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


***Brian C. Howard***
*Legal Data Scientist & Director of Analytics Services*

***Jason Maples***
*Legal Data Analyst*


Lex Machina

## Executive Summary

This report covers 1,671 cases, filed from 2009 through September 2014, with over 1,100 patents, and involving over 400 applications to the FDA. Of the 1,671 cases, less than 3% were based on paper NDAs.

The majority of ANDA litigation is concentrated in three districts: the District of Delaware (678 cases), the District of New Jersey (481 cases), and the Southern District of New York (148 cases). These three districts account for just under 80% of the total ANDA litigation, and no other district had more than 50 cases over this time period. Unsurprisingly, the judges of the District of Delaware lead in the number of cases they see (Sleet 195 cases, Robinson 187 cases, Stark 139 cases, Andrews 122 cases), followed by those of the District of New Jersey (Pisano 64 cases, Cooper 49 cases, Chesler 38 cases, Sheridan 34 cases). Judge Irene Kelly, of the Northern District of West Virginia is the only top 15 judge not from Delaware, New Jersey, or S.D.N.Y.

The number of ANDA cases filed each year has held steady between 239 and 293, although 2014 has already set a record with 323 new cases. Much of the increase in 2014 comes in the top two districts of Delaware and New Jersey, and at the expense of S.D.N.Y.

Far fewer ANDA cases are filed each year than non-ANDA patent cases, by roughly an order of magnitude. Reaching consent judgment is more than three times as frequent (occurring in 13.5% of terminated ANDA vs 4.0% otherwise). Summary judgments on patents is less common in ANDA cases (1.8% of terminated ANDA cases vs 3.1% otherwise). In ANDA cases reaching judgment, an injunction issues more often than not (70.3% of terminated ANDA cases vs 42.4%). ANDA cases granting costs have awarded a far higher median amount ($58,384) than non-ANDA case ($11,932).

Oxycontin (a pain relief medication) is the most litigated drug trade name by number of cases. By number of asserted patents, Metformin Hydrochloride (diabietes drug AvKARE) is the most frequently litigated ingredient. The vast majority of cases and litigated patents involve prescription drugs (98.2% of cases, 98.1% of patents). Although a majority of litigated patents have no listed therapeutic equivalence (TE) code, the most common among those that do is AB ("products meeting the necessary bioequivalence requirements").

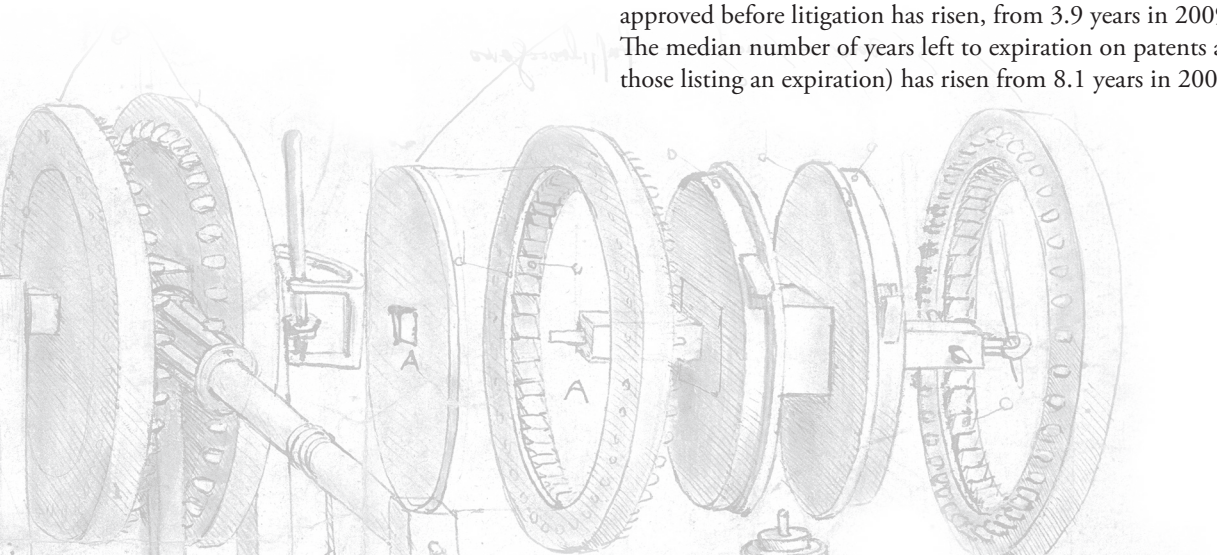
Since 2009, the median age of patents being litigated has generally declined, peaking at 10.4 years in 2011 before dropping to 5.1 in cases filed in 2014. Over the same time, the median time between approval and the filing of litigation for patents approved before litigation has risen, from 3.9 years in 2009 to 4.9 years in 2014. The median number of years left to expiration on patents at the time of approval (for those listing an expiration) has risen from 8.1 years in 2009 to 15.4 years today.

### Introduction

**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 as well as showing the ways in which ANDA litigation differs significantly from other, non-ANDA patent litigation.**



Lex Machina – Patent Litigation Damages Report

## Data and Methodolgy

This report considers the last 5 years of patent litigation related to Abbreviated New Drug Applications (ANDA) and paper New Drug Applications (paper NDA), including cases filed from 2009 through the end of September 2014.

Data derived from the Orange Book is current at the time of press (August 2014 update).

### *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 they 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 that the branded drug listed patents in the 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 and in the U.S. International Trade Commission (ITC). On a daily basis, Lex Machina requests and receives data from the various 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).

## Table of Contents

### ANDA Litigation by Court, Judge, and Year

Figure 1: Top 15 judges for ANDA cases 2
Figure 2: Top 15 districts for Hatch-Waxman cases 2
Figure 3: ANDA cases, by year (showing partial 2014 - already a record year) 3
Figure 4: ANDA cases, by quarter 3
Figure 5: Top districts over time, by quarter (2009-2012) 4
Figure 6: Top districts over time, by quarter (2013-2014) 4

### ANDA vs Non-ANDA cases

Figure 7: Total patent cases filed, by year 5
Figure 8: Injunctions in terminated cases 5
Figure 9: Outcomes in terminated cases 6
Figure 10: Median Costs 7
Figure 11: Median Attorneys' Fees 7
Figure 12: Word cloud of ingredients, sized by number of asserted patents and colored by number of cases 8
Figure 13: Word cloud of trade names, sized by number of cases and colored by number of asserted patents (omitting tradenames with less than 3 cases) 8

### Trade names, Ingredients and Other Orange Book Data

Figure 14: Relationship between number of cases filed and number of patents asserted, for top ingredients with more than 10 cases and more than 10 patents 9
Figure 15: Application types, by number of cases and number of asserted patents 9
Figure 16: Therapeutic equivalence (TE) codes, by number and percentage of asserted patents having each code 10
Figure 17: TE codes, chart 11
Figure 18: Orange Book TE code definitions 11
Figure 19: Drug and product flags, by patent assertions 11

### Patent Age, Case Timing, and Approval Dates

Figure 20: Median patent age at time of case filing, by year of case filing (omitting assertions where the patent was filed after the case) 12
Figure 21: Median FDA approval of NDA to case filing, by year of case filing 12
Figure 22: Patent age at time of case filing, by years (omitting assertions where the patent was filed after the case) 13
Figure 23: FDA approval of NDA to case filing, by year of case filing 14
Figure 24: Time before expiration at approval, by year of case filing, based on reported expiration 15
Figure 25: Median time before expiration at approval, by year of case filing, based on reported expiration 16

