

2012 Patent Litigation Study

Litigation continues to rise amid growing awareness of patent value

1995-2011

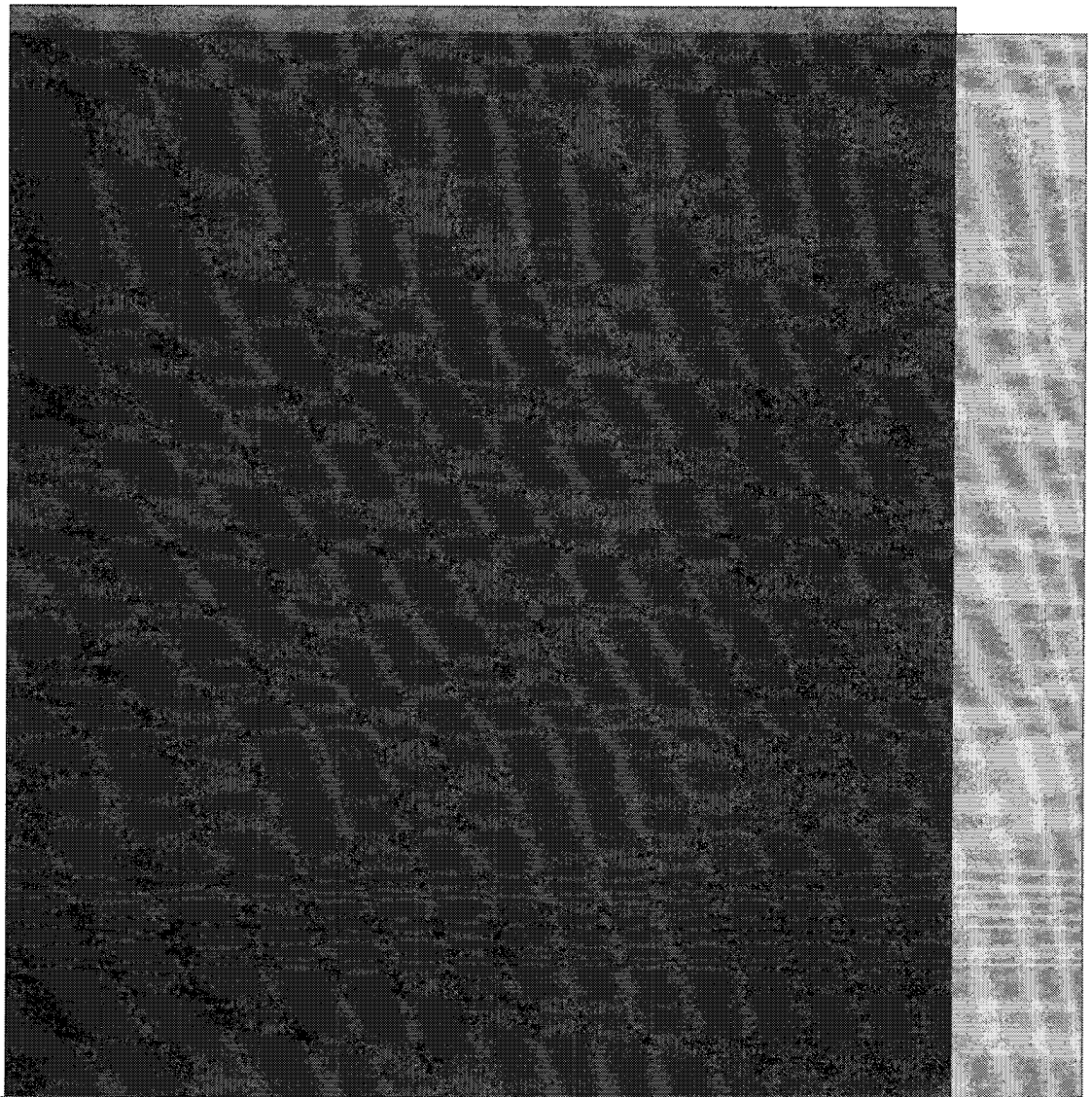


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Introduction

Last year marked the most significant change to the US patent system in almost 60 years. President Obama signed the Leahy-Smith America Invents Act (AIA) into law on September 16, 2011, converting the patent system from a 'first to invent' to a 'first inventor to file' system. The new law also changed inter partes reexamination proceedings and instituted post-grant opposition, among other reforms.

Despite these resounding changes, the AIA does not address the calculation of damages in patent infringement matters. In last year's *2011 Patent Litigation Study*, we commented that the absence of reform guidance in this area suggested that Congress believed that the subject of patent damages is best left for the courts to address and regulate. We further posited that the elimination of the 25 percent rule of thumb, as well as rulings in a variety of other court decisions, demonstrated that the courts, rather than Congress, would continue to shape the future of patent law and play the primary role in how patent damages are determined.

The events of the first half of 2012 affirmed these beliefs. In particular, with the 25 percent rule of thumb removed from the practitioner's royalty assessment toolkit, a complex mathematical proof for determining royalty apportionment, known as the Nash Bargaining Solution, has recently appeared in some patentees' damages calculations, receiving mixed reviews

from the courts. In *Oracle v. Google*, the Court excluded expert testimony partly because, "the Nash Bargaining Solution would invite a miscarriage of justice by clothing a fifty-percent assumption in an impenetrable facade of mathematics." The Court concluded that, "Instead, the normal Georgia-Pacific factors, which have been approved by the Court of Appeals for the Federal Circuit and which are more understandable to the average fact-finder, will guide our reasonable royalty analysis."

Conversely, in *Mformation Techs v. Research in Motion*, the Court did not exclude expert testimony that referenced the Nash Bargaining Solution, noting that the expert used the technique only as a reasonableness check against a royalty rate determined through analysis of the Georgia-Pacific factors, the time-tested standard approach. To date, the Court of Appeals for the Federal Circuit has not had the opportunity to squarely address use of the Nash Bargaining Solution in determining reasonable royalty damages.

The broader lesson of these decisions, among others issued in recent years, is that the courts have been applying greater scrutiny to damages assessments in patent infringement matters; we expect this to continue. Patent litigation counsel and parties should monitor ongoing rulings that could affect damages opinions and methodologies.

New to this year's study is an analysis of Abbreviated New Drug Application (ANDA) cases, which are increasingly prevalent in the dockets. The volume of such cases has increased substantially over the last five years, and the success rates experienced by the patent holders, or the brand drug manufacturers, have to date been higher than traditional patent actions.

2011 proved to be a historic year for strategic intellectual property acquisitions, particularly in the telecommunications sector, which saw two high-profile acquisitions of patent portfolios:

- 1) The 'Rockstar Group', a consortium of buyers including Apple, Microsoft, Research in Motion, and Sony, acquired the 6,000-patent portfolio of the defunct Nortel Networks for \$4.5 billion in July 2011.
- 2) About a month later, Google acquired Motorola Mobility for \$12.5 billion, reportedly for its extensive 17,000-patent portfolio to protect the Android operating system from patent lawsuits.

As the stakes for patent infringement litigation remain high, we expect such strategic patent acquisitions will continue to make headlines.

Summary of key observations

Recognizing these developments and business leaders' continuing deep interest in intellectual property matters, PwC maintains a database of patent damages awards extending from 1980 through 2011. We collect information about patent holder success rates, time-to-trial statistics, and practicing versus nonpracticing entity (NPE) statistics from 1995 through 2011. This year's study also includes data related to ANDA litigation.

Our analysis yields a number of observations that can help executives, legislators, and litigators assess their patent enforcement or defense strategies, as well as the impact of NPEs.

- Annual median damages awards (in 2011 dollars) ranged from \$1.9 million to \$16.1 million between 1995 and 2011. The median damages award from 2006 to 2011 was approximately \$4.0 million.
- Damages awards for NPEs averaged almost double those for practicing entities over the last decade.
- The disparity between jury and bench awards continues to widen as the median jury award amounted to more than 20 times the median bench award between 2006 and 2011.
- Reasonable royalties remain the predominant measure of patent damages awards, representing more than 80% of awards over the last six years.
- NPEs have been successful 23% of the time overall versus 34% for practicing entities, due to the relative lack of success for NPEs at summary judgment. However, both have about a two-thirds success rate at trial.
- The median damages award in the telecommunications industry was significantly higher than that in other industries. Other industries with higher relative median damages awards include biotechnology/pharma, medical devices, and computer hardware/electronics.
- While the median time-to-trial has remained fairly constant, averaging 2.3 years since 1995, we see significant variations among jurisdictions.
- Certain federal district courts (particularly Virginia Eastern, Delaware, and Texas Eastern) continue to be more favorable to patent holders, with shorter time-to-trial durations, higher success rates, and larger median damages awards.
- The top five federal district courts (out of a total of 94) accounted for 38% of all identified decisions involving an NPE as the patent holder. The Eastern District of Texas accounted for 12% of NPE decisions.
- All NPEs are not created equal. While university/non-profit NPEs have the highest success rate among NPE litigants, their median damages award is considerably lower than the median award of company NPEs.
- While ANDA litigation continues to grow rapidly, success rates since 2006 have varied significantly, given the small number of cases that reach a dispositive court conclusion.

Patent actions rise dramatically, set record high

Chart 1

2011 saw continued growth in patent actions filed and patents granted

As Chart 1 illustrates, the annual number of patent actions filed has increased at an overall compound annual growth rate (CAGR) of 6.4% since 1991. We attribute this upswing in part to a 22% increase in the number of filings in 2011 over

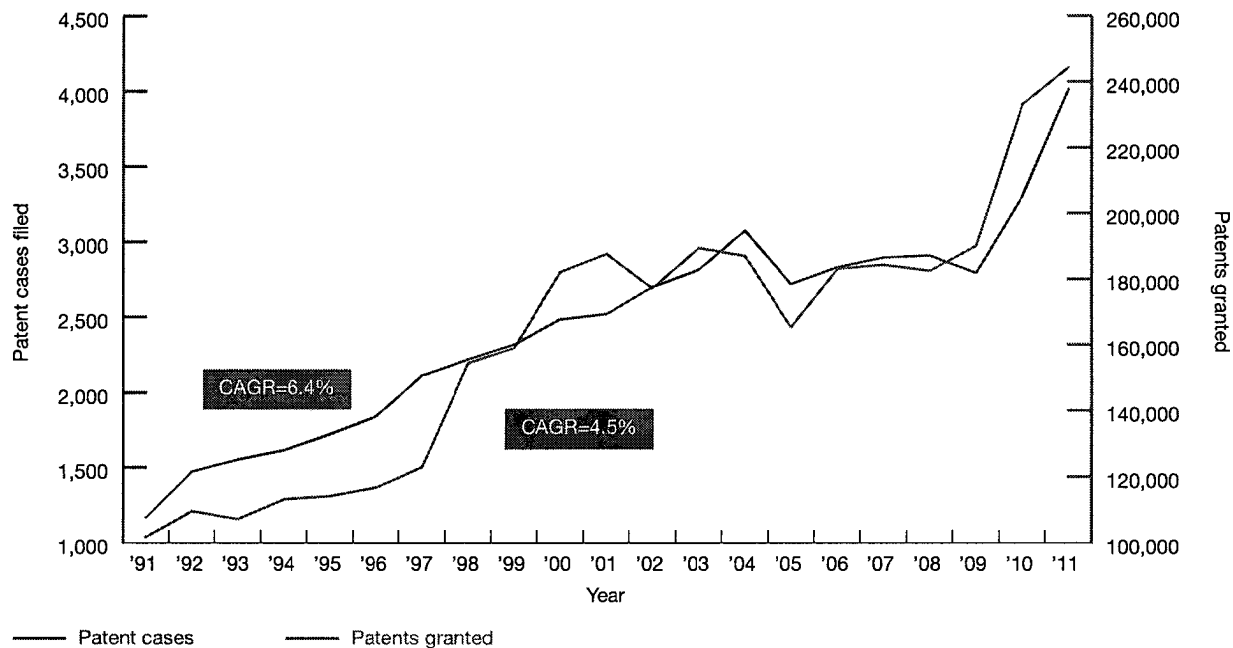
2010. The number of patent actions filed reached 4,015 in 2011—the highest number of annual filings ever recorded.

Meanwhile, the number of patents granted by the United States Patent and Trademark Office (USPTO) has also grown steadily, increasing at a CAGR of 4.5% since 1991 and increasing by 5% in 2011 to 244,430.

While this continues the upward trend in patents granted, it's moderated from the 23% growth rate we saw between 2009 and 2010, more closely paralleling the historical CAGR.

As the chart further shows, 2011 continued the trend of high correlation (approximately 96% since 1991) between patent cases filed and patents granted by the USPTO.

Chart 1. Patent case filings and grants



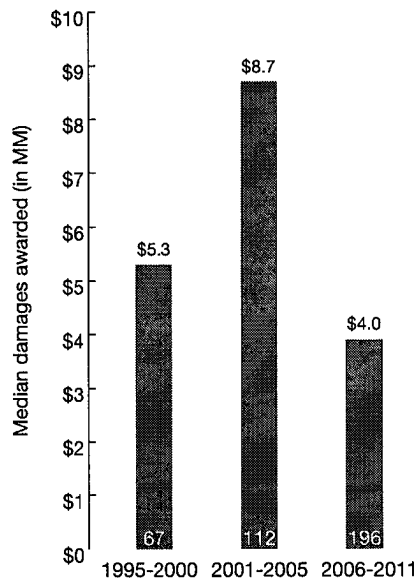
Years are based on September year-end
 Sources: US Patent and Trademark Office: Performance & Accountability Report and US Courts: Judicial Facts & Figures

Median damages award declines

Chart 2a

Adjusting for inflation using the consumer price index (CPI), the annual median damages award ranged from \$1.9 million to \$16.1 million between 1995 and 2011, with an overall median award of \$5.3 million over the last 17 years. As Chart 2a illustrates, when we segment the time period from 1995 through 2011 into approximate thirds, we see that the median damages award over the most recent period represents the lowest relative point, falling to less than half of the median award between 2001 and 2005.

Chart 2a. Patent holder median damages awarded



Median damages are adjusted for inflation and represented in 2011 US dollars.

The number of cases is indicated within the respective column.

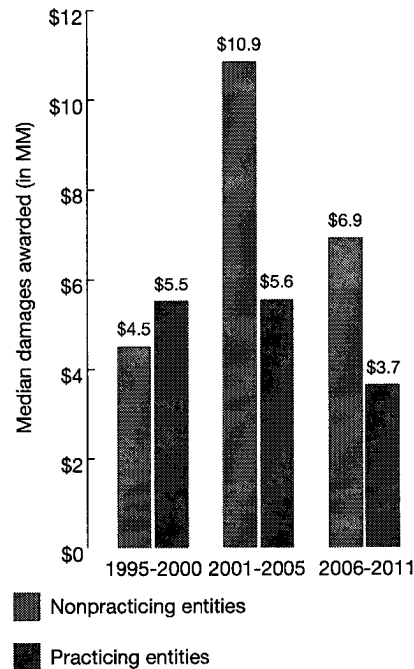
NPE awards outpace practicing entities

Chart 2b

Over the last decade, median damage awards for NPEs have significantly outpaced those of practicing entities.

Chart 2b shows the continuation of a trend that started in 2001: a wide variance (almost double in the last decade) in the damages awarded to NPEs compared to those awarded to practicing entities.

Chart 2b. Patent holder median damages awarded: nonpracticing entities vs. practicing entities



Median damages are adjusted for inflation and represented in 2011 US dollars.

