationship between cases filed and number of patents asserted) in cases filed 2009-2017Q1

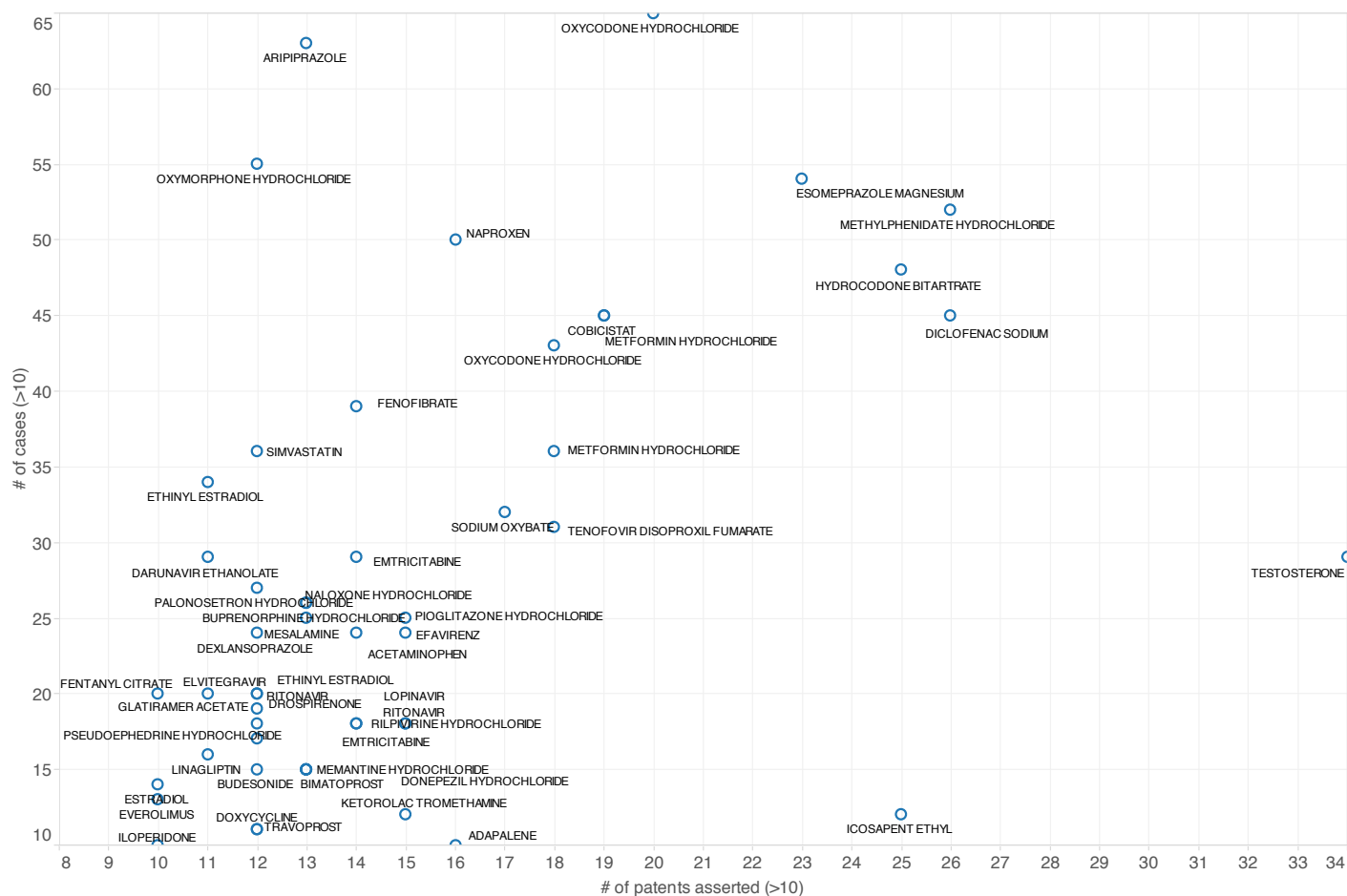


Figure 30: Top Ingredients (relationship between cases filed and number of patents asserted) in cases filed 2015-2017Q1