## ANDA Litigation by Court, Judge, and Year

*Figure 1: Top 15 districts for Hatch-Waxman cases*

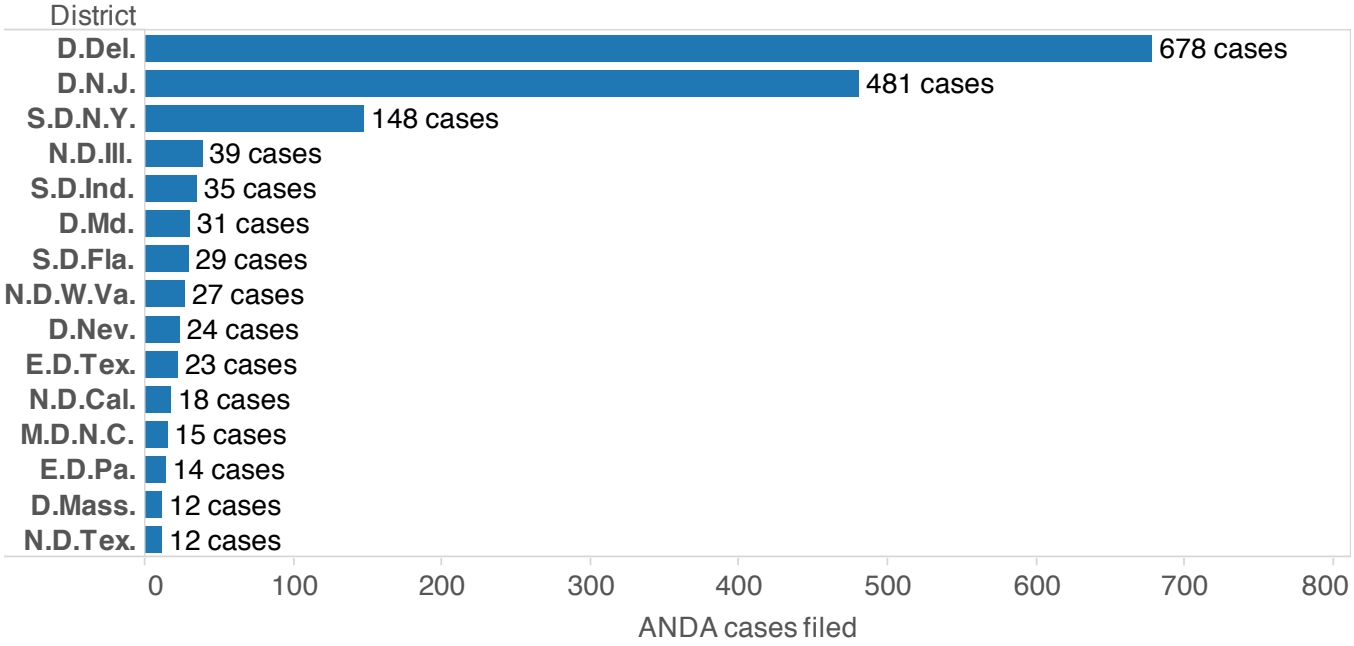



*Figure 2: Top 15 judges for ANDA cases*

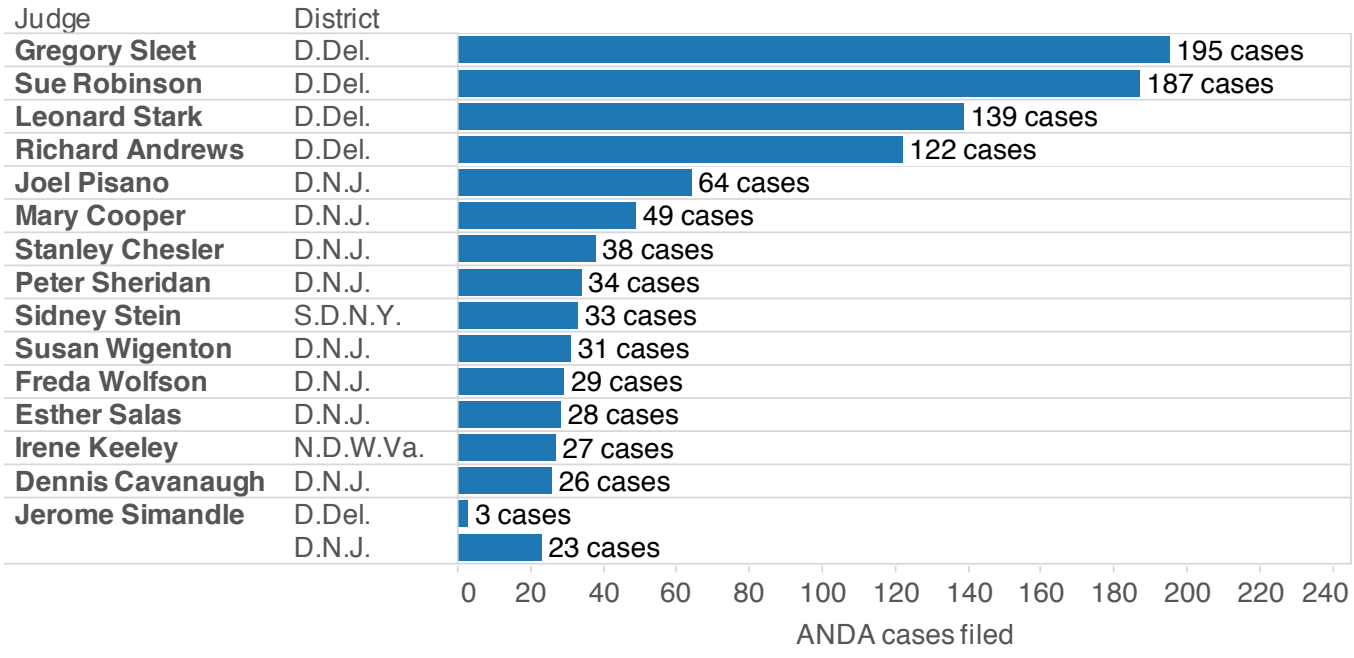


*Figure 3: ANDA cases, by year (showing partial 2014 - already a record year)*