The largest historical awards have rarely been upheld

Chart 2c

Enormous damages awards continue to garner headlines and keep corporate management keenly aware of the risks of potential infringement, as well as the rewards of enforcing patent rights. Chart 2c displays the top 10 damages awards in federal district courts since 1995. In 2011, one

decision cracked the top 10 list: a \$593 million damages award to Dr. Bruce Saffran against Johnson & Johnson. This award represents Dr. Saffran's second award in the top 10. Dr. Saffran had previously been awarded \$432 million in damages against

Boston Scientific, later settled for \$50 million. It is important to note that the awards reflected in Chart 2c are those identified during initial adjudication; most of these awards have since been vacated, remanded, or reduced, while some remain in the appellate process.

Chart 2c. Top 10 largest initial adjudicated damages awards: 1995–2011

Year	Plaintiff	Defendant	Technology	Award (in MM)
2009	Centocor Ortho Biotech Inc.	Abbott Laboratories	Arthritis drugs	\$1,848
2007	Lucent Technologies Inc.	Microsoft Corp.	MP3 technology	\$1,538
2010	Mirror Worlds LLC	Apple Inc.	Operating system	\$626
2011	Bruce N. Saffran M.D.	Johnson & Johnson	Drug-eluting stents	\$593
2003	Eolas Technologies Inc.	Microsoft Corp.	Internet browser	\$521
2008	Bruce N. Saffran M.D.	Boston Scientific Corp.	Drug-eluting stents	\$432
2009	Uniloc USA Inc.	Microsoft Corp.	Software activation technology	\$388
2008	Lucent Technologies Inc.	Microsoft Corp.	Data entry technology	\$368
2006	Rambus Inc.	Hynix Semiconductor Inc.	Memory chips	\$307
2009	i4i Limited Partnership	Microsoft Corp.	Electronic document manipulation technology	\$277

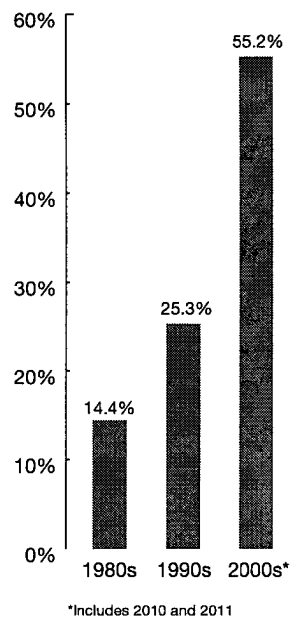
Jury trials are favored

Chart 3a

Juries have become the preferred trier of fact

Unlike the 1980s and 1990s, the last decade has seen juries evolve as the preferred trier of fact in patent infringement litigation. This preference is probably linked to the higher median damages awarded by juries.

Chart 3a. Use of jury trials by decade

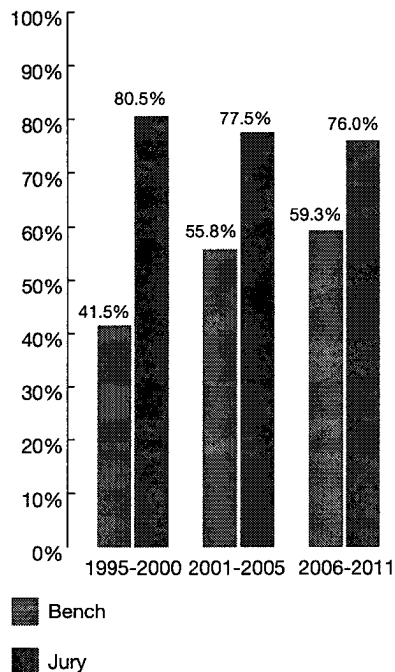


Patentees still winning with juries, and increasingly with bench

Chart 3b

Numerous factors contribute to the increased use of juries as the preferred forum for patent cases. In general, over the last 17 years, trial success rates for patent holders are higher when decided by juries as compared to the bench. However, as Chart 3b shows, the margin in success rates has shrunk. Segmenting the 17-year period into approximate thirds illustrates a narrowing of the margin between bench and jury success rates, from 39% between 1995 and 2000 to 17% between 2006 and 2011.

Chart 3b. Bench vs. jury trials: success rates

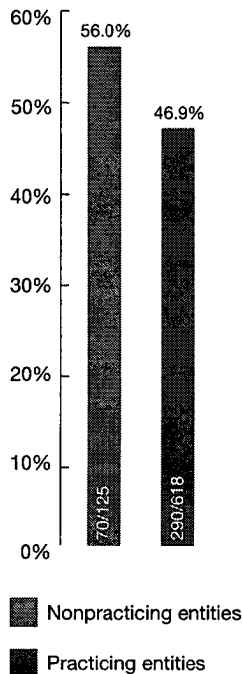


NPEs look to juries more often

Chart 3c

The increase in litigation involving NPEs over the last 17 years is most likely contributing to the increased use of juries. Since 1995, almost 56% of trials involving NPEs have been jury trials as compared to only 47% of trials involving practicing entities.

Chart 3c. Use of jury trials by type of entity: 1995 to 2011



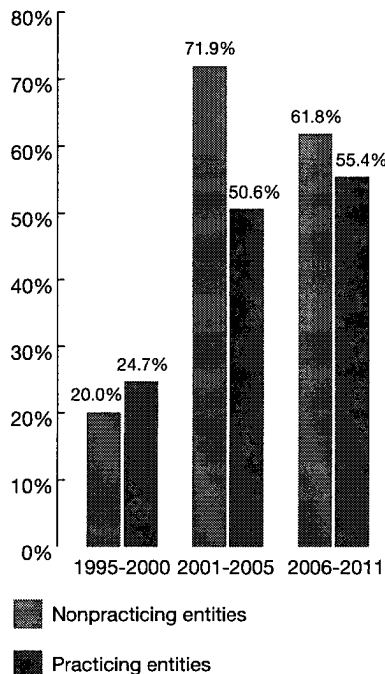
The number of cases is indicated within the respective column.

However, discrepancy in use of juries has shrunk

Chart 3d

Analyzing jury use by time period shows that while NPEs use juries more frequently than practicing entities, the gap has diminished. As indicated in Chart 3d, the difference in jury use between NPEs and practicing entities shrunk between 2006 and 2011 to only 6%. In contrast, that difference was 21% from 2001 to 2005.

Chart 3d. Use of jury trials by type of entity

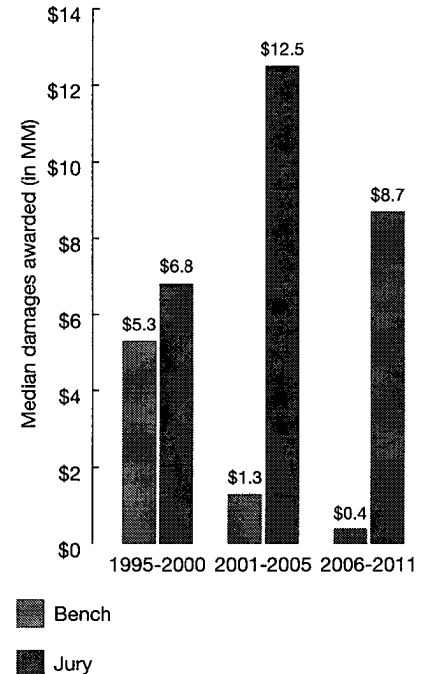


Median jury awards substantially outpace the bench

Chart 3e

Chart 3e illustrates the discrepancy in median damages awards over the last 17 years. The spread between bench and jury median awards has grown significantly, stemming from the combined effect of a sharp increase in the median jury award and a drop in the median bench award. As outlined in Chart 3e, median jury awards have represented multiples of 1.3x, 9.6x, and 21.8x of bench awards from 1995 to 2000, 2001 to 2005, and 2006 to 2011, respectively.

Chart 3e. Bench vs. jury trials: median damages awarded by period



Median damages are adjusted for inflation and represented in 2011 US dollars.

Reasonable royalties are the most prevalent damages

Chart 4

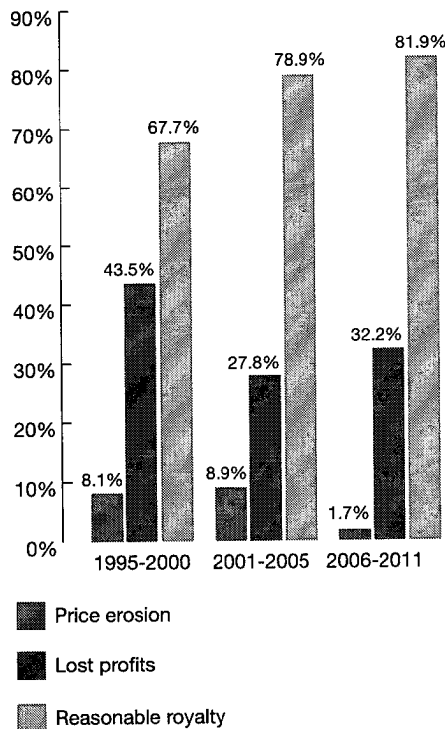
Reasonable royalties are the predominant measure of damages; price erosion is rare

As shown in Chart 4, reasonable royalties are the kind of damages most frequently awarded in patent cases, constituting a greater share with each passing year. Because some litigants receive lost profits and royalties, the totals exceed 100%. Section 284 of the Federal Code governing equitable compensation sets a reasonable royalty as the minimum level of compensation due to the patent holder from an infringer. While Chart 4 includes all identified decisions with damages, NPEs are generally not entitled to lost profits; if we omit NPE results from Chart 4, the proportion of damages awarded through reasonable royalties decreases by about 6%.

Lost profits damages are not as common as reasonable royalties for several reasons:

- NPEs, which bring an increased proportion of patent actions, are ineligible for lost profits damages because they do not sell products or services embodying their patents.
- Even in circumstances where the patentee may be eligible for lost profits awards, the entity might seek recovery through the reasonable royalty approach. The complexity and cost of the analysis for determining lost profits is usually greater than it is for reasonable royalties. Lost profits can be quantified by determining specific sales taken by the infringer from the patent holder or by assessing

Chart 4. Composition of damages awards to all entities



particular facts and circumstances in a 'but for' situation, taking into account the following questions:

- Is demand for the product tied to the patent's claims?
- Are acceptable non-infringing alternates available?
- Does the patent holder have adequate manufacturing and marketing capabilities to have captured the defendant's sales?
- Is sufficient financial information available to complete the quantification?

In addition, market share data is often required to allocate the

infringer's sales if the market consists of more than two participants. Patent holders can find the process of supporting such analysis distracting to their core operations or they might not want to risk disclosing proprietary cost and profit information.

- Lost profits entitlement can be more difficult to establish. The proliferation of competition provides greater access to substitute products. The presence of these alternatives means that even without an alleged infringer's products in the market, consumers may not have automatically bought the patent holder's products. Furthermore, the growing use of specialized distribution channels for reaching a specific consumer demographic may support an alleged infringer's contention that its customers are separate and distinct from those of the patent holder.
- Damages awards for price erosion claims have become almost non-existent over the last six years. Globalized competition, turbulent economic conditions, and the cost and complexity of price erosion analyses have reduced the recovery (and most likely pursuit) of price erosions claims.

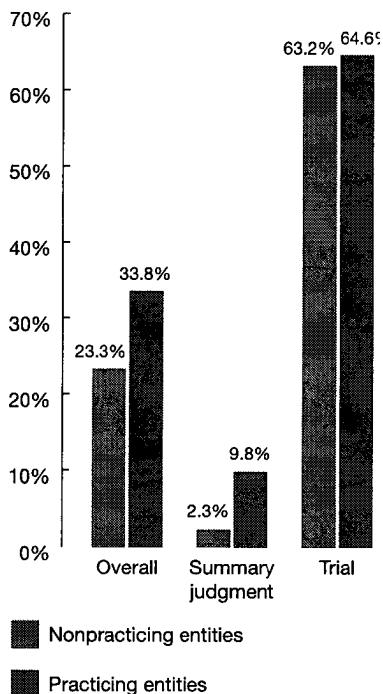
Assessing success rate factors

Chart 5a

Success rates vary considerably by year, type of entity (NPE versus practicing entity), and trier of fact

Chart 5a demonstrates that the overall success rate for practicing entities is almost 10% higher than that of NPEs over the last 17 years. In instances when a final decision is reached at summary judgment, NPEs are successful only 2% of the time, as opposed to almost 10% for practicing entities. Meanwhile, the trial success rate for practicing entities is only about 1% higher than that of NPEs.

Chart 5a. Patent holder success rates: 1995 to 2011

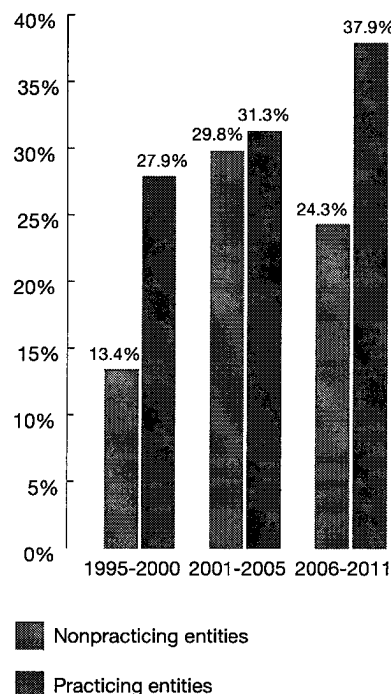


NPEs see declining overall success rates

Chart 5b

As Chart 5b demonstrates, segmenting overall success rate data for NPEs and practicing entities across various time periods within the last 17 years reveals an interesting pattern. While the difference in overall success rates for NPEs versus practicing entities between 2001 and 2005 had shrunk to less than 2%, the gap widened over the last six years. Between 2006 and 2011, practicing entity overall success rates have outpaced those of NPEs by almost 14%. This difference is similar to the margin in overall success rates between 1995 and 2000.

Chart 5b. Patent holder overall success rates



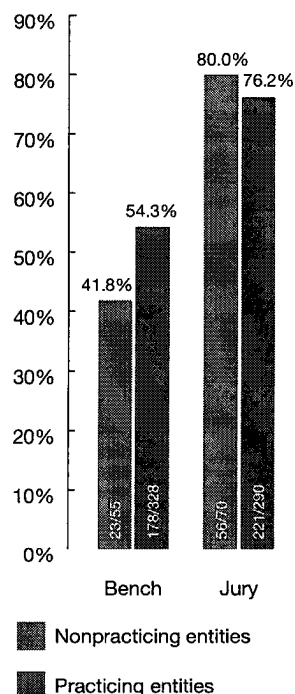
Trial success rates: diverging results

Chart 5c

The growing gap in overall success rates between 2006 and 2011 results from an increase in practicing entity success paired with a decline in NPE success.

Consistent with last year's study, Chart 5c illustrates that since 1995, practicing entities and NPEs have been significantly more successful with jury than bench trials. The chart also captures an interesting divergence in success rates: while practicing entities enjoy a success rate almost 13% higher than NPEs with the bench, their success rates with juries are actually about 4% less than NPEs.