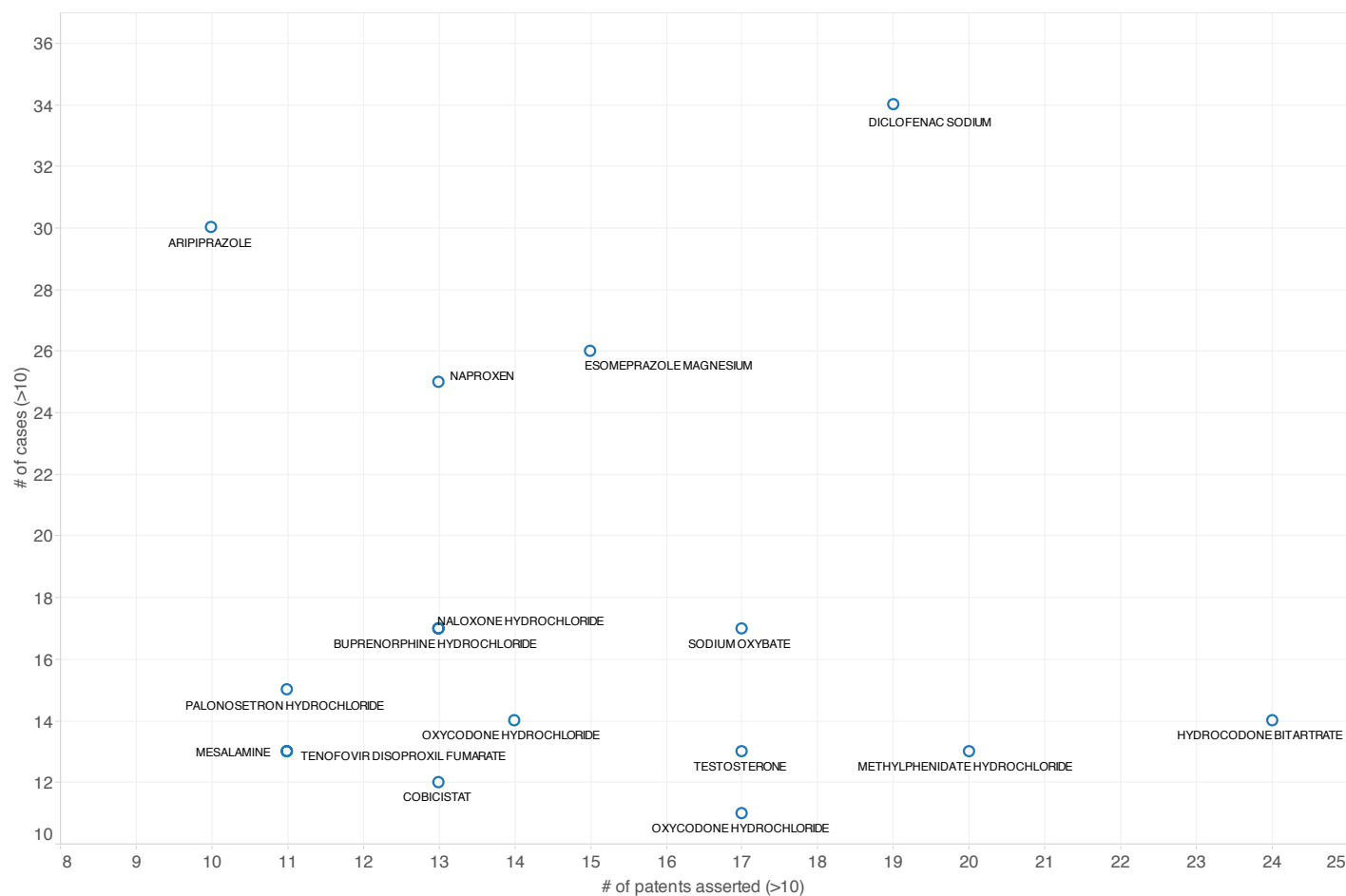


Figure 31: Drug substance and product