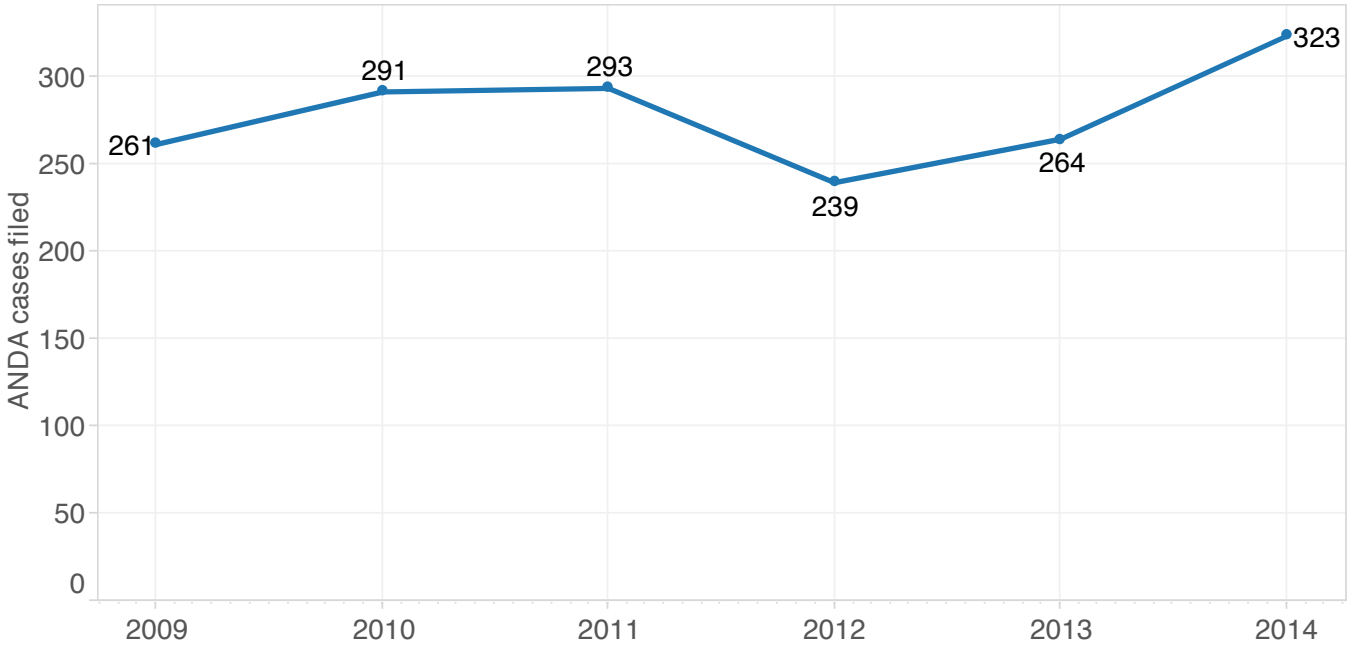



*Figure 4: ANDA cases, by quarter*

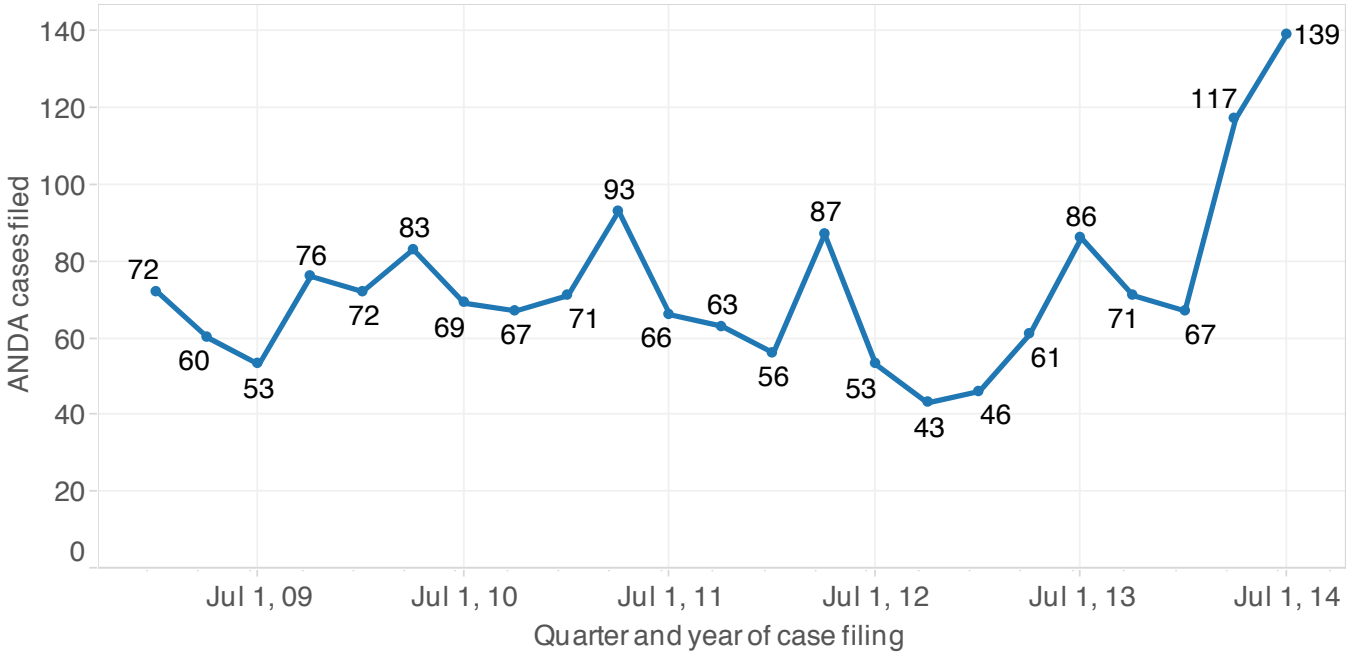


*Figure 5: Top districts over time, by quarter (2009-2012)*

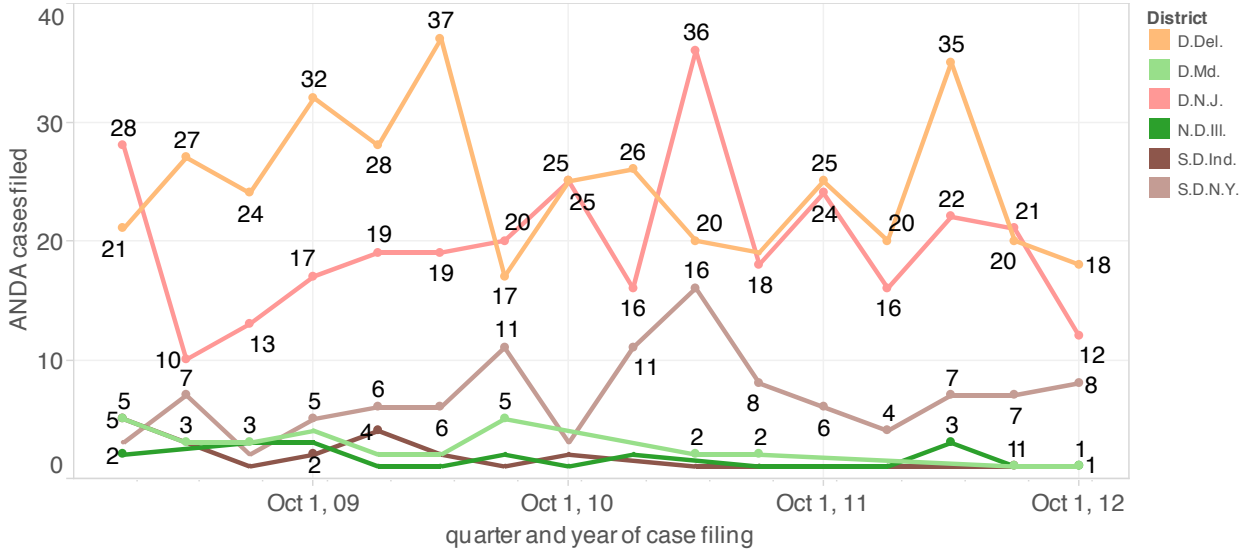
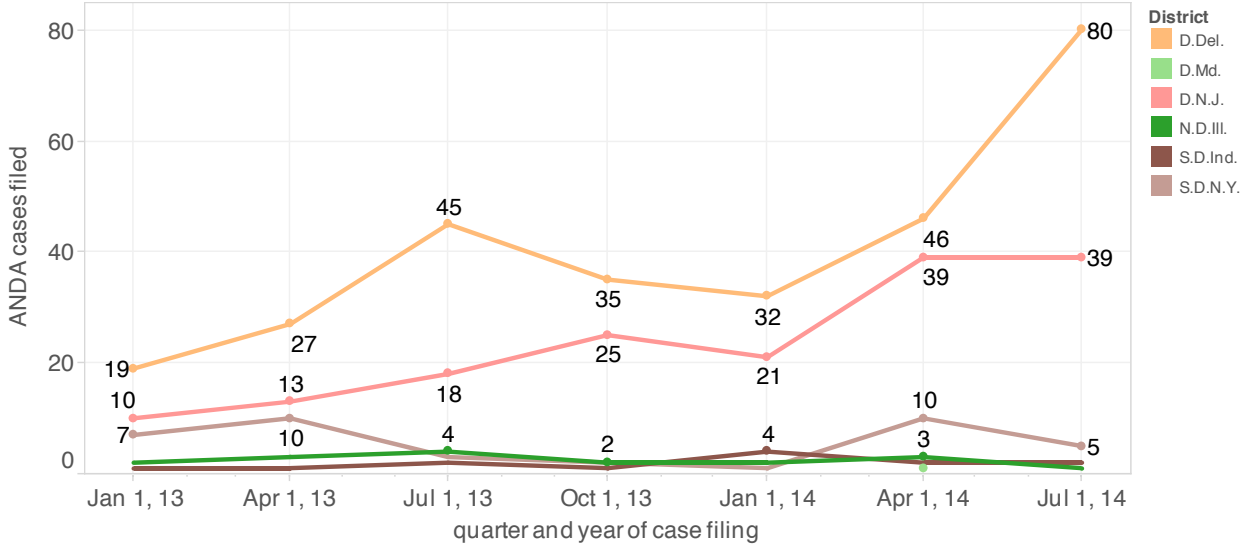