Chart 5c. Patent holder success rates at trial: 1995 to 2011



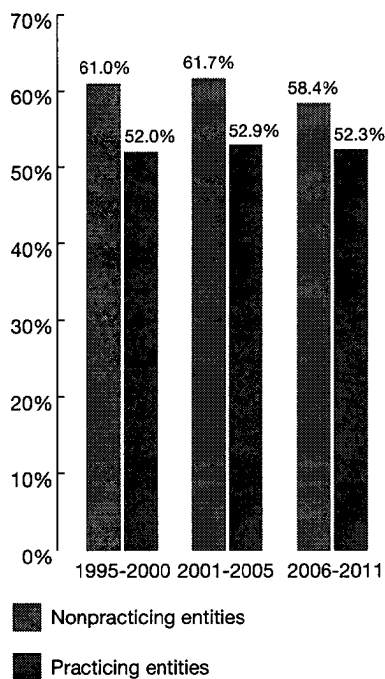
The number of cases is indicated within the respective column.

Summary judgment impact on NPEs

Chart 5d

In another interesting finding, we see a greater percentage of NPE cases decided at summary judgment than cases involving practicing entities. Chart 5d shows that across distinct time periods over the last 17 years, more NPE decisions consistently occur at summary judgment when compared to practicing entities. The gap in summary judgment decisions appears to have narrowed slightly since 2006. As previously noted, because their success rates at summary judgment are much lower than at trial, NPEs tend to experience a lower overall success rate than practicing entities when the total mix of summary judgment and trial decisions are considered.

Chart 5d. Percent of decisions at summary judgment



Consumer products technology leads in decisions

Chart 6a

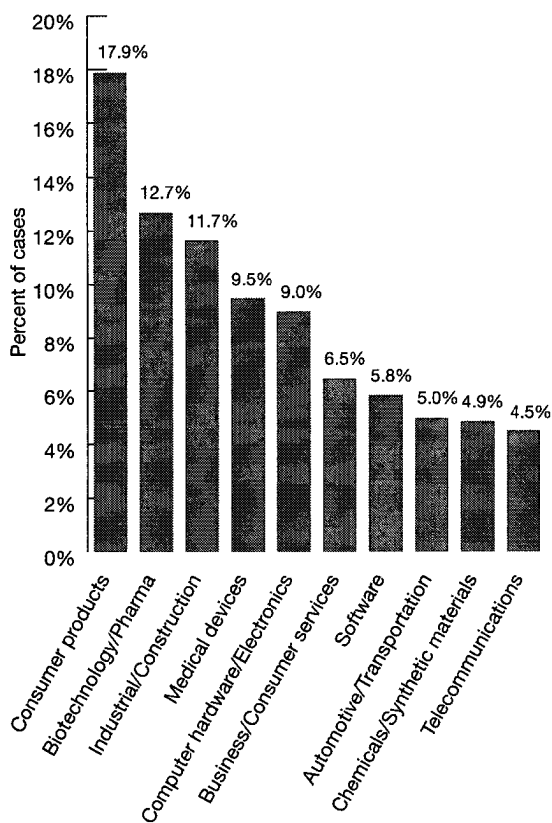
Patent litigation trends diverge across industries

We mapped each decision to one of 20 industries, based on the nature of the technology embodied by the patent(s) at issue.

Chart 6a reflects the percentage of total identified decisions for the ten most active industry classifications,

which collectively account for 88% of all patent case decisions. As the chart demonstrates, technology associated with the consumer products industry led in terms of the percentage of identified decisions from 1995 through 2011, representing 18% of the total decisions.

Chart 6a. Distribution of cases: top ten industries, 1995-2011



Biotechnology and information technology (computer hardware, software, Internet) cases on the rise

Chart 6b

Chart 6b provides additional insight into the number of identified decisions by industry from 1995 through 2011. While Chart 6a considers the entire period 1995 through 2011, by trifurcating the 17-year period, the consumer products industry ranks first in the percentage of decisions in each of the three time segments.

The number of decisions and relative ranking of the biotechnology/pharma industry have increased. In addition, the computer hardware/electronics, software, and Internet/online services industries experienced significant increases in identified decisions from 2006 through 2011. In fact, no identified decisions in Internet/online

services occurred prior to 2006. This data reflects the increasing importance and size of biotechnology and information technology.

Chart 6b. Number of cases by industry

Overall rank	Industry	1995 - 2000		2001 - 2005		2006 - 2011		Total cases
		Cases	Rank	Cases	Rank	Cases	Rank	
1	Consumer products	82	1	80	1	151	1	313
2	Biotechnology/Pharma	40	4	70	2	112	2	222
3	Industrial/Construction	66	2	57	3	81	4	204
4	Medical devices	42	3	45	4	79	5	166
5	Computer hardware/Electronics	24	6	32	6	101	3	157
6	Business/Consumer Services	19	8	33	5	61	7	113
7	Software	14	10	23	8	65	6	102
8	Automotive/Transportation	24	7	25	7	38	10	87
9	Chemicals/Synthetic Materials	30	5	16	10	39	9	85
10	Telecommunications	14	11	22	9	43	8	79
11	Food/Beverages/Tobacco	15	9	8	12	16	12	39
12	Metals/Mining	12	12	10	11	10	17	32
13	Clothing/Textiles	11	13	8	13	12	14	31
14	Energy	7	14	7	15	11	15	25
15	Agriculture	5	15	8	14	11	16	24
16	Financial institutions/Investment management/Insurance	1	18	3	17	16	13	20
17	Internet/Online services	0	20	0	20	17	11	17
18	Aerospace/Defense	3	17	2	18	8	18	13
19	Media	5	16	4	16	4	20	13
20	Environment/Waste Management	1	19	2	19	6	19	9
Total		415		455		881		1,751

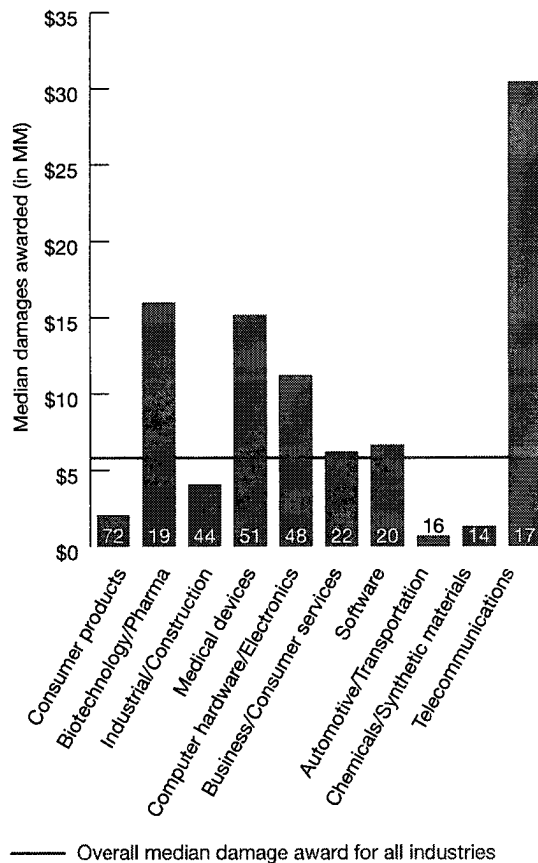
Median damages largest in telecommunications industry

Chart 6c

Chart 6c reflects that while technology associated with the consumer products industry represented the largest percentage of identified decisions, the median damages awarded were relatively low compared to the other top ten most active industries.

Consistent with last year's study, technology associated with the telecommunications, biotechnology/pharma, medical devices, and computer hardware/electronics industries experienced significantly higher median damages awards than other industries.

Chart 6c. Patent holder median damages awarded: top ten industries, 1995–2011



Median damages are adjusted for inflation and represented in 2011 US dollars.

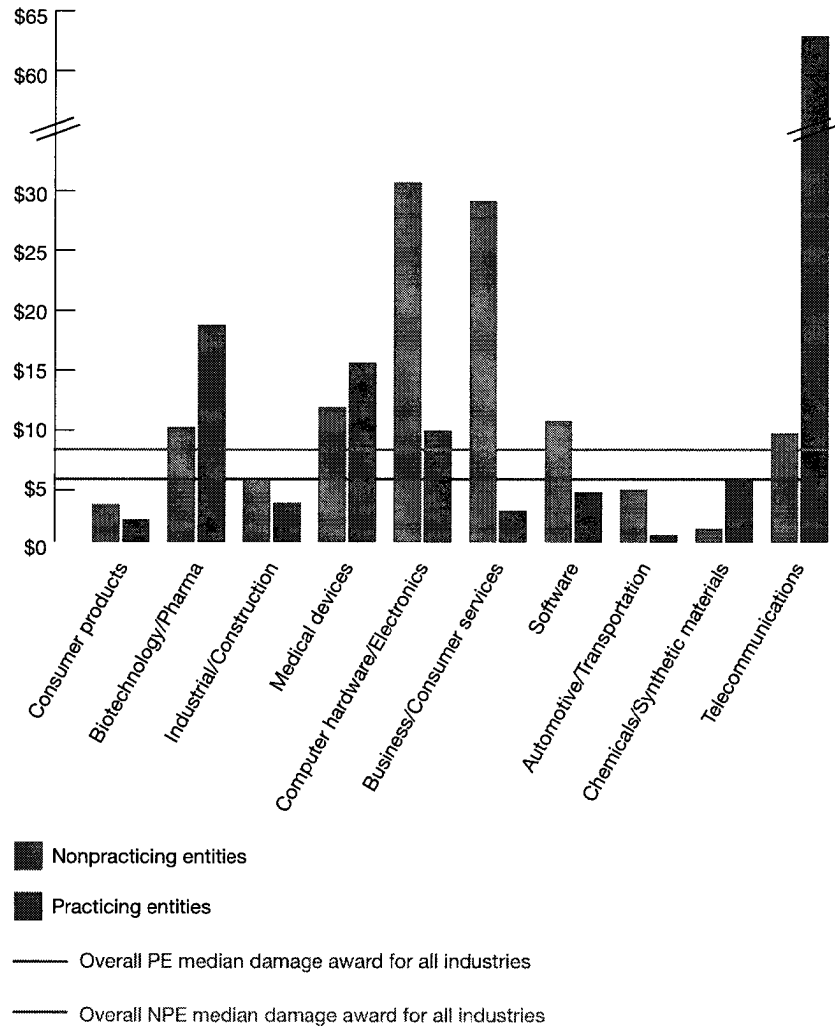
The number of cases is indicated within the respective column.

NPE versus practicing entity damages vary widely by industry

Chart 6d

Chart 6d separates the median damages awards for each of the top ten industries into practicing entity and NPE median damages. This chart demonstrates that the relationship between NPE and practicing entity damages is volatile across industry classification. The telecommunications and biotechnology/pharma industries have experienced significantly greater awards for practicing entities, while the computer hardware/electronics and business/consumer services industries reflect substantially higher awards for NPEs.

Chart 6d. Patent holder median damages awarded: top ten industries, 1995–2011



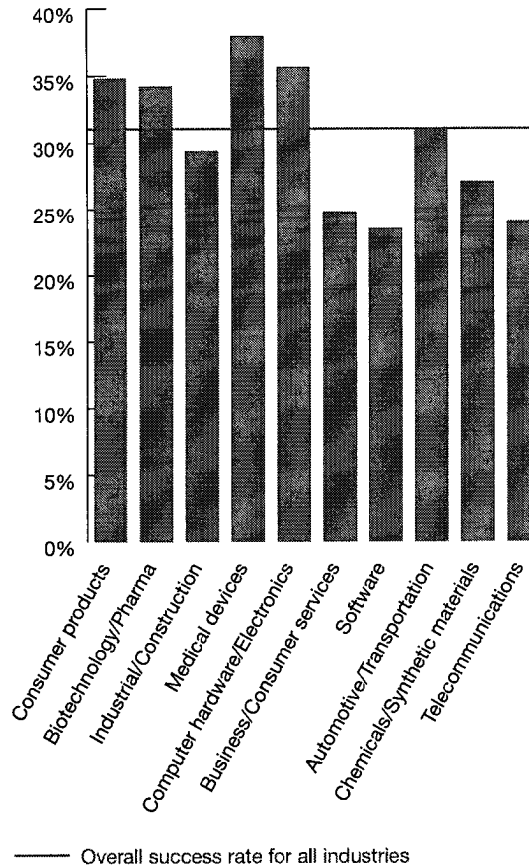
Median damages are adjusted for inflation and represented in 2011 US dollars.

Success rates by industry

Chart 6e

While the overall success rate (trial and summary judgment combined) for all industries during the period was approximately 32%, patent holders with technology that related to the consumer products, biotechnology/pharma, medical devices, and computer hardware/electronics industries achieved success rates higher than the overall median. Chart 6e also demonstrates that success rates across the top ten industries are relatively concentrated, falling within a band of +/- 15%.

Chart 6e. Patent holder success rate: top ten industries, 1995–2011

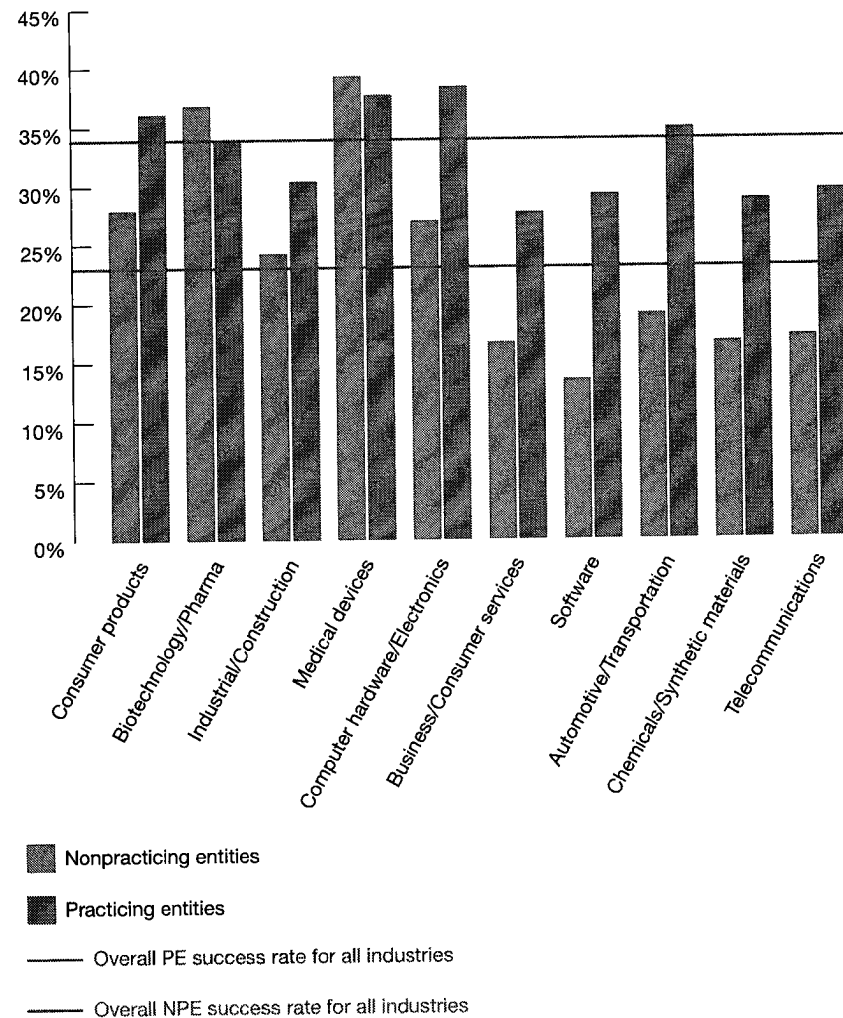


Practicing entity versus NPE success rates by industry

Chart 6f

Chart 6f expands on the analysis provided in Chart 6e by reflecting practicing entity versus NPE success rates by industry. The chart demonstrates that while the overall success rate is higher for practicing entities than for NPEs, the volatility of success rates for NPEs is very high across industries. The contrast between the high NPE success rates of the biotechnology/pharma and medical device industries and the low NPE success rates of the software and business/consumer services industries is particularly striking.