flags, by patent assertions 2009-2017Q1

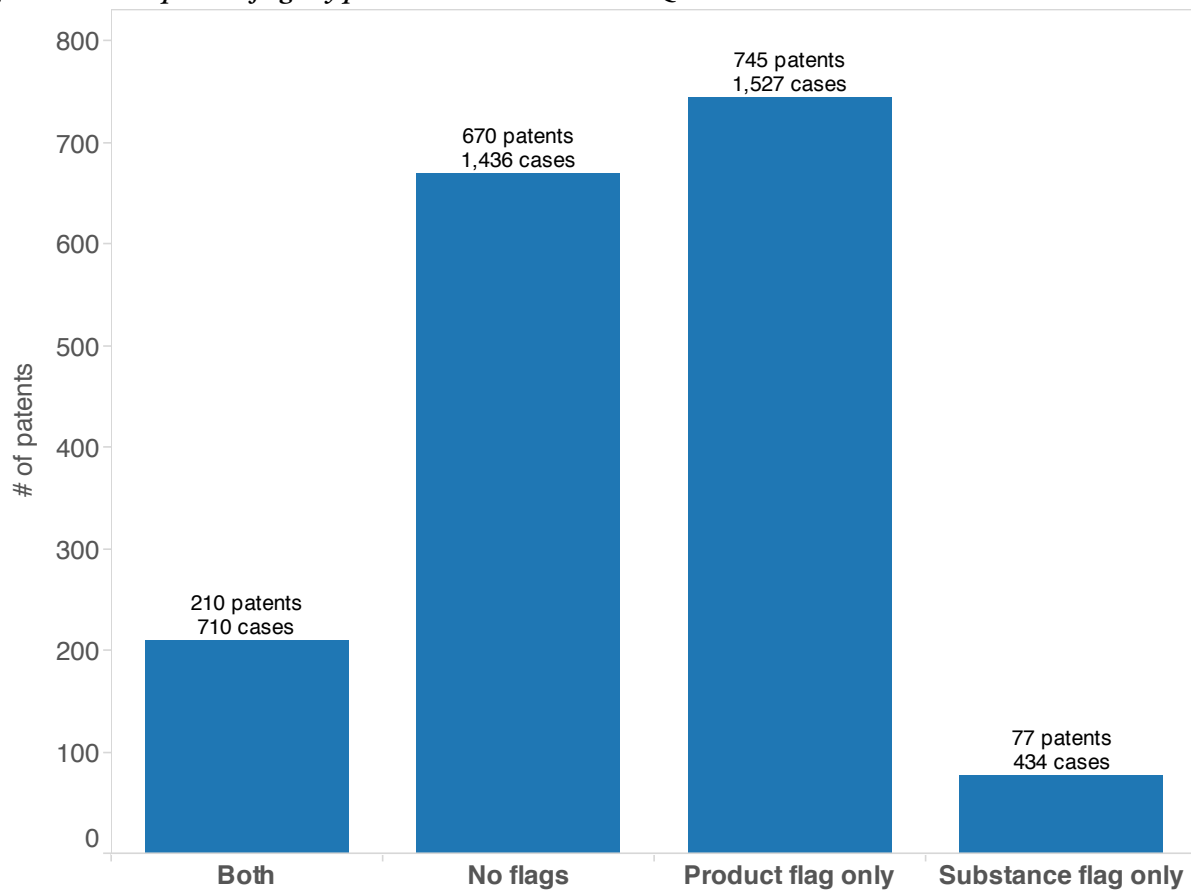