*Figure 6: Top districts over time, by quarter (2013-2014)*



**ANDA vs Non-ANDA cases**

*Figure 7: Total patent cases filed, by year*

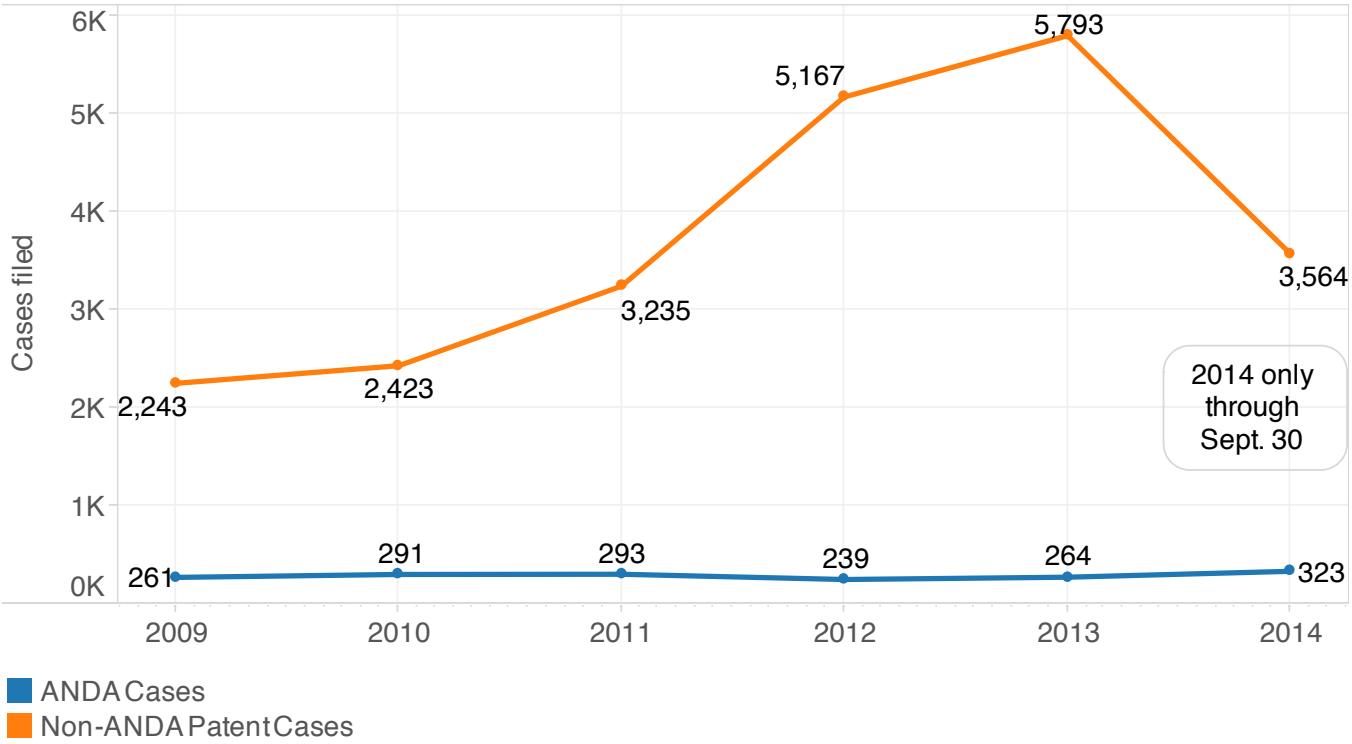



*Figure 8: Injunctions in terminated cases*

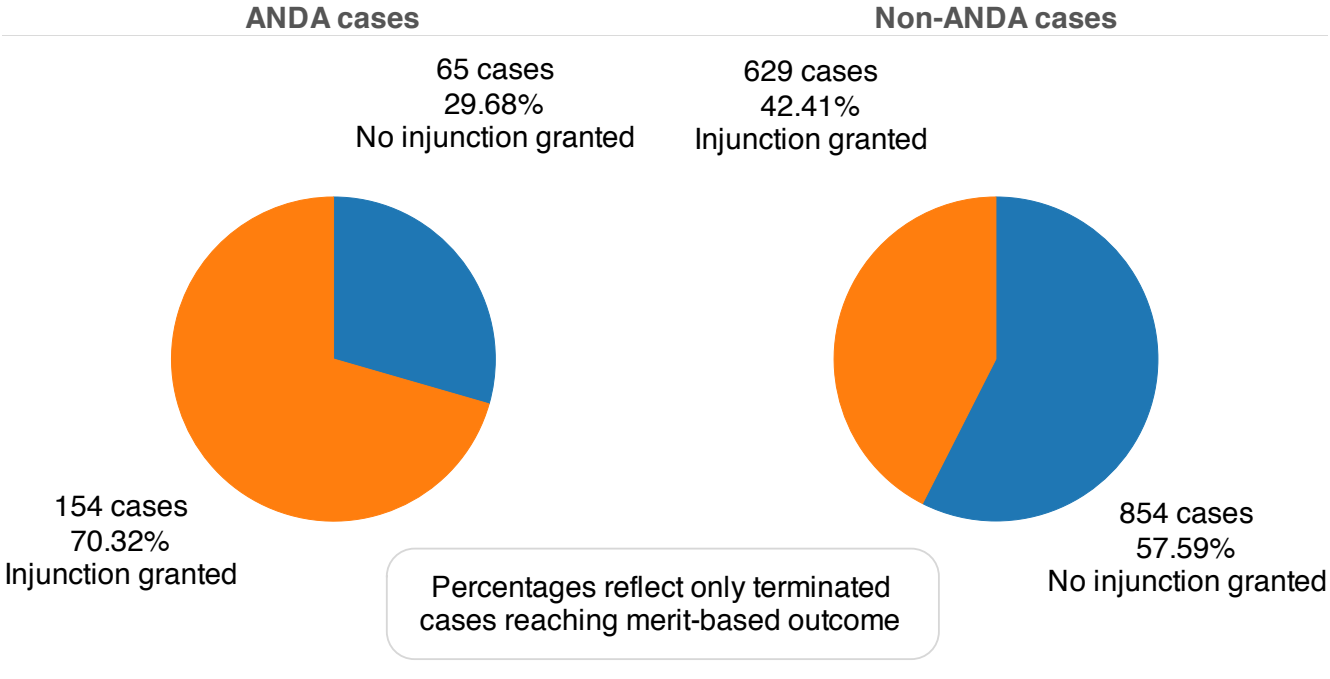


*Figure 9: Outcomes in terminated cases*

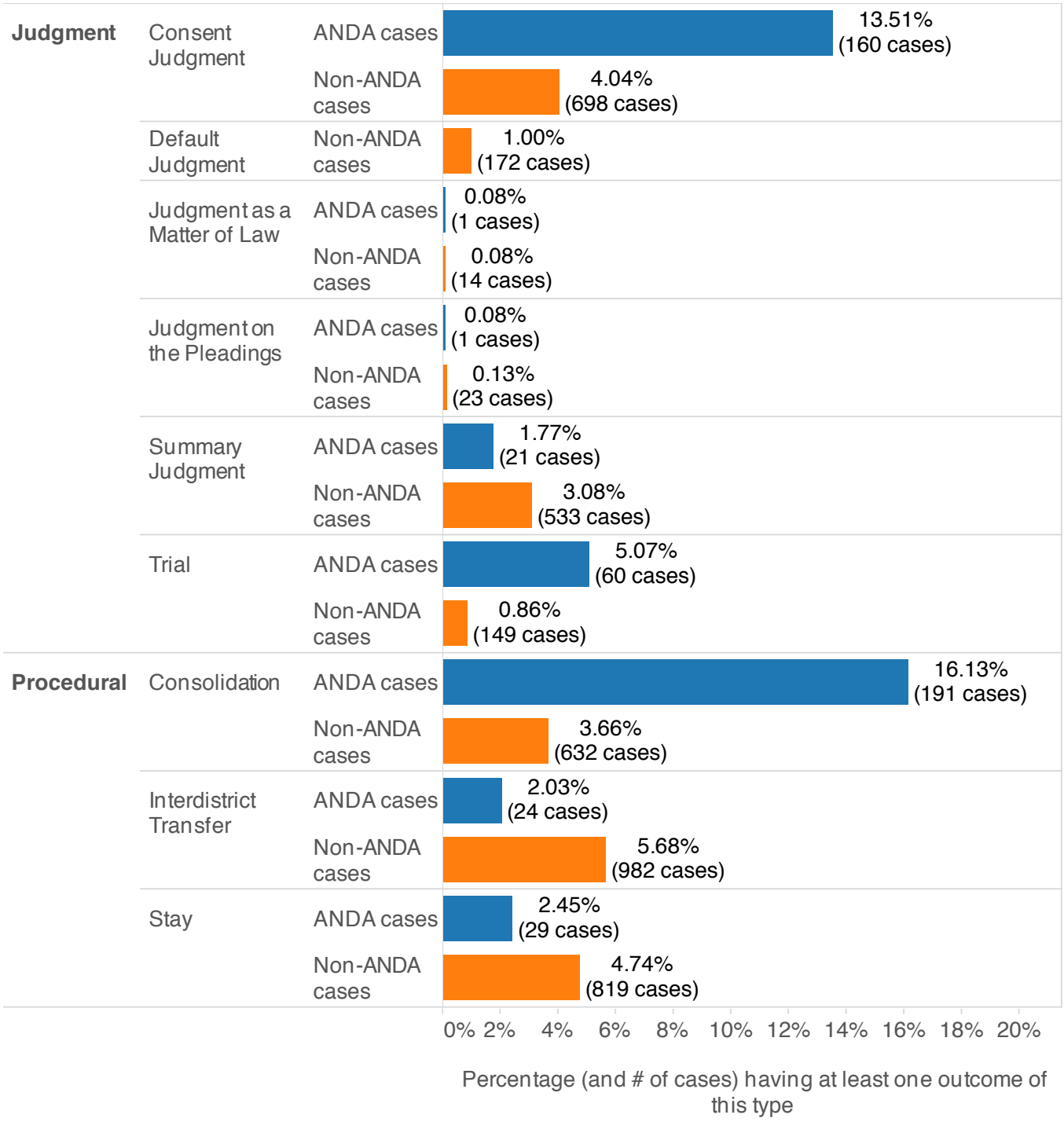
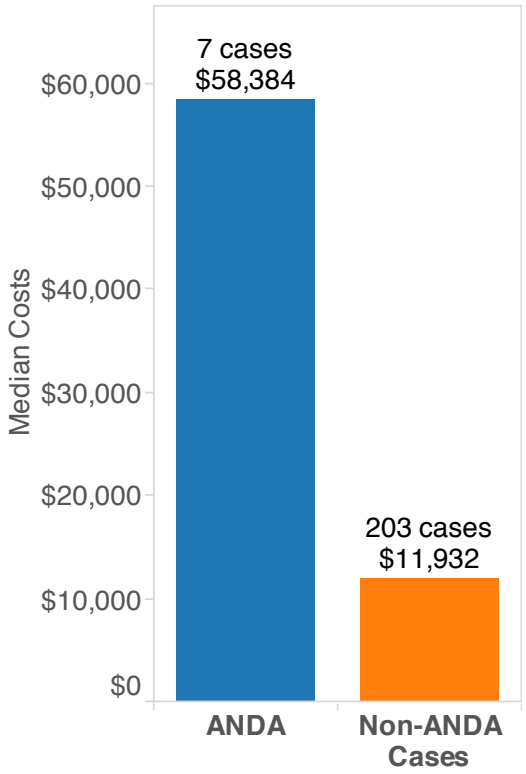
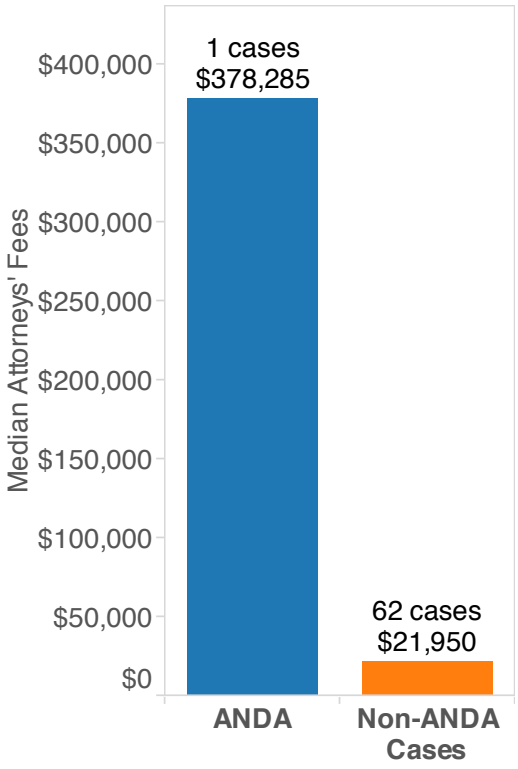


*Figure 10: Median Costs*




The costs shown above are the clerical costs (e.g. witness and deponent per-diems, costs of transcripts, photocopying expenses, etc.) provided for in 28 U.S.C. § 1920, which Fed. R. Civ. P. Rule 54(d)(1) allows a prevailing party to recover from its opponent.