Chart 6f. Patent holder success rate: top ten industries, 1995–2011

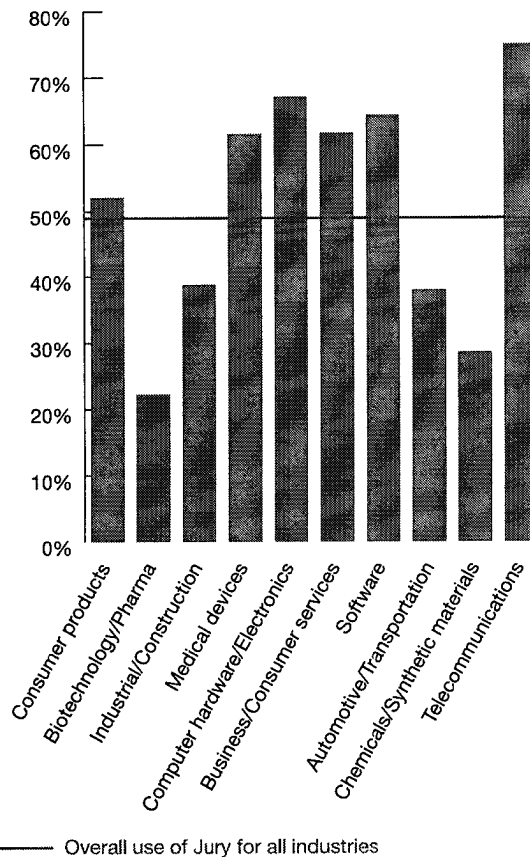


Telecommunications industry leads in jury use

Chart 6g

Use of jury trials varied widely by industry, as illustrated in Chart 6g. Highlighting the wide disparity of jury trials by industry are the telecommunications and chemicals/synthetic materials industries, with a margin in jury use of more than 40%. As previously noted, the telecommunications industry also had the highest median damages award by a significant margin. The biotechnology/pharma industry had a considerably lower use of jury trials than the other top 10 industries; this is partly due to the frequent incidence of ANDA-related litigations, which are tried primarily by the bench.

Chart 6g. Use of jury trials: top ten industries, 1995 to 2011



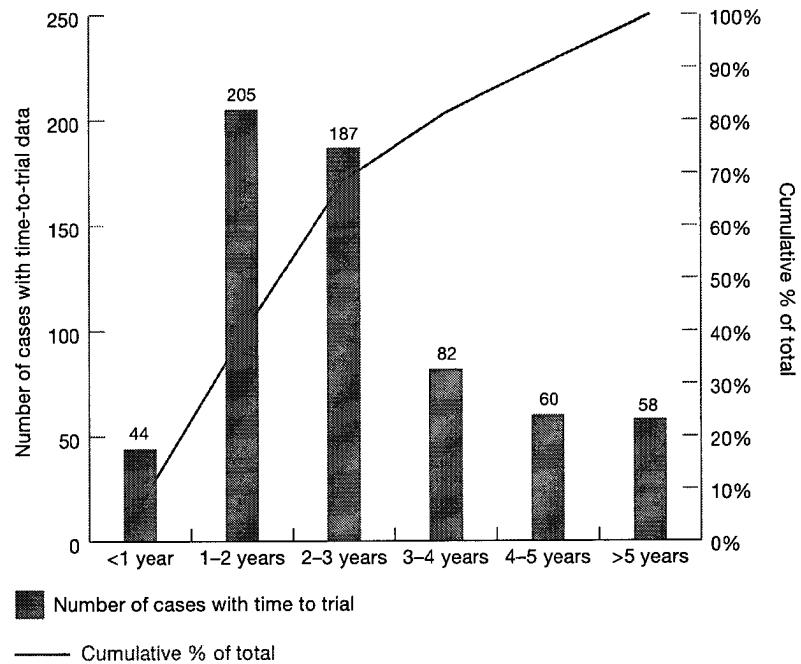
**Most patent cases
(70%) reach trial
within three years**

Chart 7a

While median time-to-trial has remained relatively consistent, significant variations exist across jurisdictions

We captured time-to-trial data for 636 cases in 68 districts, using the court dockets for each matter. We then calculated time-to-trial from the complaint date to the first day of trial for each case. In Chart 7a, the overall time-to-trial distribution indicates that about 70% of cases reached trial within three years from the filing of the initial complaint.

Chart 7a. Time-to-trial distribution of cases: 1995 to 2011

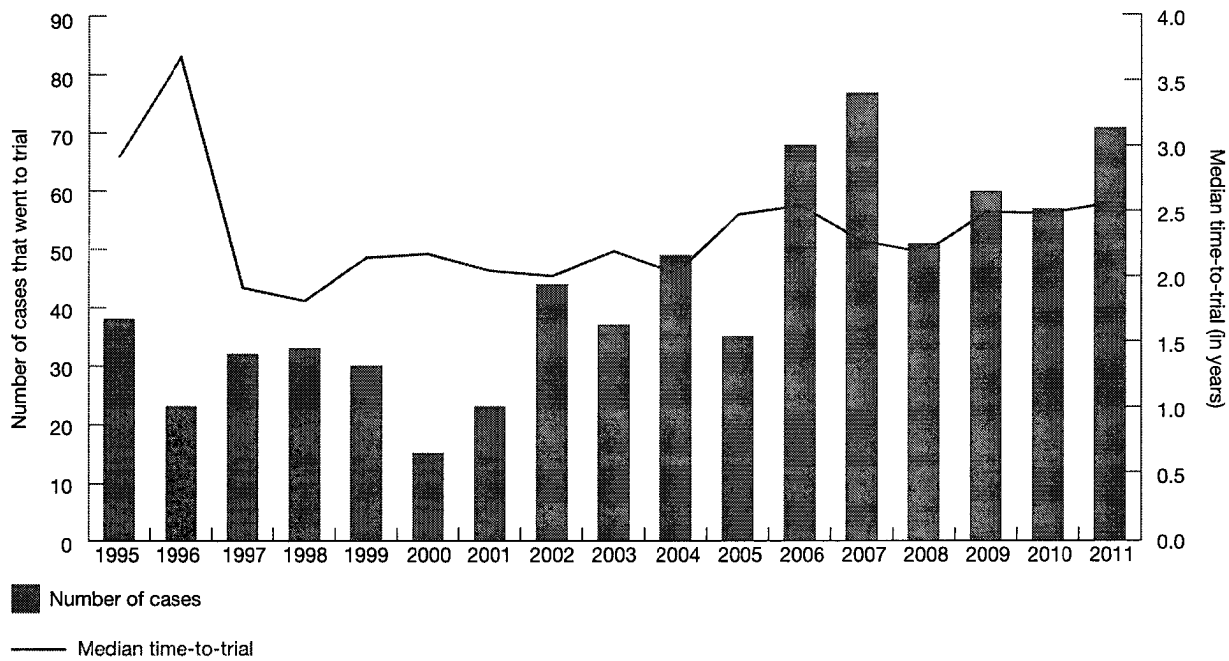


**Average time-to-trial:
approximately
2.5 years**

Chart 7b

Overall, time-to-trial appears to have remained relatively steady at about 2.5 years since 2005, and no significant variations are noted since 1997. However, in recent years, as case volume has increased, time-to-trial has also risen slightly.

Chart 7b. Median time-to-trial

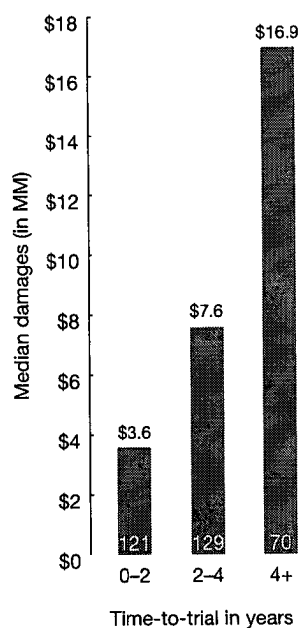


Median damages rise with time-to-trial

Chart 7c

Chart 7c reflects the direct relationship between the median damages award and the number of years to trial. Several factors might influence this relationship. Cases involving higher potential damages awards are more complex and, thus, take longer to reach trial. Also, increased time-to-trial provides a longer period over which sales can occur, thereby increasing the potential damages base.

Chart 7c. Median damages based on time-to-trial: 1995 to 2011



Median damages are adjusted for inflation and represented in 2011 US dollars.

The number of cases is indicated within the respective column.

Virginia Eastern District, Wisconsin Western District speediest in time-to-trial

Chart 7d

Since 1995, significant variations have occurred in the median time-to-trial across jurisdictions. To assess the lead time, we focused on the most active districts. Chart 7d summarizes the median time-to-trial among these courts from 1995 to 2011. As indicated, the Virginia Eastern and Wisconsin Western districts boast the shortest time-to-trial. Interestingly, the top five districts and overall median time-to-trial have remained consistent from our last study, with little change in the overall time-to-trial.

Chart 7d. Median time-to-trial by district from 1995 to 2011

Rank	District	Total # of Identified decisions with time-to-trial data	In Years
1	Virginia Eastern District Court	17	0.97
2	Wisconsin Western District Court	10	1.07
3	Florida Middle District Court	13	1.74
4	Delaware District Court	105	1.90
5	Texas Southern District/ Bankruptcy Courts	11	2.00
6	Texas Eastern District Court	80	2.17
7	California Central District Court	28	2.28
8	Florida Southern District Court	14	2.39
9	Texas Northern District Court	17	2.42
10	Minnesota District Court	11	2.58
11	New York Southern District Court	36	2.65
12	California Northern District Court	33	2.72
13	New Jersey District Court	21	2.73
14	Illinois Northern District Court	34	3.42
15	Massachusetts District Court	26	3.58
Overall (all decisions identified)		636	2.30

Includes only the 15 most active districts for which time-to-trial data was available.

Certain districts are more favorable to patent holders

Chart 8

Considering median time-to-trial, median damages awarded, and overall success rates, certain jurisdictions (particularly Virginia Eastern, Delaware, and Texas Eastern) continue to be more favorable venues for patent holders, with shorter time-to-trial

and higher success rates and median damages awards. Chart 8 presents the top 15 districts from 1995 to 2011 based on an average of their categorical rankings for each of the three statistical measures mentioned earlier. Interestingly, the overall

rankings for district courts varied only slightly from last year's study, with Florida Southern moving up in ranking to 12 from 15, and Massachusetts, Minnesota, and Illinois Northern each dropping down by one spot.

Chart 8. District Court rankings: 1995 to 2011

Overall rank	District	Median time-to-trial (in years)	Rank	Overall success rate	Rank	Median damages awarded	Rank
1	Virginia Eastern District Court	0.97	1	34.1%	5	\$36,025,989	1
2	Delaware District Court	1.90	4	41.7%	3	\$20,636,247	2
3	Texas Eastern District Court	2.17	6	55.7%	2	\$8,782,738	5
4	Wisconsin Western District Court	1.07	2	31.4%	7	\$4,730,027	9
5	Florida Middle District Court	1.74	3	57.1%	1	\$151,392	15
6	California Central District Court	2.28	7	32.4%	6	\$6,728,379	7
7	Texas Southern District/ Bankruptcy Courts	2.00	5	20.5%	15	\$11,042,883	4
8	Texas Northern District Court	2.42	9	38.7%	4	\$1,756,750	13
9	New Jersey District Court	2.73	13	28.8%	11	\$16,976,883	3
10	New York Southern District Court	2.65	11	29.3%	9	\$3,269,254	11
11	California Northern District Court	2.72	12	22.6%	14	\$7,848,405	6
12	Florida Southern District Court	2.39	8	23.1%	13	\$2,836,043	12
13	Massachusetts District Court	3.58	15	30.6%	8	\$4,088,947	10
14	Minnesota District Court	2.58	10	28.9%	10	\$1,590,435	14
15	Illinois Northern District Court	3.42	14	24.8%	12	\$5,768,892	8
Overall (all decisions identified)		2.30		31.6%		\$5,302,861	

Median damages are adjusted for inflation and represented in 2011 US dollars.

Federal district courts with most NPE cases

Chart 9a

Of NPE decisions, 38% were concentrated in five federal district courts

Cases with NPEs as patent holders were concentrated in a relatively smaller number of key districts: the top five districts (out of the total 94) with the most identified decisions

accounted for 38% of all identified NPE cases and the top ten districts accounted for 56%. Of particular interest is that the two districts with the most identified NPE decisions, Illinois Northern and Texas Eastern, continue to present a dichotomy in relative NPE success rates. As seen in Chart 9a, Texas Eastern ranks second

highest (46.5%), whereas Illinois Northern ranks thirteenth (12.9%) in terms of overall NPE success rates. Meanwhile, Delaware, which has the lowest percentage of identified decisions where the patent holder is an NPE, has an overall NPE success rate of 41.2%, which is among the highest and well above the average.

Chart 9a. District courts with most identified decisions with NPE as patent holder: 1995 to 2011.

Industry	Decisions involving NPEs	Total identified decisions	NPE % of total decisions	NPE success rate
Texas Eastern District Court	43	115	37.4%	46.5%
Illinois Northern District Court	31	129	24.0%	12.9%
New York Southern District Court	26	116	22.4%	15.4%
California Northern District Court	20	124	16.1%	15.0%
Delaware District Court	17	168	10.1%	41.2%
California Central District Court	15	74	20.3%	26.7%
Florida Southern District Court	14	39	35.9%	14.3%
Massachusetts District Court	14	72	19.4%	35.7%
Pennsylvania Eastern District Court	11	34	32.4%	18.2%
Minnesota District Court	10	45	22.2%	40.0%
Texas Southern District/ Bankruptcy Courts	9	44	20.5%	11.1%
US Court of Federal Claims	8	21	38.1%	12.5%
Virginia Eastern District Court	8	44	18.2%	25.0%
Colorado District Court	7	20	35.0%	28.6%
DC District Court	7	18	38.9%	0.0%
Florida Middle District Court	7	28	25.0%	57.1%
Kansas District Court	6	14	42.9%	0.0%
Maryland District Court	6	17	35.3%	0.0%
Michigan Eastern District Court	6	36	16.7%	0.0%
All identified decisions	361	1,751	20.6%	23.3%

Includes districts with more than five identified decisions involving an NPE as the patent holder.

Practicing entities and NPEs by the numbers

Chart 9b

Chart 9b reflects a summary of critical patent litigation statistics for practicing entities and NPEs. In the current and prior year, the median damage award for NPEs was significantly higher than that for practicing entities while practicing entities enjoyed higher success rates and slightly shorter median time-to-trial.

Chart 9b. Key statistics for practicing and nonpracticing entities: 1995 to 2011.

	Median time-to-trial (in years)	Overall success rate	Median damages awarded
Nonpracticing entity	2.55	23.3%	\$8,000,000
Practicing entity	2.27	33.8%	\$5,222,748

Median damages are adjusted for inflation and represented in 2011 US dollars.