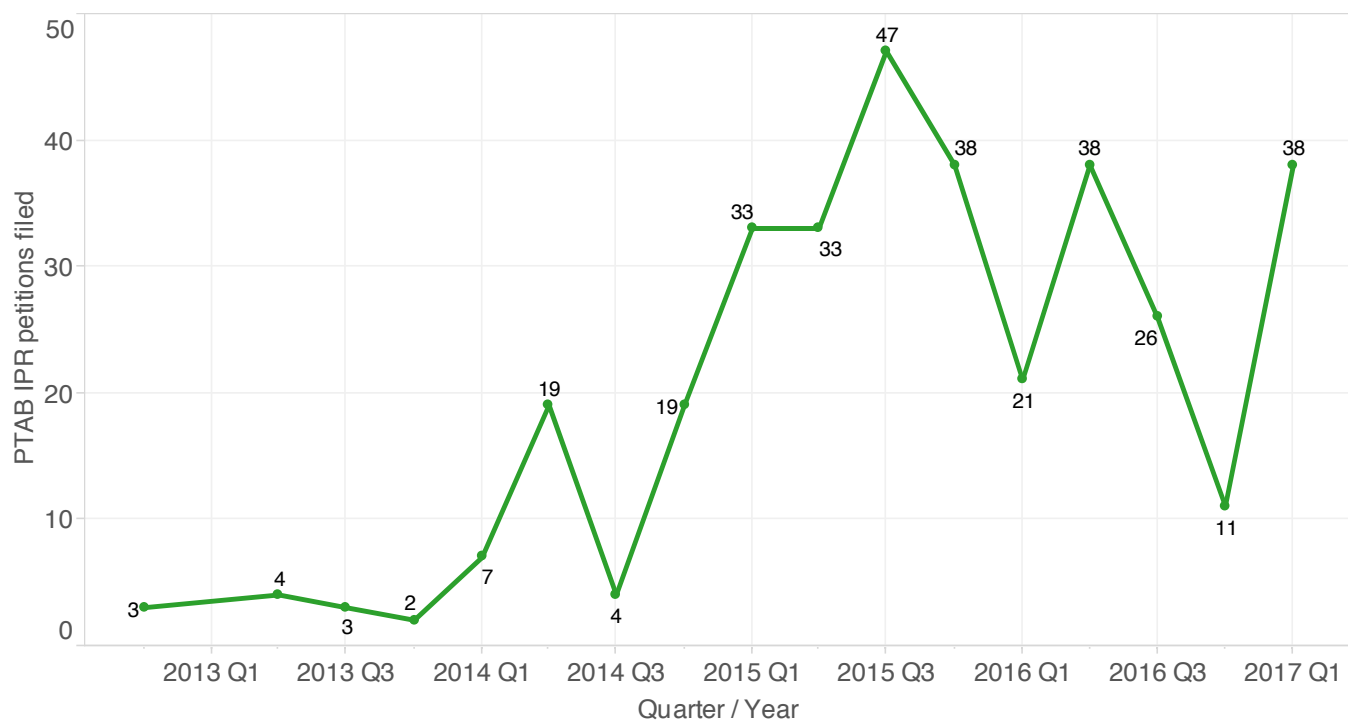
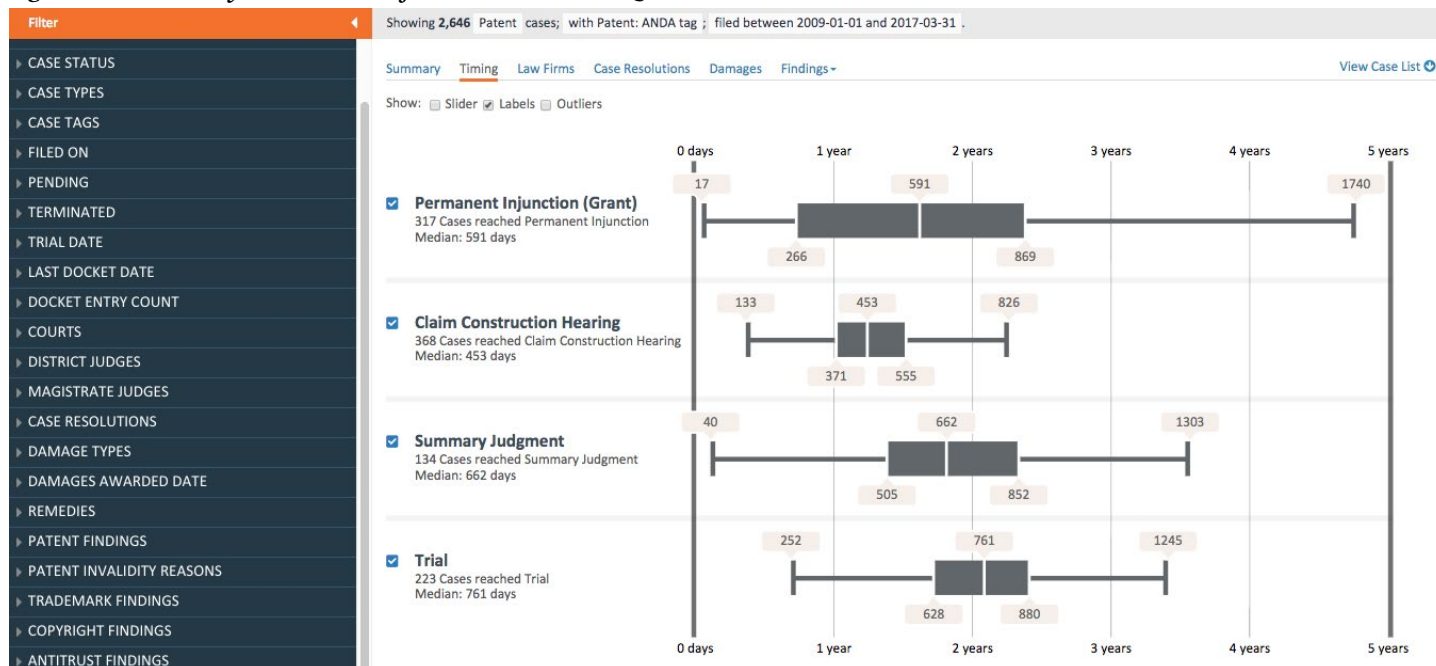