*Figure 11: Median Attorneys' Fees*




Single ANDA case is *Pfizer Inc., et al v. Teva Pharmaceuticals USA, Inc.*, E.D.Va., 2:10-cv-00128, awarded in October, 2011

## Trade names, Ingredients and Other Orange Book Data

*Figure 12: Word cloud of ingredients, sized by number of asserted patents and colored by number of cases*

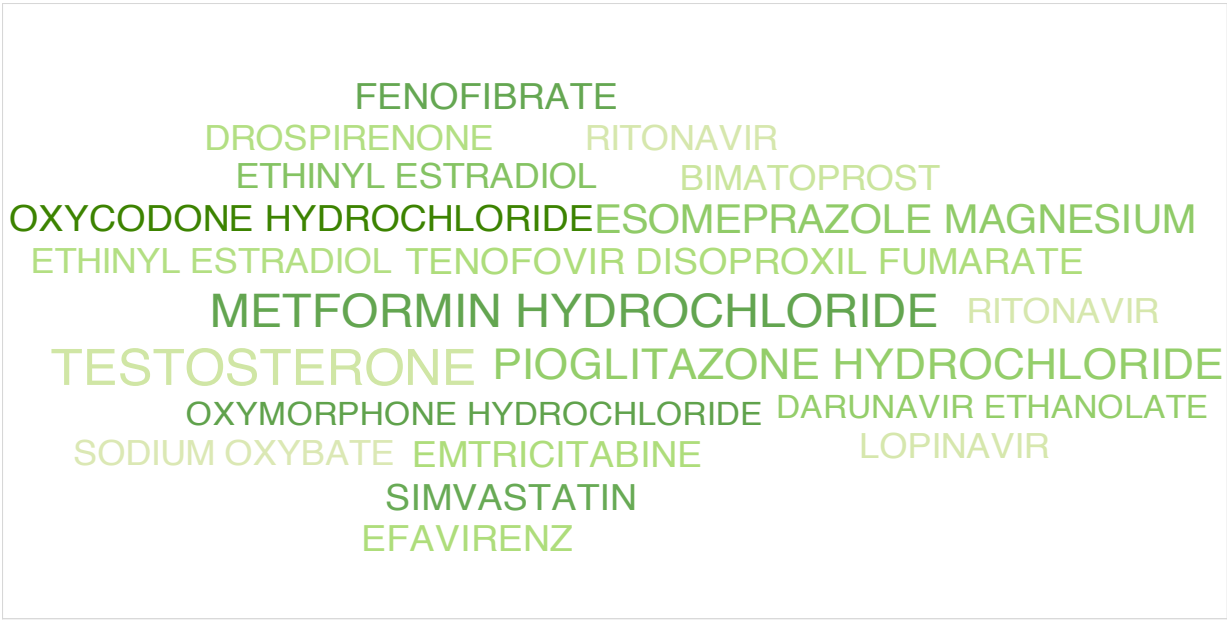



*Figure 13: Word cloud of trade names, sized by number of cases and colored by number of asserted patents (omitting tradenames with less than 3 cases)*

*Figure 14: Relationship between number of cases filed and number of patents asserted, for top ingredients with more than 10 cases and more than 10 patents*

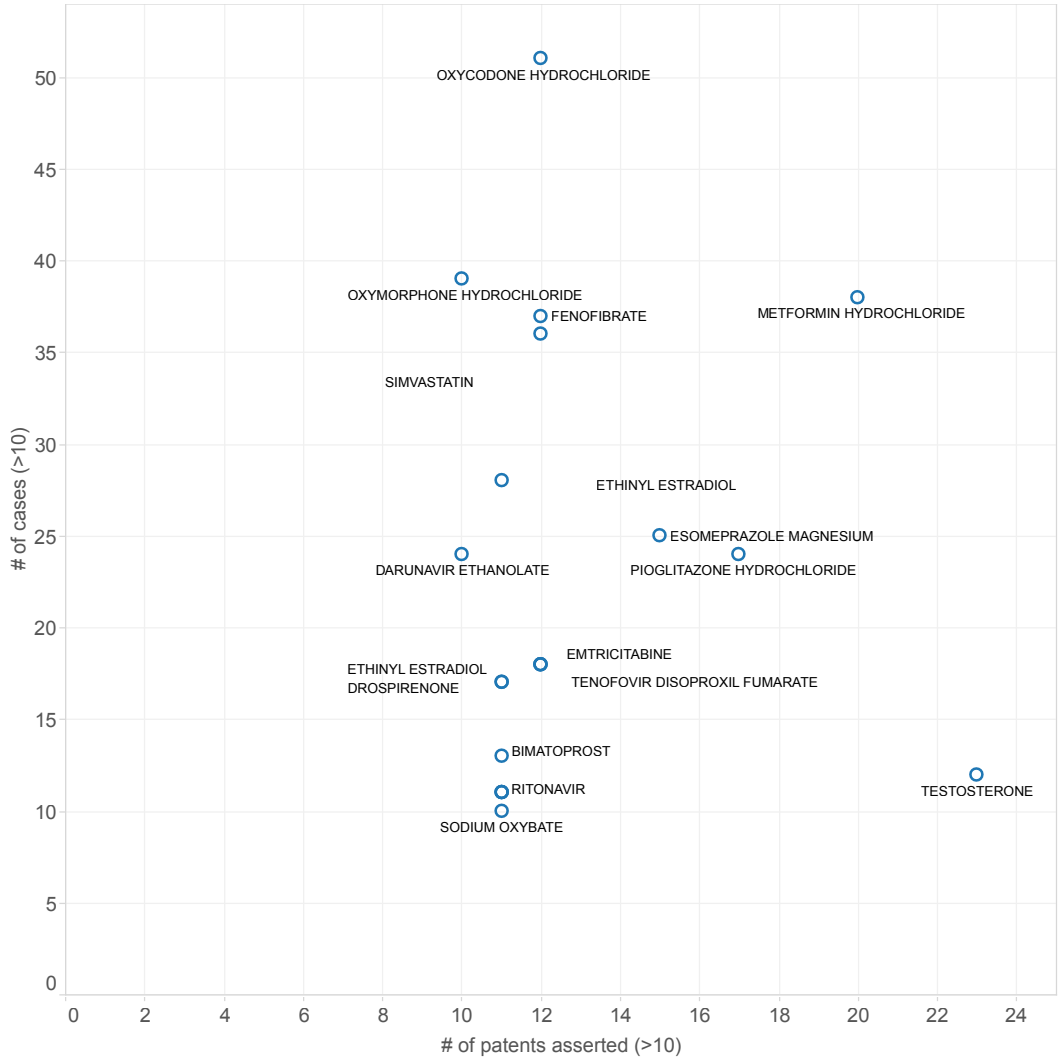
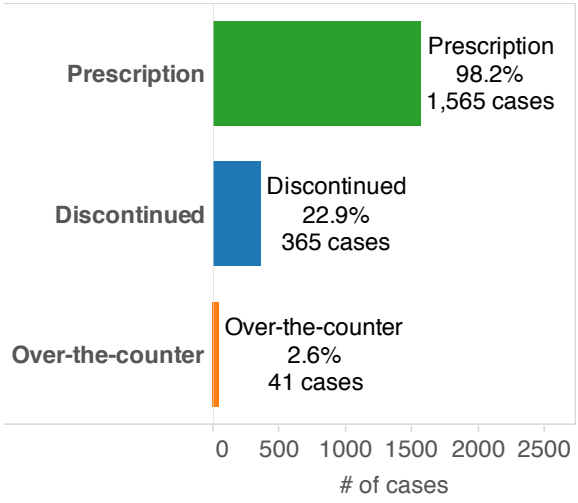



*Figure 15: Application types, by number of cases and number of asserted patents*