NPEs see variety in median damages and success rates

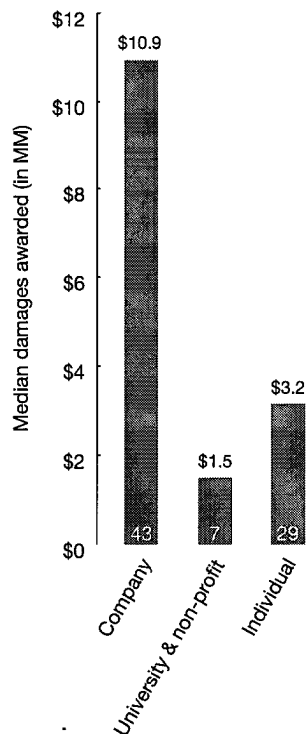
Chart 10a

Median damages awards and success rates vary significantly among NPEs

Charts 10a through 10c represent an analysis of NPE litigation by NPE type: (1) companies/for-profit organizations, (2) universities/non-profit organizations, and (3) individuals/inventors.

Chart 10a illustrates that the median damages award for NPEs that are companies/for-profit organizations is significantly higher than that for university/non-profit and individual NPEs. Notably, while damages for university/non-profit organizations and individual/inventors remained relatively consistent with last year's findings, the median damages award for NPEs that are companies/for-profit organizations declined dramatically to \$10.9 million from \$18.4 million in last year's study.

Chart 10a. Patent holder median damages awarded by NPE type: 1995–2011



Median damages are adjusted for inflation and represented in 2011 US dollars.

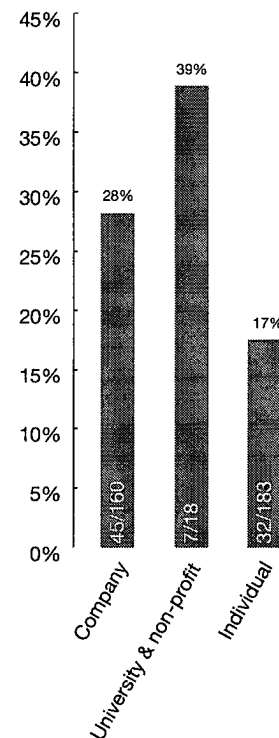
The number of cases is indicated within the respective column.

Individual NPEs experience lower success rates

Chart 10b

While company NPEs are awarded higher damages, university/non-profit NPEs have by far the highest success rate among NPEs. Individual NPEs lag far behind, as shown in Chart 10b. Each reading was consistent with the calculations in last year's study, with company and individual NPEs remaining constant and university/non-profit NPEs edging down two points to a 39% success rate.

Chart 10b. Patent holder success rates by NPE type: 1995–2011



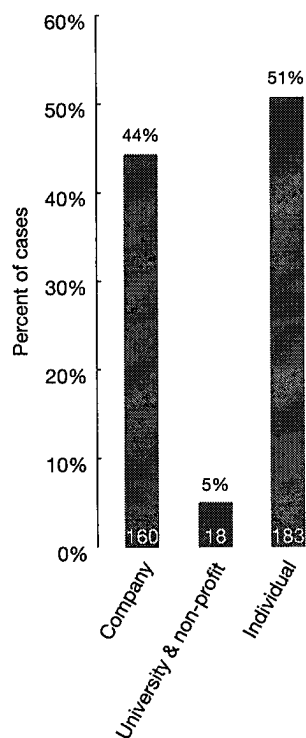
The number of cases is indicated within the respective column.

Vast majority of NPE litigation involves company and individual NPEs

Chart 10c

Chart 10c shows the distribution of NPE litigation over the last 17 years between the three NPE types. About 95% of NPE litigation involves company and individual NPEs. While individual NPEs have the lowest median damages award and success rate, they represent the most frequent kind of NPE litigant, accounting for more than half of identified NPE decisions.

Chart 10c. Distribution of cases by NPE type: 1995-2011



The number of cases is indicated within the respective column.

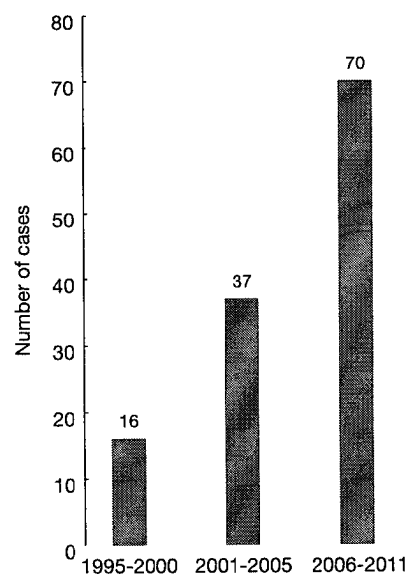
ANDA litigation trends upward

Chart 11a

A view of ANDA litigation is new to this year's study. This litigation results from a generic drug manufacturer's filing with the Food and Drug Administration (FDA) an ANDA paragraph IV certification, which effectively challenges a brand drug manufacturer's patent(s). Due to the nature of ANDA litigation, damages are rarely, if ever, awarded because the alleged infringer does not generally make any infringing sales prior to the filing of the litigation. However, the economic ramifications of ANDA litigation are significant due to the potential for lost patent protection of highly profitable brand name drugs. In addition, the first generic filer of a successful patent challenge is awarded a period of exclusivity in the generic drug market.

Chart 11a illustrates that the number of court decisions from ANDA litigation has grown substantially, consistent with the upward trend of overall patent litigation identified in Chart 1.

Chart 11a. ANDA cases



New Jersey and Delaware are favored ANDA districts

Chart 11b

Chart 11b reflects the top five most active judicial districts for ANDA litigation. Given the concentration of pharmaceutical companies in the New Jersey/New York area, it is not surprising that a large number of ANDA cases are brought in those districts and in Delaware, where many corporations are incorporated. These five districts comprise almost 70% of the ANDA cases during our study period.

Chart 11b. Top five districts with ANDA cases: 1995 to 2011

Top five districts	Number of cases
1 Delaware District Court	27
2 New Jersey District Court	27
3 New York Southern District Court	13
4 Illinois Northern District Court	12
5 Florida Southern District Court	6

Historical ANDA success rates have varied significantly

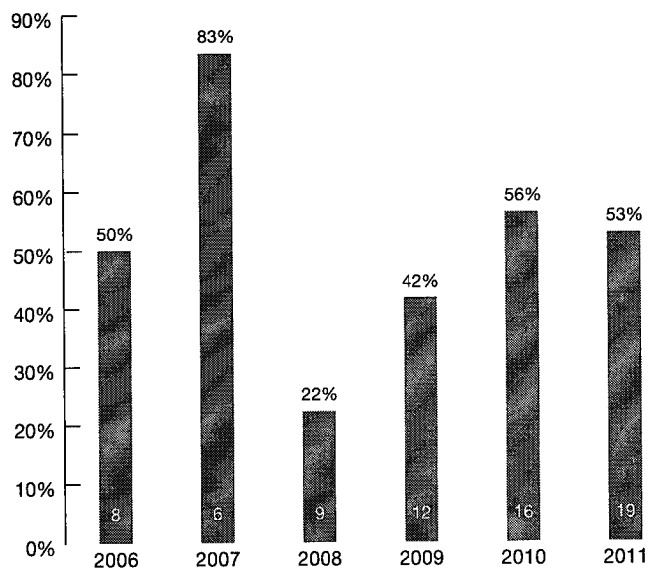
Chart 11c

Chart 11c reflects ANDA success rates, which we have defined here as the patent holder's (the brand name drug manufacturer) success. Since 2006, ANDA litigation success rates have ranged from a low of 22% to a high of 83%. However, the sample size (the number of ANDA cases reaching a dispositive conclusion) in the earlier years was low, possibly explaining the wide swings in success rates. Because

the majority of ANDA litigations continue to end in settlement, the adjudicated case sample size remains modest.

As the sample size increases, which appears to be the trend, it will be interesting to observe whether a pattern materializes, in which the 2010 and 2011 success rates of just over 50% repeats over time.

Chart 11c. ANDA success rates



The total number of cases are indicated within the respective column.

Top ANDA litigants

Chart 11d and 11e

Charts 11d and 11e represent the most active ANDA litigants, where plaintiffs are the proprietary drug makers and defendants are the generic drug manufacturers. More than half of identified ANDA decisions involve the five most active ANDA defendants. Not surprisingly, Teva, which is considered the world's largest generic drug manufacturer, tops the list.

On the other hand, approximately one-third of identified ANDA decisions involve the top five plaintiffs, or the branded drug manufacturers.

Chart 11d: Top five ANDA Defendants: 1995 to 2011

Defendant	Number of cases
Teva (including, Barr Laboratories, Cephalon & Novopharm)	29
Apotex	13
Mylan	11
Watson (including, Andrx Pharmaceutical)	6
Sandoz	5

Chart 11e: Top five ANDA Plaintiffs: 1995 to 2011

Plaintiff	Number of cases
Glaxo (including, SmithKline Beecham)	11
Pfizer (including Pharmacia & Upjohn, King, Warner-Lambert & Wyeth)	11
Johnson & Johnson (including, Alza, Janssen, McNeil-PPC, & Ortho-McNeil)	9
Abbott Laboratories	6
Astrazeneca	6

Our methodology

To study the trends related to patent decisions, PwC identified final decisions at summary judgment and trial recorded in two WestLaw databases, Federal Intellectual Property – District Court Cases (FIP-DCT) and Combined Jury Verdicts and Settlements (JV-ALL), as well as in corresponding Public Access to Court Electronic Records (PACER) system records.

The study focuses on 1,751 district court patent decisions issued from 1995 to 2011. Definitions for critical terms used throughout the study are listed here.

Term definitions

Cases decided at summary judgment include those district court patent infringement cases where a judge has issued a dispositive opinion regarding invalidity and/or infringement.

Cases decided at trial include those district court patent infringement cases where an opinion was rendered by a judge or jury at trial.

A **success** includes instances where a liability and damages/permanent injunction (if included) decision was made in favor of the patent holder.

Time-to-trial is calculated from the complaint date to the first day of either the bench or jury trial for each case.

A **nonpracticing entity (NPE)** is defined as an entity that does not have the capability to design, manufacture, or distribute products with features protected by the patent.

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Companies Mentioned**Cephalon, Inc.**

(Nasdaq: CEPH, \$64.14; Sector Perform, Above Average Risk)

Endo Pharmaceuticals Holdings

(Nasdaq: ENDP, \$20.82; Sector Perform, Above Average Risk)

Forest Laboratories, Inc.

(NYSE: FRX, \$31.35; Underperform, Above Average Risk)

King Pharmaceuticals, Inc.

(NYSE: KG, \$12.97; Sector Perform, Above Average Risk)

Medicis Pharmaceutical Corp.

(NYSE: MRX, \$24.91; Outperform, Above Average Risk)

Mylan Inc.

(Nasdaq: MYL, \$17.87; Outperform, Above Average Risk)

Par Pharmaceutical Co., Inc.

(NYSE: PRX, \$26.17; Sector Perform, Above Average Risk)

Perrigo Company

(Nasdaq: PRGO, \$42.13; Outperform, Above Average Risk)

Teva Pharmaceutical Industries Limited

(Nasdaq: TEVA, \$59.02 Outperform, Above Average Risk)

Warner Chilcott plc

(Nasdaq: WCRX, \$28.53; Outperform, Above Average Risk)

Watson Pharmaceuticals Inc.

(NYSE: WPI, \$41.10; Outperform, Above Average Risk)

INDUSTRY | COMMENT

JANUARY 15, 2010

**Pharmaceuticals
Analyzing Litigation Success Rates**

In this report we analyze over 370 court rulings since the beginning of the decade to establish litigation success rates by company, court and judge. We also look at other trends in the pharmaceutical industry such as at-risk launches, patent settlements and authorized generics. Based on our review, we conclude that while patent challenges by generics are extremely common, winning is not.

Below are the key conclusions from our analysis:

- Patent challenges remain on the rise with a record 65 new first-to-file lawsuits in 2009, up from 51 in the prior year and more than double the number just three years ago.
- Over the last decade, the overall success rate for the generic drug industry is 48% for cases that have gone to trial. However, the success rate increases to 76% when settlements are included. Over half of all cases are settled or dropped.
- Perrigo has the best overall litigation success rate, taking top honors in best overall success rate, best batting average in court and highest percent of cases settled/dropped. Watson has the second best overall success rate.
- The top three courts by volume -- NJ, DE and SDNY -- accounted for 69% of all decisions. Unfortunately, these courts have a combined success rate of just 36% for generics. However, just over half of the cases in these three courts get settled or dismissed.
- Four courts have never ruled against a generic --California-CD, New York-ED, Minnesota and Missouri-ED.
- The top five judges by volume accounted for 31% of the total decisions. These five judges ruled in favor of generics only 33% of the time. The total success rate, however, including settlements is 75%.
- Last year we saw six at-risk launches, up from four in the last few years. Teva remains the most likely to go at-risk with 12 of the 28 at-risk launches since 2002.
- The number of settlements in 2009 reached an all-time high of 54, up from 45 in the prior year. Settlements occur on average 47% of the time with Teva accounting for nearly one-third of all settlements. On the innovator side, Glaxo and Novartis have settled the most.
- We counted 25 authorized generics launched in 2009 compared to 18 in the prior year. However, more products are launching without an AG than in prior years.
- By our count, Watson has introduced the most AGs, nearly one fifth of the industry's total.

Priced as of prior trading day's market close, EST (unless otherwise noted).

All values in USD unless otherwise noted.

For Required Conflicts Disclosures, see Page 23.

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Summary

Patent challenges remain on the rise, with 65 new first-to-file paragraph IV challenges initiated in 2009, which brings the total to over 300 active cases. In this report we analyze over 370 court rulings since the beginning of the decade to establish litigation success rates by company, court and judge. We also look at other relevant trends in the industry such as at-risk launches, patent settlements and authorized generics. Exhibit 1 below summarizes litigation trends over the past seven years.