Figure 32: IPR petitions filed 2009-2017Q1 on Orange Book patents



Timing and Injunctions

Figure 33: Time to key events in cases filed 2009 to 21017Q1



The timing of key events in a case often directly influence its cost. For lawyers who have to budget cases, whether at firms or in-house, having good information on how long it takes to reach these key events can be critical to an accurate budget.

Lex Machina helps users understand the timing of events, and this section shows a few of those events across all districts as an example. To better understand how to read these graphs, see the section on Understanding Boxplots at the end of this report.

The median time to the grant of a permanent injunction is 591 days (just over a year and a half), and is the least predictable of these events (as indicated by the wide box).

The time to claim construction is faster and is the most consistent of these events (as indicated by the smaller box), with a median time of only 453 days - about a year and a quarter.

Time from case filing to summary judgment is 662 days (about 1 year and 9 months) on median while time to trial is 761 days (just over 2 years) on median.

Lex Machina users can click the icon below to explore case timing for a particular district or judge, or for a different time-frame.

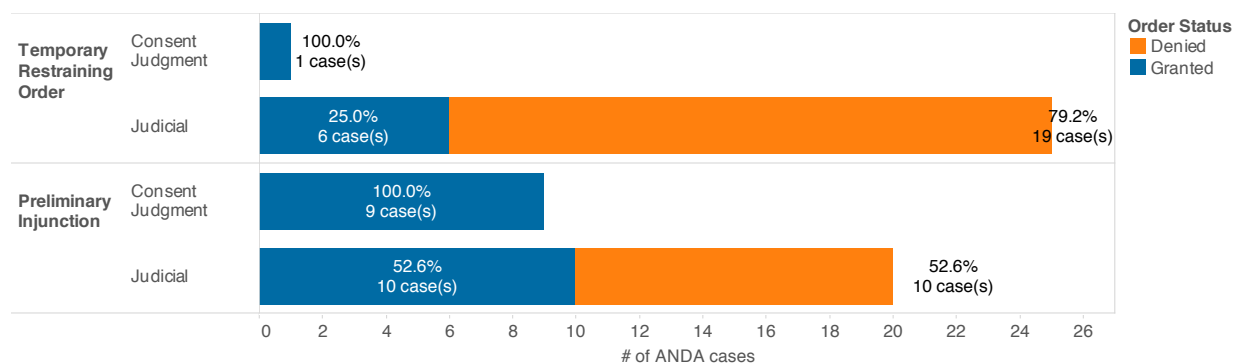


Subscribers can click to explore ANDA case timing on Lex Machina's site!

When viewing live analytics, please note that numbers may vary marginally from those captured in this report as a result of Lex Machina's ongoing data quality improvement efforts.

In ANDA cases, injunctions are often the most important remedy, so grant rates matter. On seeking a temporary restraining order, only 25% of motions are granted. However, on preliminary injunction the grant rate rises to more than 50%.

Figure 34: Injunction grant rate and timing, injunctions decided 2009-2017Q1 (in cases filed 2005-2017Q1)



Damages

Very few ANDA cases reach damages. In cases filed since 2000, only six cases have reached compensatory damages. Three were jury verdicts, one a summary judgment, one a consent judgment, and the last a mixture of consent and a bench trial. Damages theories include both lost profits and reasonable royalty. Of the three awards based on a reasonable royalty, one jury trial was based on a 25% rate, a second jury trial was based on a 35% rate, and the bench trial was based on a 50% rate.

Brigham and Women's Hospital, Inc. et al v. Perrigo Company et al

1:13-cv-11640-RWZ | filed 2013-07-09 | D.Mass.

Jury verdict

\$10,210,071.00 in reasonable royalty for patent 5,229,137

Reasonable royalty based on 35% rate in jury verdict

Case is still open and currently in post-trial briefing

Meda Pharmaceuticals Inc. v. Perrigo Israel Pharmaceutical Ltd. et al

3:14-cv-01241 | filed 2014-02-25 | District of New Jersey

Consent judgment that did not disclose damages amount.