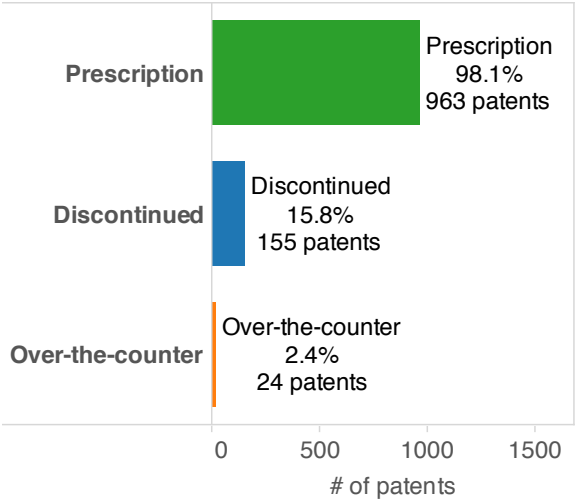
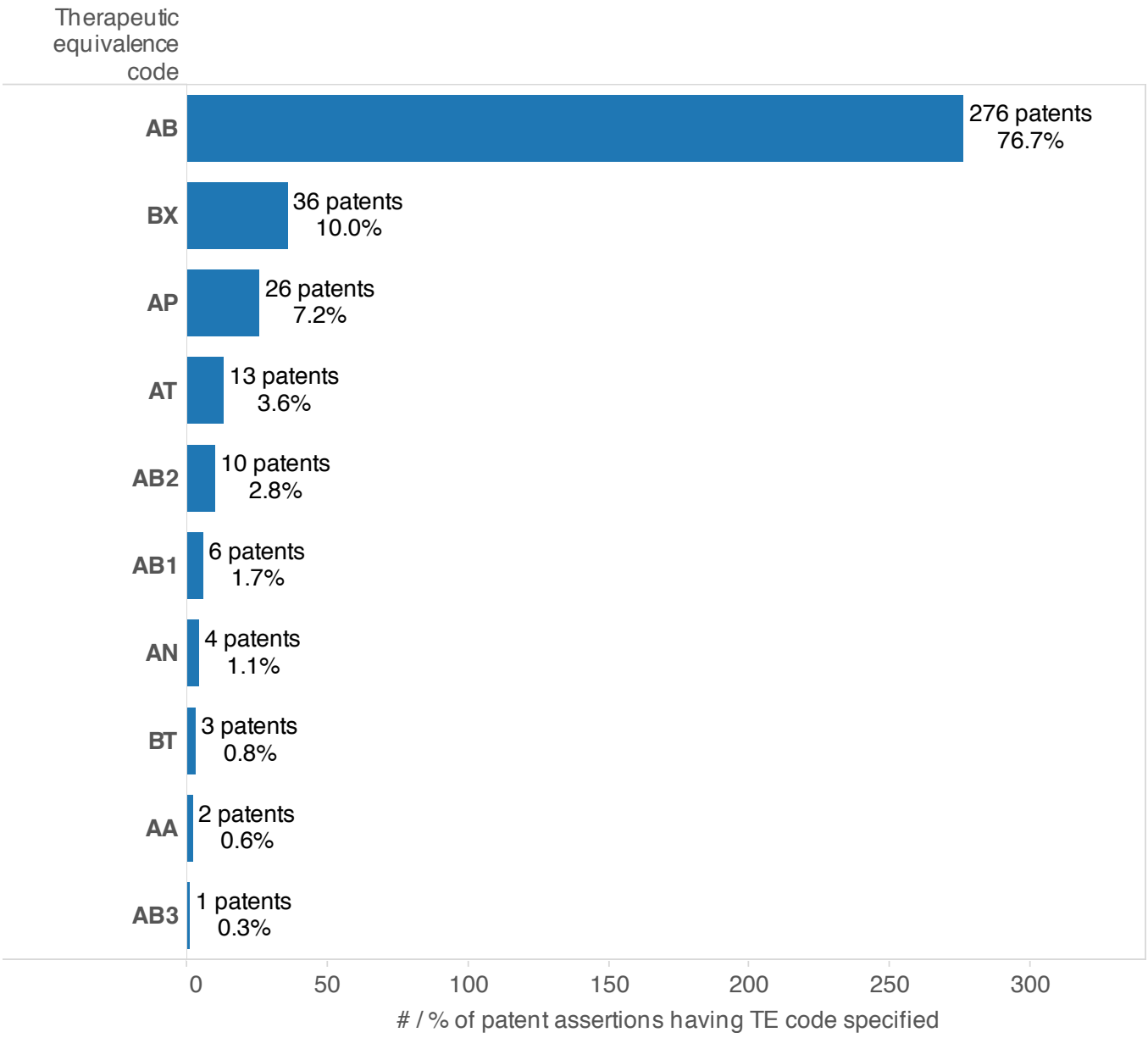



*Figure 16: Therapeutic equivalence (TE) codes, by number and percentage of asserted patents having each code*




A patent may be cited by more than one Orange Book NDA application. When a patent corresponds to multiple categories of Orange Book information (e.g. one application contains a AB code, while the other contains a BT code) that patent is counted once for each applicable category.

*Figure 17: TE codes, chart*

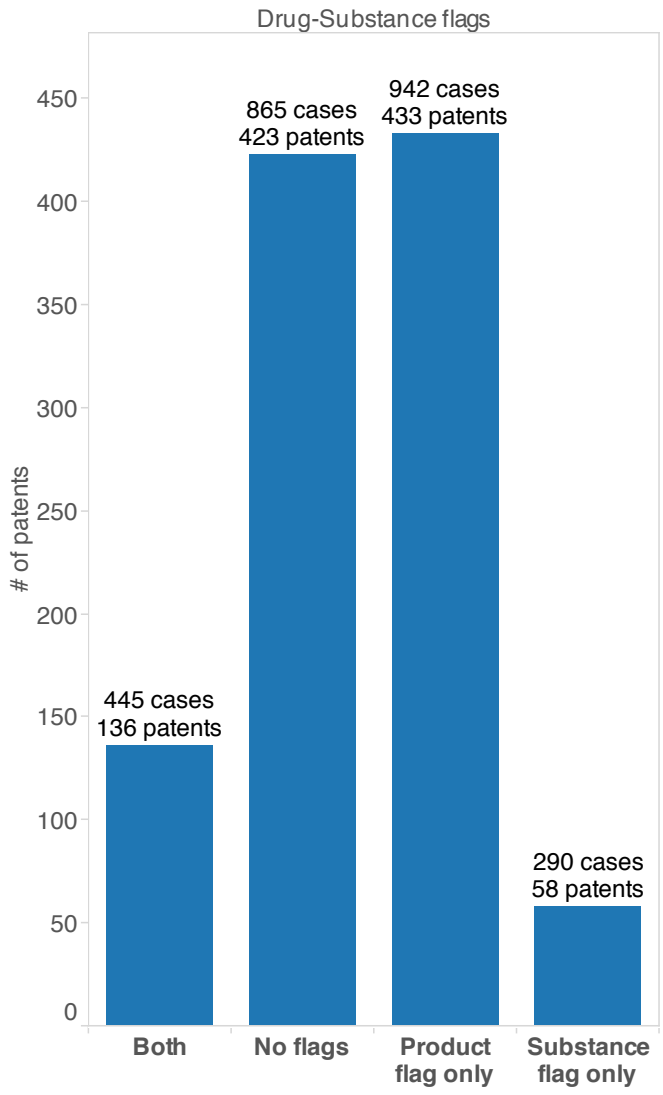
| Therapeutic equivalence code | |
|---|---|
| AA | 2 patents<br>3 cases |
| AB | 276 patents<br>562 cases |
| AB1 | 6 patents<br>25 cases |
| AB2 | 10 patents<br>16 cases |
| AB3 | 1 patents<br>1 cases |
| AN | 4 patents<br>6 cases |
| AP | 26 patents<br>73 cases |
| AT | 13 patents<br>24 cases |
| BT | 3 patents<br>6 cases |
| BX | 36 patents<br>51 cases |
| No code specified | 725 patents<br>1,166 cases |

*Figure 18: Orange Book TE code definitions*

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

*Figure 19: Drug and product flags, by patent assertions*




A patent may be cited by more than one Orange Book NDA application. When a patent corresponds to multiple categories of Orange Book information that patent is counted once for each applicable code. For example, if a patent had two applications, one with no flags, and the other with both, it would be represented in the "Both" and "No flags" counts above.

## Patent Age, Case Timing, and Approval Dates

*Figure 20: Median patent age at time of case filing, by year of case filing (omitting assertions where the patent was filed after the case)*