Exhibit 1: Litigation Summary

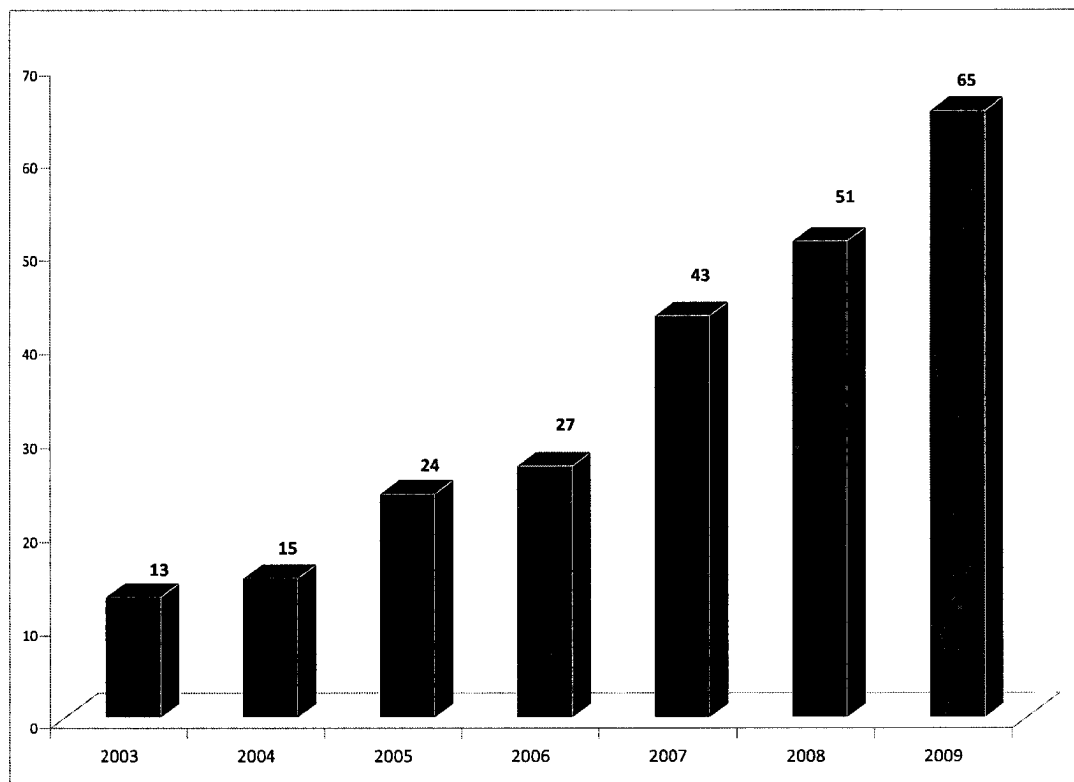
	2003	2004	2005	2006	2007	2008	2009
Settlements	6	4	8	20	21	45	54
At-Risk Launches	2	5	3	4	4	4	6
First to File P4 Suits	13	15	24	27	43	51	65

Source: PACER, Company reports, RBC Capital Markets estimates

Paragraph IV Challenges

In recent years patent challenges have become the rule rather than the exception for generics. According to our database there are approximately 300 active first-to-file paragraph IV challenges, most of which have multiple filers. The incentive is clear: the first ANDA filer to make a paragraph IV certification receives 180 days of market exclusivity during which no other ANDA can be approved for that drug. With very little downside and huge upside, exclusivity is the driving force to the huge increase in first-to-file paragraph IV filings (exhibit 2).

Exhibit 2: First-to-File Lawsuits



Source: PACER, Company reports, RBC Capital Markets estimates.

The litigation process starts with the filing of an ANDA with a paragraph IV certification, an acknowledgment that patents exist but the generic doesn't infringe or the patents aren't valid. The FDA has 60 days to accept the ANDA filing and then the generic filer has 20 days to notify the patent holder of its paragraph IV filing. Paragraph IV certifications are required for all products with patents listed in the FDA's Orange Book (the official patent listing). The patent holder then has 45 days to sue in order to initiate a 30 month stay of FDA approval of the generic version (companies may sue after 45 days but no stay would be granted). The approval stay is lifted at the end of 30 months or after a court decision, whichever is earlier. Following the Medicare Modernization Act (MMA) in



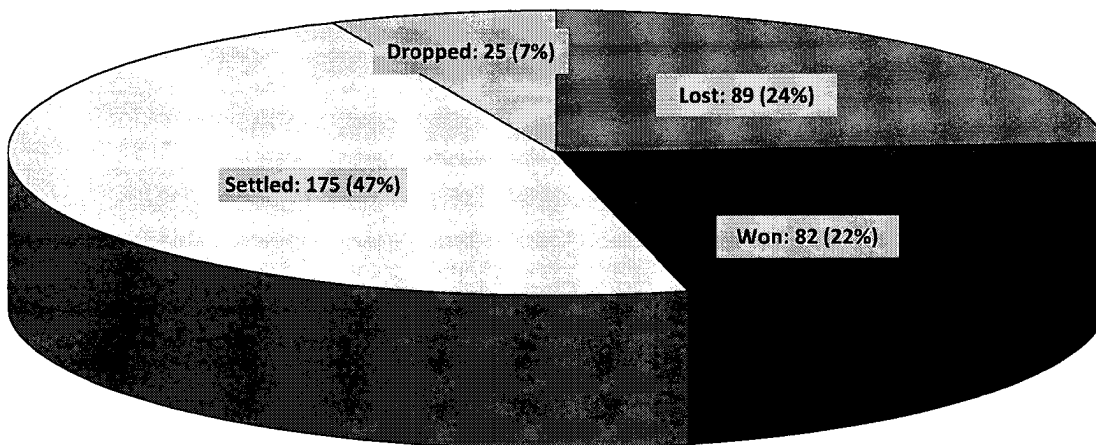
December 2003, patent holders are entitled to only one 30 month stay and are not entitled to a stay if a patent is listed after an ANDA is pending at the FDA (a late-listed patent). The 30 month clock is important because at the end of the stay companies are free to receive FDA approval and launch their generic products. However, this would be considered an *at-risk* launch if there is no court decision prior to launch. As such, generic companies may be responsible for up to triple damages if their products are found to infringe after an *at-risk* launch.

As a result of the large incentive to be first-to-file, we expect every patented product to be challenged, regardless of its size, i.e., Rozerem. We believe that if a drug does not have a challenge it speaks to the difficulty of formulating that product (i.e., Lidoderm). We count around 65 new first-to-file lawsuits in 2009 up 27% from 2008, but nearly a three-fold increase since 2005 (exhibit 2).

Patent Challenge Success Rates

The question we are most frequently asked relates to the success rate of paragraph IV patent challenges. According to our database on over 370 resolved cases over the last decade, the outcome is fairly even, with generics winning 82 of the rulings compared to losing 89. Thus, **the overall success rate for the generic industry is 48%** based on court decisions. However, when you take into account patent settlements and cases that were dropped, the **success rate for generics jumps to 76%**, substantially in favor of challenging patents (exhibit 3). With 54% of all cases either settled or dropped, it's easy to see why generic firms focus on first-to-file opportunities. Settlements provide clarity for the company and shareholders and we see them as a win-win for the generic and brand company. As we discuss later in the report, there were 54 disclosed patent settlements last year, an all time high.

Exhibit 3: Generic Drug Industry: Litigation Success Rate



Source: PACER, Company reports, RBC Capital Markets estimates.

The Best Generic Challengers

The second most common question we get is which generic companies are the most successful at winning patent challenges. We have highlighted in exhibits 4 and 5 the track records over the past decade for companies with five or more resolved paragraph IV challenges.

Perrigo takes the top honors for best overall success rate (defined as winning or settling a case), highest percentage of cases won and the highest settlement percentage. To be fair, Perrigo has only won one case, Pepsid Complete, but favorably resolved its other seven cases. That said, in our opinion, a settlement is as good as a win for shareholders, or possibly even better as it eliminates uncertainty and legal costs. Of the generic companies that have at least one court decision, Perrigo is the most likely to settle its case with seven cases settled/dropped of eight that have concluded, followed by Watson with 29 of its 39 cases either settled or dropped.

Watson has the second best overall success rate, having settled/dropped almost three quarters of its cases. Sandoz had the second best track record for court outcomes, but this is boosted by the inclusion of Eon Labs. Excluding Eon from Sandoz's results, the company would be tied with Par, Impax and Actavis for second with a 67% success rate. The results are presented in the scorecard below.

Exhibit 4: Best Generic Challengers 2000-2009

Best Overall Success Rate		Cases Won As % of Decisions		Cases Lost As % of Decisions		Cases Settled/Dropped As % of Total P4s		Most Number Of Concluded P4 Cases	
Perrigo	100%	Perrigo	100%	Apotex	86%	Perrigo	88%	Teva	108
Watson	90%	Sandoz	79%	Ranbaxy	78%	Watson	74%	Watson	39
Sandoz	88%	Par	67%	Dr. Reddy's	78%	KV Pharm	71%	Mylan	25
Par	87%	Impax	67%	Sun	75%	Lupin	63%	Sandoz	24
KV Pharm	86%	Actavis	67%	Lupin	67%	Par	60%	Apotex	21
Impax	86%	Watson	60%	URL Pharma	67%	Impax	57%	Ranbaxy	19
Actavis	83%	Teva	53%	Mylan	56%	Sun	56%	Dr. Reddy's	18
Teva	78%	KV Pharm	50%	KV Pharm	50%	Teva	53%	Par	15
Lupin	75%	Mylan	44%	Teva	47%	Ranbaxy	53%	Impax	14
Sun	67%	Lupin	33%	Watson	40%	Dr. Reddy's	50%	Sun	9
Mylan	64%	URL Pharma	33%	Par	33%	Actavis	50%	Perrigo	8
Ranbaxy	63%	Sun	25%	Impax	33%	Sandoz	42%	Lupin	8
Dr. Reddy's	61%	Ranbaxy	22%	Actavis	33%	URL Pharma	40%	KV Pharm	7
URL Pharma	60%	Dr. Reddy's	22%	Sandoz	21%	Mylan	36%	Actavis	6
Apotex	43%	Apotex	14%	Perrigo	0%	Apotex	33%	URL Pharma	5

**Includes predecessor firms.*

Source: PACER, Company reports, RBC Capital Markets estimates

Exhibit 5: Legal Scorecard Summary 2000-2009

	Lost	%	Won	%	Dropped/ Settled	%	TOTAL	Success %	Launched At Risk
Actavis	1	17%	2	33%	3	50%	6	83%	1
Apotex	12	57%	2	10%	7	33%	21	43%	1
Dr. Reddy's	7	39%	2	11%	9	50%	18	61%	0
Impax	2	14%	4	29%	8	57%	14	86%	0
KV Pharm	1	14%	1	14%	5	71%	7	86%	0
Lupin	2	25%	1	13%	5	63%	8	75%	0
Mylan	9	36%	7	28%	9	36%	25	64%	1
Par	2	13%	4	27%	9	60%	15	87%	1
Perrigo	0	0%	1	13%	7	88%	8	100%	1
Ranbaxy	7	37%	2	11%	10	53%	19	63%	0
Sandoz	3	13%	11	46%	10	42%	24	88%	6
Sun	3	33%	1	11%	5	56%	9	67%	2
Teva	24	22%	27	25%	57	53%	108	78%	13
URL Pharma	2	40%	1	20%	2	40%	5	60%	0
Watson	4	10%	6	15%	29	74%	39	90%	0

Source: PACER, Company reports, RBC Capital Markets estimates

Court Information

We have also reviewed our database to determine which districts are the best to try a case (exhibit 6). Three districts were responsible for nearly 70% of all court decisions -- New Jersey (35%), Delaware (21%) and the Southern District of New York (12%). The bad news for generics is that the combined historical success rate in these three districts is just 36%, which likely explains the 52% settlement rate in these districts. The most pro-generic courts include the Central District of California, the Eastern District of New York, Minnesota and the Eastern District of Missouri, having a perfect record of ruling in favor of generics every time.



Exhibit 6: Decisions By Court

	Ruled For Generics	Ruled Against Generics	Total Rulings	Generic Success Rate	Case Settled	Case Dismissed	Overall Generic Success Rate	Total Cases
California (Central District)	8	0	8	100%	9	0	100%	17
California (Northern District)	2	2	4	50%	2	0	67%	6
DC	3	2	5	60%	0	0	60%	5
Delaware	10	17	27	37%	46	8	79%	81
Florida (Southern District)	2	1	3	67%	4	0	86%	7
Georgia (Northern District)	0	0	0	NM	5	0	100%	5
Illinois (Northern District)	8	8	16	50%	6	1	65%	23
Indiana (Southern District)	1	5	6	17%	0	2	38%	8
Maryland	0	0	0	NM	2	0	100%	2
Massachusetts	0	3	3	0%	1	2	50%	6
Michigan (Eastern District)	2	2	4	50%	1	0	60%	5
Michigan (Western District)	0	0	0	NM	1	0	100%	1
Minnesota	2	0	2	100%	0	0	100%	2
Missouri (Eastern District)	1	0	1	100%	0	1	100%	2
New Jersey	27	47	74	36%	55	3	64%	132
New York (Eastern District)	2	0	2	100%	1	0	100%	3
New York (Southern District)	8	16	24	33%	22	1	66%	47
North Carolina (Eastern District)	0	0	0	NM	1	0	100%	1
North Carolina (Middle District)	0	1	1	0%	0	0	0%	1
Ohio (Southern District)	0	1	1	0%	2	0	67%	3
Pennsylvania (Eastern District)	1	3	4	25%	1	1	50%	6
Pennsylvania (Western District)	1	1	2	50%	1	0	67%	3
Virginia (Eastern District)	4	2	6	67%	0	0	67%	6
West Virginia (Northern District)	1	3	4	25%	1	0	40%	5

Source: PACER, Company reports, RBC Capital Markets estimates

Drilling down more to review how each judge ruled in the past. The top five judges accounted for 31% of the total decisions with Judges Farnan and Sleet in Delaware issuing the most decisions. The generic success rate for bench rulings from these five judges is 33%. The total success rate, however, including settlements is 75%.

When looking at judges that have issued five or more decisions (exhibit 7), the success rate for rulings for generics is just 37%. The total overall success rate for generics among these judges increases to 64% when including cases dropped or settled for this group of judges.

Exhibit 7: Decisions By Most Active Judges

Judge	District	Ruled For Generics	Ruled Against Generics	Total Rulings	Generic Success Rate	Case Settled	Case Dismissed	Overall Generic Success Rate	Total Cases
Joseph J. Farnan Jr	DE	6	10	16	38%	20	4	75%	40
Dennis M. Cavanaugh	NJ	7	4	11	64%	0	1	67%	12
John C. Lifland	NJ	3	7	10	30%	8	0	61%	18
Joel A. Pisano	NJ	4	5	9	44%	6	0	67%	15
Stanley R. Chesler	NJ	1	8	9	11%	2	0	27%	11
Sue L. Robinson	DE	3	5	8	38%	5	1	64%	14
Barbara S. Jones	NY-SD	3	5	8	38%	0	0	38%	8
Mary L. Cooper	NJ	1	5	6	17%	12	0	72%	18
Mariana R. Pfaelzer	CA-CD	5	0	5	100%	3	0	100%	8
Sidney H. Stein	NY-SD	2	3	5	40%	9	0	79%	14
David H. Coar	IL-ND	1	4	5	20%	4	0	56%	9
Sarah Evans Barker	IN-SD	1	4	5	20%	0	0	20%	5
Dickinson R. Debevoise	NJ	1	4	5	20%	0	0	20%	5
		38	64	102	37%	69	6	64%	177

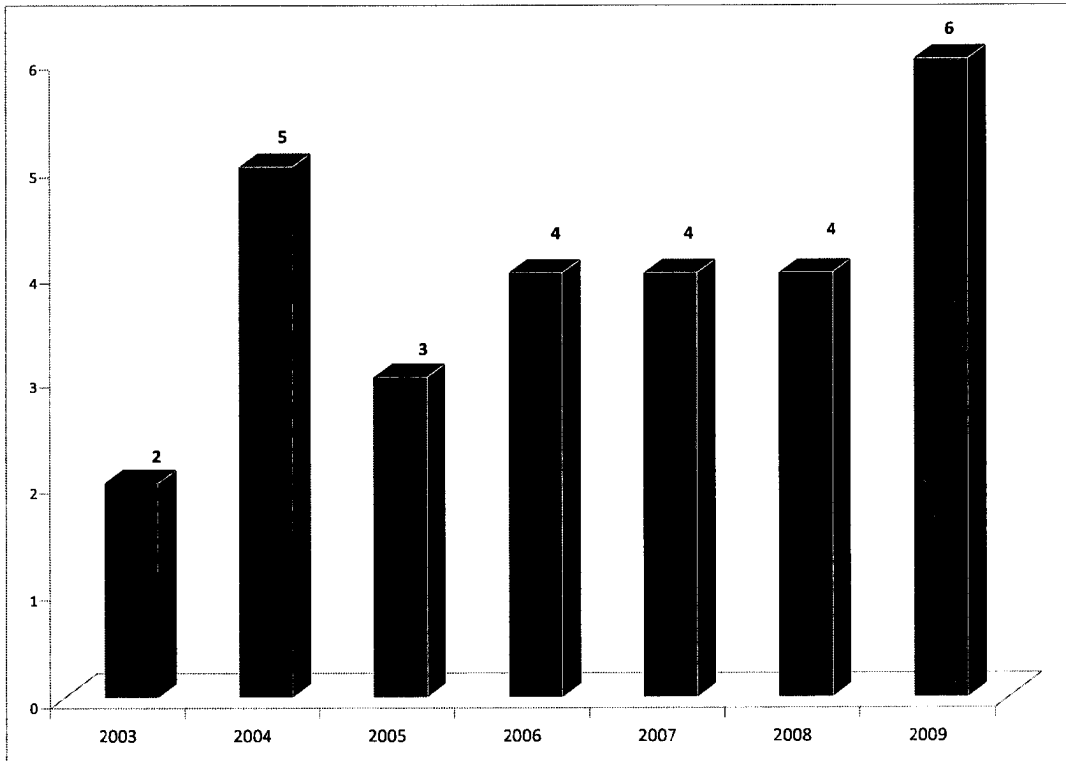
Source: PACER, Company reports, RBC Capital Markets estimates



At-Risk launches

While at-risk launches get a lot of attention, they are still fairly uncommon. We define an at-risk launch as any launch without a lower court ruling. Last year we saw six at-risk launches, up from four in the last few years (exhibit 8). Teva is the most likely to launch at-risk, having launched 12 of the 28 at-risk launches over the last seven years. This is followed by Sandoz with six and Mylan, Par and Sun each launching two products at-risk.