Sanofi-Aventis Deutschland GmbH. et al v. Glenmark Pharmaceuticals Inc., USA, et al

2:07-cv-05855 | filed 2007-12-07 | District of New Jersey

Jury verdict:

\$15.2m of lost profits for patent 5,721,244

\$0.8m for price erosion

Judgment affirmed on appeal

Sunovion Pharmaceuticals v. Dey Pharma et al

1:06-cv-00113 | filed 2006-02-22 | District of Delaware

Jury verdict

\$17m in lost profits and \$1m in reasonable royalty for patents 5,547,994, 5,362,755, 6,083,993, 5,844,002, and 5,760,090.

Reasonable royalty based on 25% rate in jury verdict.

Sanofi-Synthelabo, et al v. Apotex Inc., et al

1:02-cv-02255 | filed 2002-03-21 | S.D.N.Y.

Infringement and enforceability were tried, but damages were limited by consent and determined by summary judgment after appeal

Damages were 40-50% of sales by Apotex by pre-agreement

Astrazeneca AB, et al v. Apotex Corporation, et al

1:01-cv-09351 | filed 2001-10-25 | S.D.N.Y.

Summary judgment:

\$76m of reasonable royalty on patents 4,853,230 and 4,786,505

Reasonably royalty based on 50% rate in bench trial

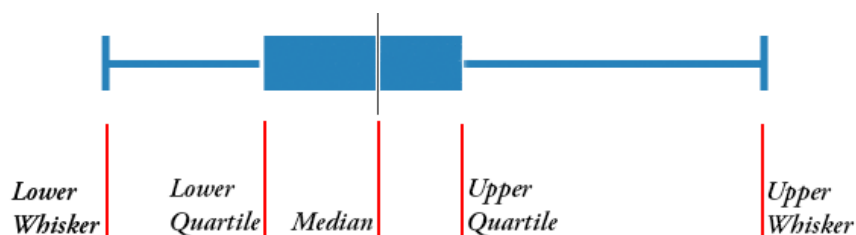
Judgment affirmed on appeal

Using Boxplots to Understand Timing

Lex Machina's analytics use a data visualization known as the boxplot to convey information about the timing of significant events in a case. Knowing how to interpret this data gives you an advantage when it comes to strategy, budgeting, and setting expectations, as well as in other decisions that involve case timing.

Consider a newly filed case: Regardless of whether you're an outside counsel, say, trying to determine how large of a flat fee to charge or trying to make sure two trials don't overlap, or an inside counsel estimating legal spend and evaluating a firm's proposed budget, case timing matters. Knowing the lower and upper bounds of how long it may reasonably take the case to reach injunction can give both kinds of counsel a strategic advantage over opponents lacking such nuanced information. Moreover, knowing the best and worst case scenarios for timing, or exactly how likely it is that a case will be active in 6 months enables more far-sighted contingency planning.

A boxplot summarizes a series of data points to help you understand the shape, or distribution of the values in those points. The boxplot is drawn based on five numbers: the median, the upper and lower quartiles, and the whiskers for a distribution.



Paying attention to these key parts of the plot will help you quickly understand what you need to know. Although boxplots provide a wealth of information, the four observations below, in order from simplest onwards, are all one needs to easily grasp the significance of a boxplot.

Median: the middle dividing line of the box splits the data points evenly so that 50% fall to either side. It's a form of average that gives a single number representation of what to reasonably expect.

Box bounds: the box encloses the middle-most 50% of the datapoints (from the 25th percentile to the 75th), with 25% of the datapoints falling outside to either side. This makes the box a good representation of the range one can reasonably expect.

Box compressed or elongated: a more compressed box means that more datapoints fall into a smaller range of time and therefore are more consistent; in contrast a longer box means that the datapoints are spread out over a wider time period and are therefore less predictable.

Whiskers: Whiskers are drawn to show the outside bounds of reasonable expectation, beyond which datapoints are considered outliers.¹

¹ By statistical convention, boxplots define outliers as points beyond more than 1.5 times the width of the box (sometimes called the "interquartile range").



Lex Machina
1010 Doyle Street, Suite 200
Menlo Park, CA 94025
Phone: (650) 390-9500
www.lexmachina.com

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