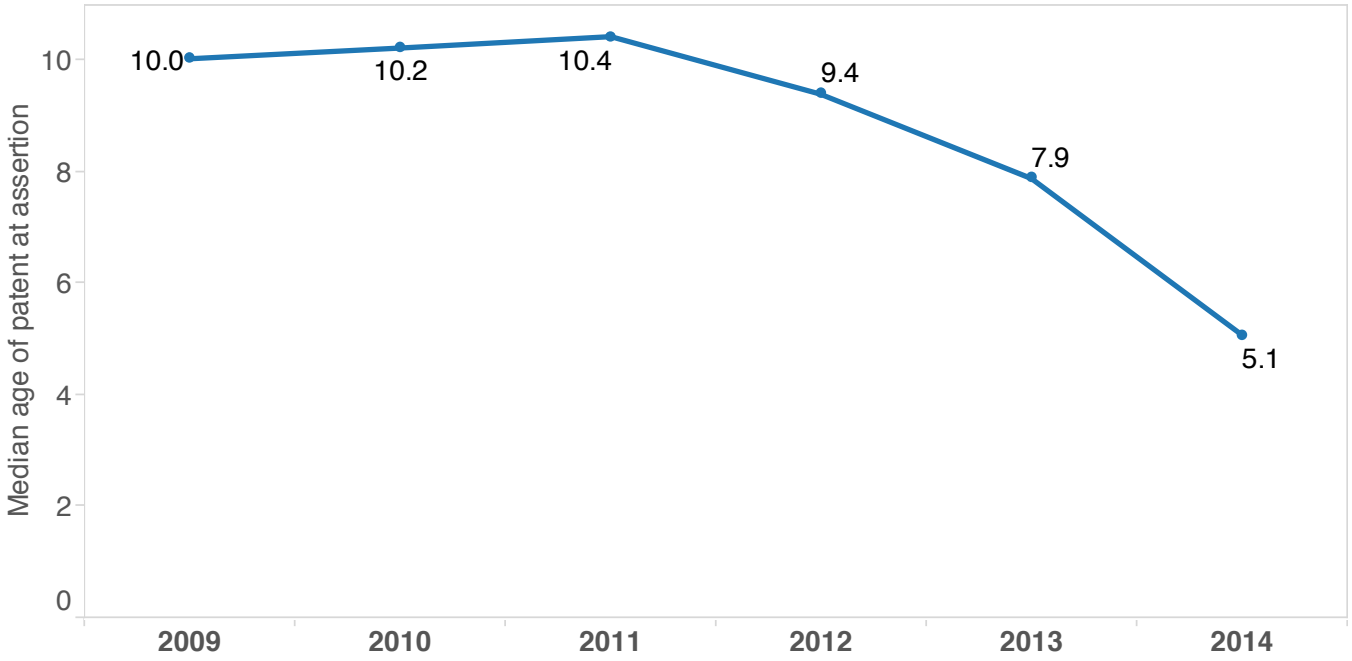



*Figure 21: Median FDA approval of NDA to case filing, by year of case filing*

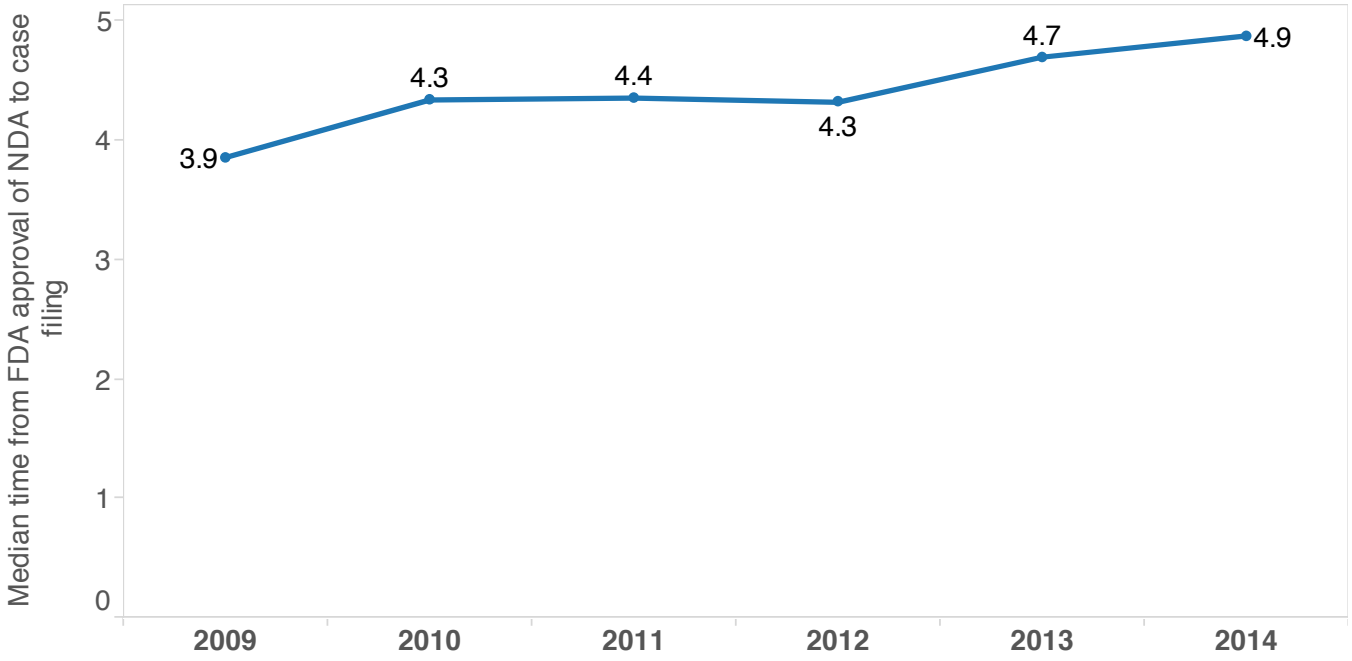
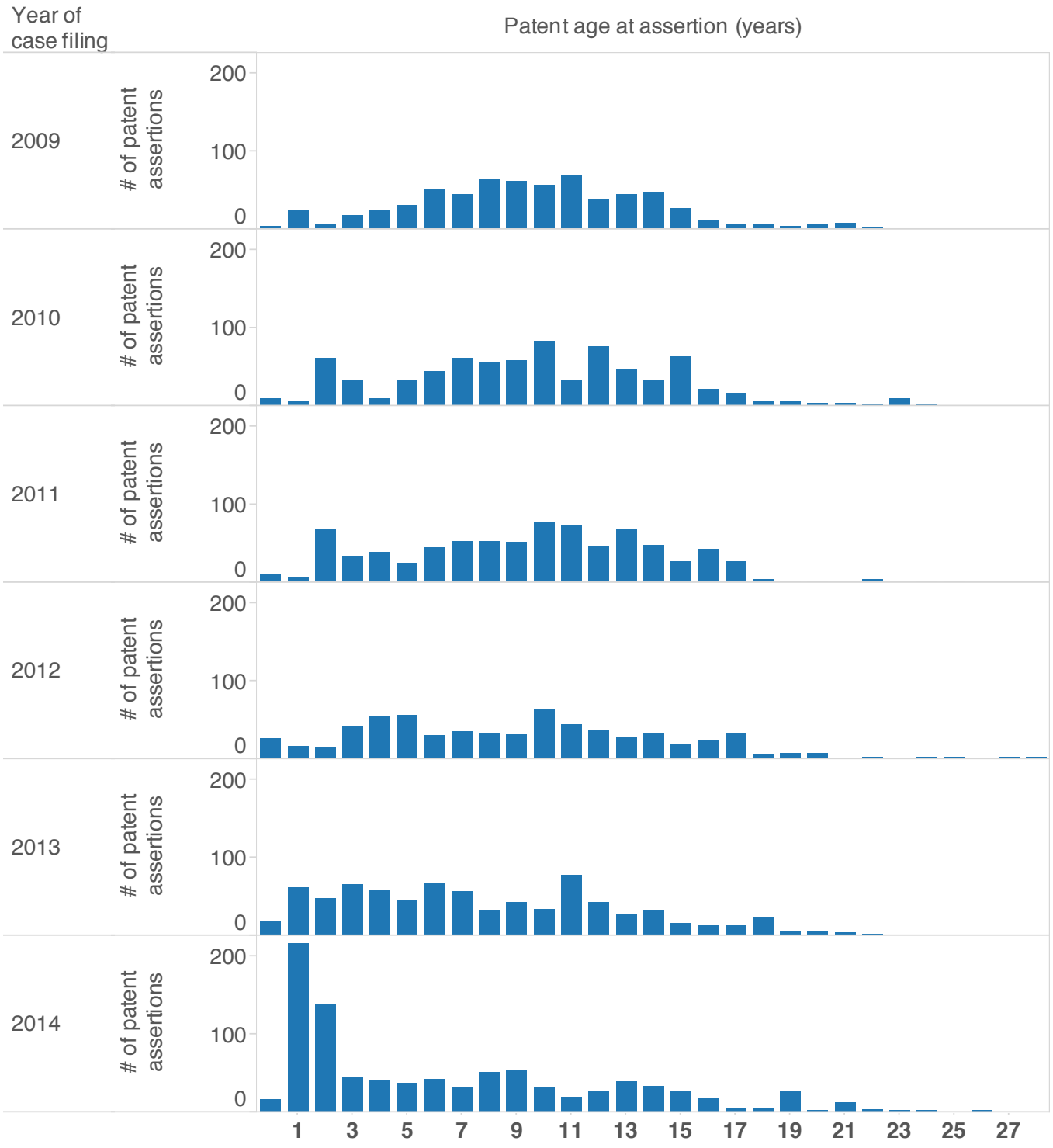
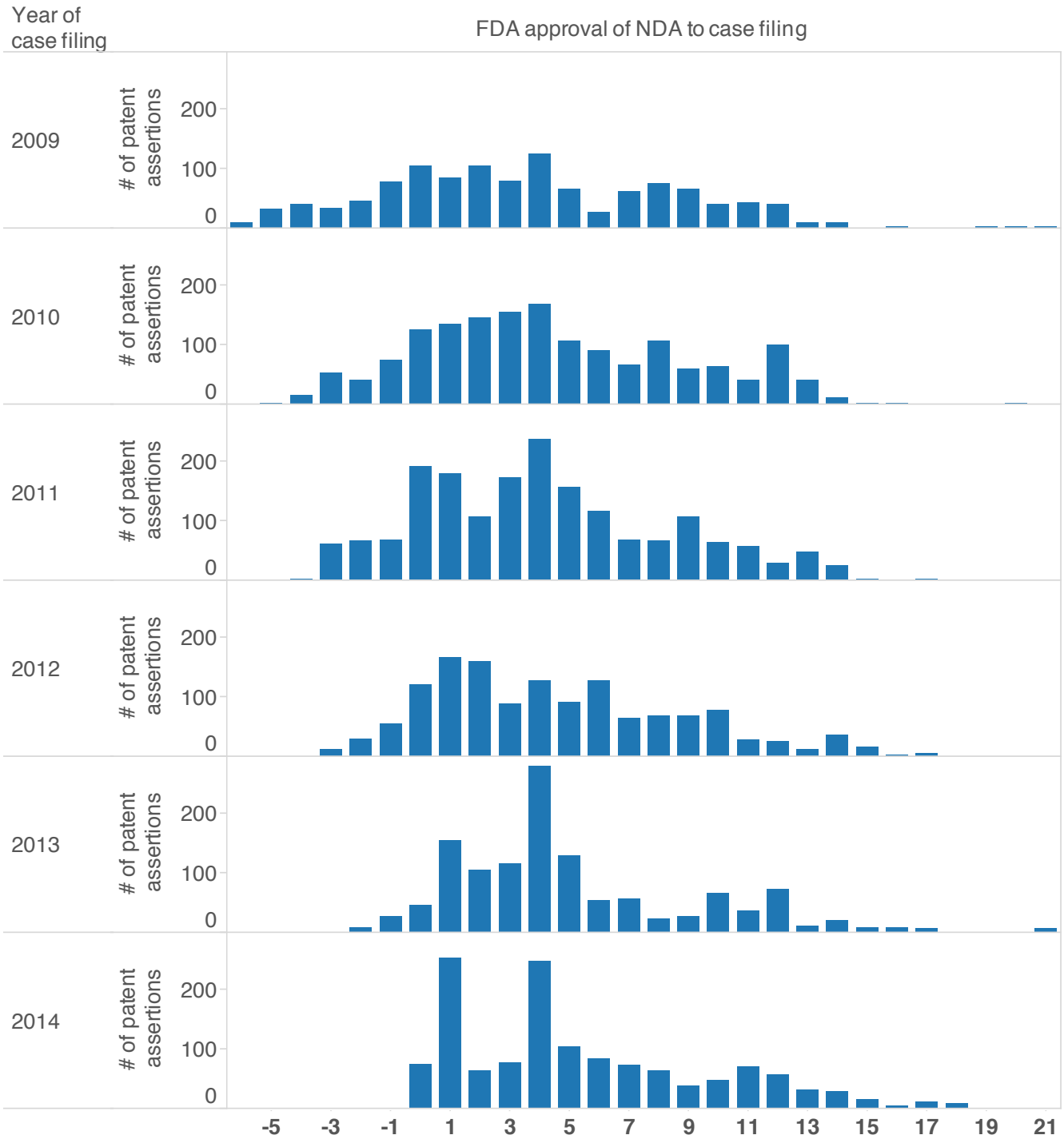