Exhibit 8: Number of At-Risk Launches 2003-2009



Source: PACER, Company reports, RBC Capital Markets estimates.

Last year was the first year we did not see any at-risk launches of blockbuster products like Protonix, Pulmicort or Plavix that occurred in prior years. However, 2009 was unusual in that of the six at-risk launches, two were on very small drugs – Niravam and Xopenex solution – and the other four were settled after launch – Solodyn by both Teva and Sandoz, as well as Ortho Tri Cyclen Lo and Loprox Shampoo (exhibit 9). Settling after launch appears to be a new emerging trend with two in 2008 and four in 2009.

Exhibit 9: At-Risk Launches 2008-2009

Date	Drug	Generic	Comments
Jan-08	Protonix	Sun/Caraco	
Mar-08	Olux	Perrigo	
Mar-08	Ethylol	Sun/Caraco	Settled after launch
Nov-08	Pulmicort	Teva	Settled after launch
Mar-09	Solodyn	Teva	Settled after launch
Jan-09	Niravam	Par	Very small drug
Jul-09	Ortho Tri Cyclen Lo	Teva	Settled after launch
Aug-09	Solodyn	Sandoz	Settled after launch
Aug-09	Xopenex concentrate	Mylan	Very small drug
Nov-09	Loprox shampoo	Paddock	Settled after launch

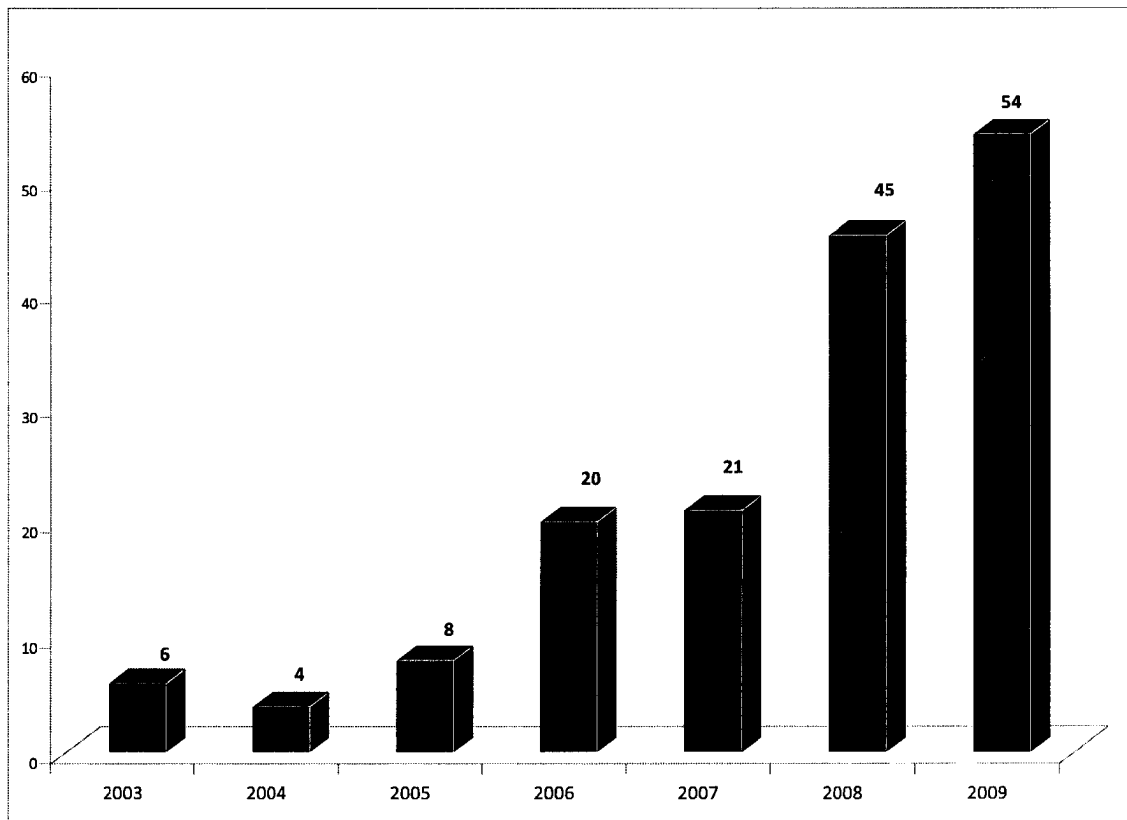
Source: Company reports and RBC Capital Markets estimates.



Settlements

The number of settlements in 2009 reached an all-time high of 54, up from 45 in 2008 (exhibit 10). Settlements spiked in 2006 following the June 2006 decision by the Supreme Court to not hear the FTC’s appeal in *Schering Plough vs. Upsher-Smith*. This case questioned whether monetary payment from a brand company to a generic company was lawful. In 2009, legislation heated up to limit patent settlements and in October the Senate Judiciary Committee passed the Kohl Bill. The bill was eventually revised to make payments presumptively illegal rather than *per se* illegal. This allows generics and brands to defend their settlement as pro-competitive. It is difficult to say whether the activity in Washington had a direct impact on the number of settlements, but of the 54 cases, there were 10 settled in both the first and second quarter of 2009 and 17 in each of the final quarters of the year. Thus, there was no discernable up tick in settlements near year end.

Exhibit 10: Number of Patent Settlements 2003-2009



Source: PACER, Company reports, RBC Capital Markets estimates.

Despite the noise in Washington, we expect settlements to remain fairly common. For active paragraph IV firms with over five resolved cases, settlements occur on average 54% of the time. Teva accounts for almost 30% of all settlements but this is just 53% of their caseload (exhibit 11). Of all generics, Wockhardt tends to walk the most, settling all four of its patent challenges. We have also included in the exhibit 11 the innovator firms with the most patent settlements. GlaxoSmithKline and Novartis have each settled about 9% of the total.

Exhibit 11: Most Cases Settled (Generics), Most Likely to Settle, Most Cases Settled (Brand)

Generic	Settled/ Dropped	Total Cases	% Cases Settled	Generic	Settled/ Dropped	Total Cases	% Cases Settled	Brand	Number of Settlements	% of Total
Teva	57	108	53%	Wockhardt	4	4	100%	Glaxo	14	8.8%
Watson	29	39	74%	Orchid	2	2	100%	Novartis	14	8.8%
Sandoz	10	24	42%	Upsher Smith	2	2	100%	Schering-Plough	12	7.5%
Ranbaxy	10	19	53%	Alcon	1	1	100%	Forest	11	6.9%
Mylan	9	25	36%	Amneal	1	1	100%	Abbott	11	6.9%
Dr. Reddy's	9	18	50%	Bedford	1	1	100%	J&J	8	5.0%
Par	9	15	60%	Breath	1	1	100%	Wyeth	8	5.0%
Impax	8	14	57%	Covidien	1	1	100%	Pfizer	7	4.4%
Apotex	7	21	33%	Cypress Pharma	1	1	100%	Shire	7	4.4%
Perrigo	7	8	88%	Tolmar	1	1	100%	Cephalon	6	3.8%
Sun	5	9	56%	Perrigo	7	8	88%	Medicis	6	3.8%
Lupin	5	8	63%	Anchen	3	4	75%	Purdue	6	3.8%
KV Pharm	5	7	71%	Watson	29	39	74%	Warner Chilcott	6	3.8%
Wockhardt	4	4	100%	KV Pharm	5	7	71%	Sanofi	5	3.1%
Actavis	3	6	50%	Glenmark	2	3	67%	AstraZeneca	3	1.9%

Source: PACER, Company reports, RBC Capital Markets estimates.

Exhibit 12: Patent Settlements in 2009

Settled	Brand	Generic	Drug	Launch Date
1/12/09	Loestrin-24 Fe	Warner Chilcott	Watson	01/22/2014
1/12/09	Femcon Fe	Warner Chilcott	Watson	NLT 1/1/2013
2/11/09	Lotrel	Novartis	Par	1Q11
2/19/09	Opana ER 7.5mg 15mg	Endo	Actavis	40739
3/6/09	Naprelan	Elan	Watson	41800
3/10/09	Xopenex	Sepracor	Barr	41322
3/18/09	Solodyn	Medicis	Teva	Nov 2011
3/27/09	Razadyne	J&J	KV Pharma	NA
3/27/09	Razadyne ER	J&J	KV Pharma	NA
3/30/09	Razadyne	J&J	Sandoz	NA
4/8/09	Clarinox	Schering-Plough	Mylan	07/01/2012
4/8/09	Clarinox	Schering-Plough	Sandoz	07/01/2012
4/14/09	Vanos	Medicis	Perrigo	12/15/2013
4/16/09	Oxycontin	Purdue	Actavis	TBD
4/21/09	Rythmol SR	Glaxo	Par	01/01/2011
4/23/09	Effexor XR caps	Wyeth	Lupin	06/01/2011
4/24/09	Lybrel	Wyeth	Watson	05/22/2010
4/29/09	Comtan	Novartis/Orion	Wockhardt	09/30/2012
4/29/09	Stalevo	Novartis/Orion	Wockhardt	09/30/2012
5/18/09	Effexor XR caps	Wyeth	Wockhardt	06/01/2012
7/9/09	Eloxatin	Sanofi	Ebewe	NA
7/10/09	Lexapro	Forest	Sun Pharm	10/14/2012
7/24/09	Ortho Tri Cyclen Lo	J&J	Teva	12/31/2015
8/3/09	Ethylol	Medimmune	Sun Pharm	NA
8/11/09	Clarinox RediTabs	Schering-Plough	Orchid	01/01/2012
8/11/09	Clarinox	Schering-Plough	Orchid	07/01/2012
8/11/09	Plavix	Bristol-Myers	Watson	TBD
8/30/09	Oxycontin	Purdue	Apotex	TBD
9/9/09	Lotrel	Novartis	Lupin	NA
9/11/09	Namenda	Forest	Apotex	04/11/2015
9/11/09	Namenda	Forest	Upsher Smith	01/11/2015
9/11/09	Namenda	Forest	Amneal	01/11/2015
9/11/09	Namenda	Forest	Wockhardt	01/11/2015
9/14/09	Carbatrol	Shire	Teva	NA
9/14/09	Lybrel	Wyeth	Sandoz	NA
9/24/09	Lotrel	Novartis	Dr. Reddy	NA
9/24/09	Lotrel	Novartis	Cobalt	NA
10/5/09	Flomax	Astellas	Impax	02/10/2003
10/8/09	Namenda	Forest	Sun Pharm	01/11/2015
10/13/09	Adderall XR	Shire	Sandoz	When approved
10/14/09	Vfend	Pfizer	Mylan	1Q11
10/15/09	Duac	Stiefel	Perrigo	TBD
10/19/09	Namenda	Forest	Cobalt	42015
10/27/09	Oxytrol	Watson	Barr	42120
11/5/09	Namenda	Forest	Teva	42015
11/12/09	Fentora	Cephalon	Teva	Oct 2018
11/16/09	Loprox	Medicis	Glenmark	41623
11/16/09	Vanos	Medicis	Glenmark	41623
11/30/09	Tricor 145mg	Abbott	Teva	40630
12/8/09	Effexor XR caps	Wyeth	Mylan	40695
12/8/09	Arthrotec	Pfizer	Teva	NA
12/9/09	Loprox shampoo	Medicis	Paddock	NA
12/14/09	Namenda	Forest	Dr. Reddy	42015
12/14/09	Namenda	Forest	Lupin	42015

Source: PACER, Company reports, RBC Capital Markets estimates.



30 Month Stays

As discussed earlier the expiration of the 30 month stay is important since the FDA is cleared to approve the generic at the end of the stay. At that point, the generic firm can decide to launch *at-risk* or wait for resolution of the litigation. Also, as previously discussed, *at-risk* launches are fairly uncommon. However, they do present an overhang in that the patent litigation can go in the innovator's favor after launch, leaving the generic company liable for damages. In exhibit 13, we highlight upcoming 30-month stay expirations in 2010.