*Figure 22: Patent age at time of case filing, by years (omitting assertions where the patent was filed after the case)*




Outliers omitted.

*Figure 23: FDA approval of NDA to case filing, by year of case filing*




Negative times indicate case was filed before approval. Approval often happens before a case is filed, but does not necessarily have to. Negative numbers on the above chart represent the situations where approval was gained only after a case had been filed. Outliers omitted.

*Figure 24: Time before expiration at approval, by year of case filing, based on reported expiration*

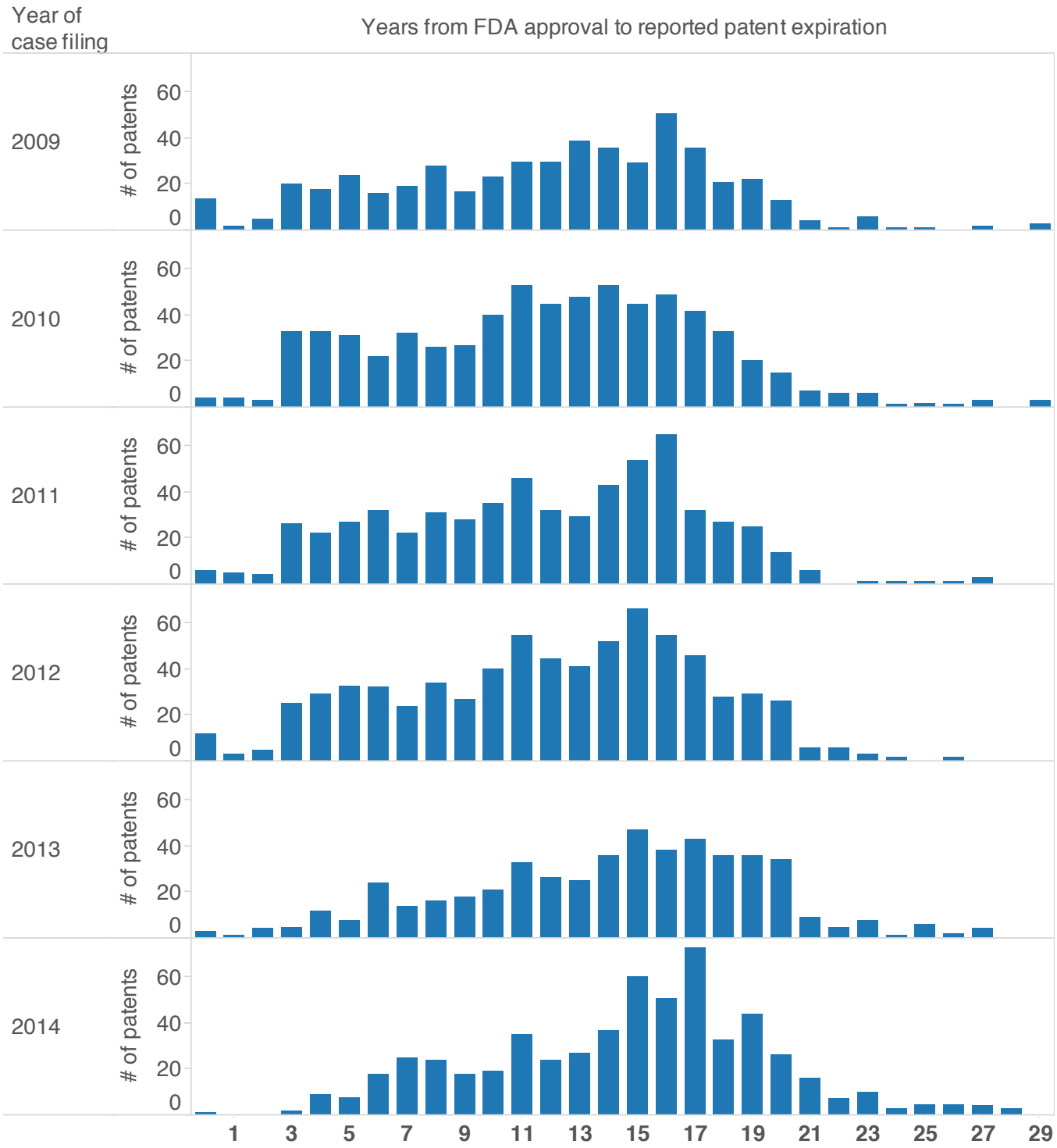
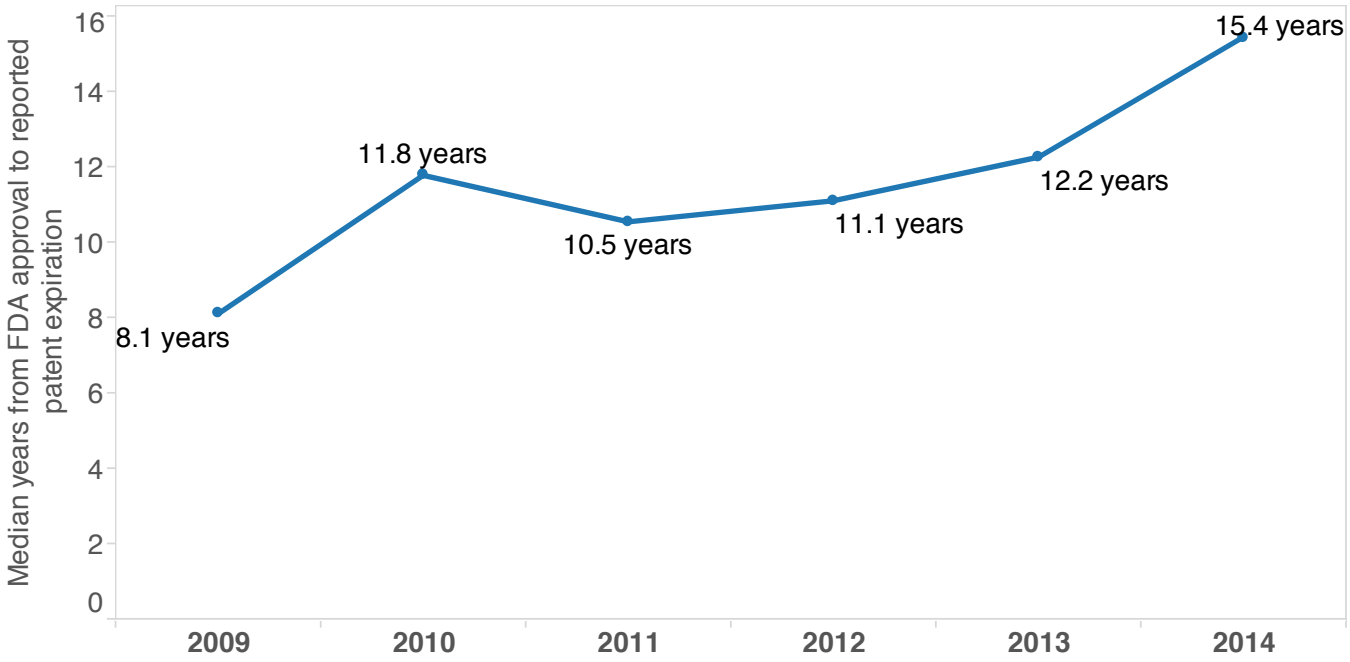


*Figure 25: Median time before expiration at approval, by year of case filing, based on reported expiration*



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