Exhibit 13: Estimated 30 Months Stays Expirations in 2010

Drug	Dose	Brand Co.	Est. First Filer	Date Sued	30 Month Stay
Boniva	2.5 and 150 mg	Roche	Shared-Multiple	9/7/07	1/24/10
Zegerid caps	20/1100mg, 40/1100mg, 20/1680mg	Santarus	Par	9/13/07	1/30/10
Focalin XR	5, 10, 20 mg	Novartis	Teva	9/14/07	1/31/10
Focalin XR	15 mg	Novartis	Par	10/4/07	2/20/10
Zanaflex (caps)	2, 4, 6 mg	Acorda	Apotex	10/11/07	2/28/10
Avinza	30, 45, 60, 75, 90, 120 mg	King	Actavis	10/18/07	3/4/10
Allegra D-24	180 mg/240 mg	Aventis	Dr. Reddy's	10/26/07	3/14/10
Asacol	400 mg	P&G	Roxane	10/26/07	3/14/10
Combivir	150 mg/300 mg	GlaxoSmithKline	Teva	11/2/07	3/20/10
Luxiq	0.12%	Connetics	Perrigo/Pentech	11/6/07	3/24/10
Taxotere	20mg/2ml, 80mg/8ml, 160mg/16ml	Sanofi-Aventis	Hospira 505b2	11/9/07	3/28/10
Stalevo 100, 150	25/100/200 mg and 37.5/150/200 mg	Novartis/Orión	Sun Pharm	11/13/07	3/31/10
Opana ER	5, 10, 20, 40 mg	Endo	Impax	11/15/07	4/2/10
Zymar	0.3% solution drops	Allergan	Apotex	11/29/07	4/16/10
Zetia	10 mg	Merck	Glenmark	3/22/07	4/24/10
Tarka	4/240mg, 2/240mg, 2/180mg, 1/240mg	Abbott	Glenmark	12/7/07	4/28/10
Detrol LA	2, 4 mg	Pfizer	Teva	12/12/07	4/29/10
Strattera	10, 18, 25, 40, 60, 80, 100mg	Eli Lilly	Shared-Multiple	8/9-9/5/2007	5/6/10
Zegerid suspension	40/1680mg per packet	Santarus	Par	12/20/07	5/13/10
Abilify	2, 5, 10, 15, 20, 30 mg	Bristol-Myers Squibb	Shared-Multiple	3/2/07	5/15/10
Abilify ODT	10, 15, 20, 30 mg	Bristol-Myers Squibb	Barr	3/16/07	5/15/10
Argatroban Injection	100 mg/ml	Encysive	Barr	12/28/07	5/19/10
Equetro	200, 300 mg	Validus Pharmaceuticals	Actavis	1/17/08	6/3/10
Clobex shampoo	0.05%	Galderma	Actavis	2/21/08	7/8/10
Avodart	0.05 mg	GlaxoSmithKline	Barr	2/25/08	7/11/10
Abilify Oral Solution	1 mg/ml	Bristol-Myers Squibb	Teva	3/31/08	8/15/10
Entocort	3mg	AstraZeneca	Barr	5/22/08	10/8/10
Fentora	.1, .2, .3, .4, .6, .8mg	Cephalon	Watson	6/2/08	10/20/10
Alimta	500mg/vial	Eli Lilly	Teva	6/5/08	10/23/10
Accolate	10mg, 20mg	AstraZeneca	Dr. Reddy	6/27/08	11/12/10
Opana ER	7.5mg, 15mg	Endo	Actavis	7/11/08	11/27/10
Zometa (inj)	4mg base/5mL, 5mg base/100mL	Novartis	Teva	7/24/08	12/9/10
Uroxatral	10 mg	Sanofi-Aventis	Shared	9/21/07	12/10/10
Sensipar	30, 60, 90mg	Amgen	Teva	7/25/08	12/11/10
Actoplus Met	15/500mg and 15/850mg	Eli Lilly/Takeda	Mylan	8/5/08	12/22/10
Taxotere	40mg/ml, 20mg/0.5ml, 80mg/2ml	Sanofi-Aventis	Apotex 505b2	8/8/08	12/26/10
Opana ER	30mg	Endo	Actavis	7/11/08	12/29/10
Ambien CR	12.5mg	Sanofi-Aventis	Anchen	Filed 1/19/06	Not Sued
Ambien CR	6.25mg	Sanofi-Aventis	Actavis	Filed 2/24/06	Not Sued
Atacand	4, 8, 16, and 32 mg	AstraZeneca	Sandoz	Filed 12/22/06	Not Sued
Atacand HCT	16/12.5, 32/12.5 mg	AstraZeneca	Mylan	Filed 12/22/06	Not Sued
Elestat	0.05%	Inspire/Allergan	Sandoz	Filed 10/14/08	Not Sued
Exforge	10/160mg	Novartis	Par	Filed 10/1/07	Not Sued
Exforge	5/160mg	Novartis	Par	Filed 10/22/07	Not Sued
Exforge	10/320mg	Novartis	Par	Filed 11/9/07	Not Sued
Exforge	5/320mg	Novartis	Par	Filed 11/26/07	Not Sued
Lescol XL	80mg	Novartis	Par	Filed 3/15/07	Not Sued
Requip XL	2, 3, 4, 8, 12mg	GlaxoSmithKline	Impax, Actavis	Filed 10/14/08	Not Sued
Rhinocort spray	0.032 mg (32 mcg)/spray	AstraZeneca	Apotex	Filed 5/14/07	Not Sued

Source: PACER, Company reports, RBC Capital Markets estimates.



Authorized Generics

There were roughly 25 authorized generics (AG) launched in 2009, up from about 18 in the prior year. However, one trend we have noticed recently is an increasing number of generics launched without an AG. We counted around a dozen generics launched last year with no AG compared to just six in 2008. We believe this is a highly correlated to the increase in settlement agreements a few years ago. Some of the recent high-profile generic launches without AGs include Adderall XR, Pulmicort and Mirapex to name just a few. We see this as a very positive trend for the generic pharmaceutical industry and expect an increase in the number of AG-free launches in the future. Launching without an AG can generate almost three times the revenue and approximately 3.7x more profit than launching with an AG.

Notwithstanding the favorable economic impact an AG-less launch presents, we still expect AGs to remain part of the industry. While margins are small, an AG presents an attractive ROI for the company launching the AG. Of the 96 AGs we count launched by independent generic firms since 2000, Watson was involved in close to 20% with Prasco close behind (exhibit 14). We also expect generic arms of big pharma companies such as J&J's Patriot, Pfizer's Greenstone and Sanofi's Winthrop to remain active players in the market going forward.

Exhibit 14: Top Five Authorized Generic Players 2000-2009

Authorized Generics	Total
Watson	19
Prasco	17
Par	9
Sandoz	9
Ranbaxy	4
Industry Total	96

Source: PACER, Company reports, RBC Capital Markets estimates.

APPENDIX



Appendix A: Potential Launches 2010-2011

Date of Gx Entry	Brand Company	Drug	Generic Company	Type
TBD	Sanofi	Ambien CR	Anchen, Par	Patent
TBD	Merck	Primaxin IV	Multiple	Patent Expiration
TBD	Warner Chilcott	Femhrt	Barr	Settlement Launch
3/1/10	Meda	Astelina	Apotex	Settlement Launch
3/2/10	Boehringer	Flomax	Ranbaxy, Impax	Settlement Launch
4/6/10	Merck	Cozaar/Hyzaar	Multiple	Patent Expiration
4/20/10	GlaxoSmithKline	Coreg CR	Mutual	Data Exclusivity
4/27/10	Boehringer	Flomax	Multiple	Patent Expiration
5/22/10	Wyeth	Lybrel	Watson	Settlement Launch
6/1/10	Wyeth	Effexor XR caps	Teva	Settlement Launch
6/27/10	AstraZeneca	Arimidex	Multiple	Patent Expiration
7/1/10	Novartis	Exelon	Dr. Reddy's, Sun	Settlement Launch
8/28/10	Meda	Astelina	Cobalt	Settlement Launch
9/1/10	Valeant	Diastat	Par/Barr	Settlement Launch
9/23/10	Medicines Co.	Angiomax	Teva	At Risk
11/15/10	Eli Lilly	Gemzar	Multiple	Patent invalidated
11/25/10	Pfizer	Aricept	Teva, Ranbaxy	Patent Expiration
1/1/11	GlaxoSmithKline	Rythmol SR	Par	Settlement Launch
1/1/11	Novartis	Lotrel	Par	Settlement Launch
1/17/11	Takeda	Actos	Multiple	Patent Expiration
1/19/11	Wyeth	Protonix	Multiple	Patent Expiration
1Q11	Pfizer	Vfend	Mylan	Settlement Launch
1Q11	Novartis	Exelon	Watson	Settlement Launch
3/22/11	Pfizer	Xalatan	Multiple	Patent Expiration
3/28/11	Abbott	Tricor 145mg	Teva	Settlement Launch
6/1/11	Wyeth	Effexor XR caps	Impax	Settlement Launch
6/1/11	Wyeth	Effexor XR caps	Anchen	Settlement Launch
6/1/11	Wyeth	Effexor XR caps	Lupin	Settlement Launch
6/15/11	Sanofi	Nasacort AQ	Barr	Settlement Launch
6/20/11	J&J	Levaquin	Multiple	Patent Expiration
7/1/11	Bayer	Yaz	Barr	Settlement Launch
7/15/11	Endo	Opana ER 7.5mg 15mg	Actavis	Settlement Launch
10/23/11	Eli Lilly	Zyprexa	Multiple	Patent Expiration
10/23/11	Eli Lilly	Symbyax	Multiple	Patent Expiration
11/1/11	Medicis	Solodyn	Impax	Settlement Launch
11/1/11	Medicis	Solodyn	Teva	Settlement Launch
11/17/11	Bristol Myers	Plavix	Multiple	Settlement Launch
11/30/11	Pfizer	Caduet	Ranbaxy	Settlement Launch
11/30/11	Pfizer	Lipitor	Ranbaxy	Settlement Launch
2011E	Novartis	Femara	Mylan	Settlement Launch

Source: PACER, Company reports, RBC Capital Markets estimates.

Appendix B: Rulings By Judge 2000-2009 (Complete)

	Ruled For		Ruled Against	
	Generics	Generics	Settled	Dismissed
California (Central District)	8	0	9	0
Cormac J. Carney	0	0	1	0
James V. Selna	1	0	5	0
Mariana R. Pfaelzer	5	0	3	0
Robert J. Timlin	2	0	0	0
California (Northern District)	2	2	2	0
Charles R. Breyer	0	1	0	0
James Ware	0	0	1	0
Marilyn Patel	1	0	0	0
Maxine M. Chesney	0	1	1	0
Vaughn R. Walker	1	0	0	0
DC	3	2	0	0
John D. Bates	0	2	0	0
Reggie B. Walton	1	0	0	0
Ricardo M. Urbina	1	0	0	0
Royce C. Lamberth	1	0	0	0
Delaware	10	17	46	8
Gregory M. Sleet	0	2	19	3
Joseph J. Faman Jr	6	10	20	4
Kent A. Jordan	1	0	2	0
Sue L. Roblnson	3	5	5	1
Florida (Southern District)	2	1	4	0
Adalberto Jordan	1	1	0	0
Daniel T. K. Hurley	0	0	2	0
Shelby Highsmith	0	0	1	0
Wilkie D. Ferguson Jr.	1	0	0	0
William P. Dimitrouleas	0	0	1	0
Illinois (Northern District)	8	8	6	1
David H. Coar	1	4	4	0
Geraldine Soat Brown	0	0	1	0
James M. Rosenbaum	0	1	0	0
Joan B. Gottschall	1	0	0	0
Joan H. Lefkow	0	1	0	0
John W. Darrah	2	0	0	1
Rebecca R. Palmeyer	1	0	0	0
Richard A. Posner	1	1	1	0
Robert W. Gettleman	0	1	0	0
Ronald A. Guzman	1	0	0	0
Wayne R. Anderson	1	0	0	0
Georgia (Northern District)	0	0	5	0
Thomas W. Thrash Jr.	0	0	1	0
William S. Duffey, Jr	0	0	3	0
J. Owen Forrester	0	0	1	0
Indiana (Southern District)	1	5	0	2
Larry J. McKinney	0	0	0	1
Richard Young	0	1	0	1
Sarah Evans Barker	1	4	0	0
Maryland	0	0	2	0
William D Quarles, Jr	0	0	1	0
Marvin J. Garbis	0	0	1	0
Massachusetts	0	3	1	2
Douglas P. Woodlock	0	0	1	0
Joseph L. Tauro	0	1	0	1
Reginald C. Lindsay	0	0	0	1
Richard G. Steams	0	2	0	0
Michigan (Eastern District)	2	2	1	0
Avern Cohn	0	1	0	0
Bernard A Friedman	1	0	1	0
George Caram Steeh	1	1	0	0
Michigan (Western District)	0	0	1	0
Paul L. Maloney	0	0	1	0
Minnesota	2	0	0	0
Ann D. Montgomery	1	0	0	0
Michael J. Davis	1	0	0	0
Missouri (Eastern District)	1	0	0	1
Donald J. Stohr	0	0	0	1
Rodney W. Sippel	1	0	0	0
New York (Eastern District)	2	0	1	0
David G. Trager	1	0	1	0
Nina Gershon	1	0	0	0
New York (Southern District)	8	16	22	1
Barbara S. Jones	3	5	0	0
Colleen McMahon	1	0	0	0
Charles L. Brieant	1	0	0	0
Denise Cote	0	1	0	0
Gerard E. Lynch	0	2	0	0
Harold Baer	0	0	3	0
Kimba Wood	0	0	1	0
Laura Taylor Swain	0	0	1	0
Lawrence M. McKenna	0	2	1	0
Loretta A. Preska	0	0	1	0
Lewis A. Kaplan	0	0	0	1
P. Kevin Castel	0	0	1	0
Richard C. Casey	0	1	0	0
Richard J. Howell	0	0	1	0
Richard J. Sullivan	0	0	1	0
Robert P. Patterson	0	1	0	0
Setphen C. Robinson	0	0	2	0
Sidney H. Stein	2	3	9	0
Victor Marrero	0	0	1	0
William H. Pauley III	1	1	0	0
New Jersey	27	47	55	3
Harold A. Ackerman	0	2	2	1
Dennis M. Cavanaugh	7	4	0	1
Dickinson R. Debevoise	1	4	0	0
Faith S. Hochberg	1	0	1	0
Freda Wolfson	1	1	2	0
Garrett E. Brown, Jr	1	2	4	0
Joel A. Pisano	4	5	6	0
John C. Lifland	3	7	8	0
John W. Bissell	1	1	1	0
Jose L. Linares	1	1	0	1
Joseph A. Greenaway Jr	2	0	4	0
Katherine S. Hayden	1	1	1	0
Mary L. Cooper	1	5	12	0
Noel L. Hillman	0	0	1	0
Peter G. Sheridan	2	1	3	0
Renee Marie Bumb	0	4	1	0
Stanley R. Chesler	1	8	2	0
Susan D. Wigenton	0	0	2	0
Tonianne J. Bongiovanni	0	0	1	0
William J. Martini	0	1	3	0
William H. Walls	0	0	1	0
North Carolina (Middle District)	0	1	0	0
James A. Beaty	0	1	0	0
North Carolina (Eastern District)	0	0	1	0
James C. Dever, III	0	0	1	0
Ohio (Southern District)	0	1	2	0
Edmund A. Sargus	0	0	1	0
Michael R. Barrett	0	1	1	0
Pennsylvania (Eastern District)	1	3	1	1
Michael M. Bayson	0	2	0	0
Paul S. Diamond	0	0	1	0
R. Barclay Surrick	1	1	0	1
Pennsylvania (Western District)	1	1	1	0
Gary L. Lancaster	0	0	1	0
Terrence F. McVerry	1	1	0	0
Virginia (Eastern District)	4	2	0	0
Henry C. Morgan Jr.	2	0	0	0
Richard L. Williams	0	1	0	0
Robert E. Payne	1	0	0	0
Robert G. Doumar	0	1	0	0
T. S. Ellis, III	1	0	0	0
West Virginia (Northern District)	1	3	1	0
Irene M. Keeley	1	2	1	0
William K. Sessions	0	1	0	0

Source: PACER, Company reports, RBC Capital Markets estimates.



Appendix C: Paragraph IV Filings (Complete)

Drug	Dose	Estimated First Filer	Date Notified	Date Sued	Case Number	Court	Judge	Outcome for Generic	Other Paragraph IV Filers (Date Sued)
Ability	2.5, 10, 15, 20, 30 mg	Teva, Sandoz, Barr, Apotex, Synthron	Multiple	3/2/2007 (earliest)	cv-01000	NJ	Mary L. Cooper	Pending	Teva (3/07), Sandoz (3/07), Barr (3/07), Apotex (3/07), Synthron (4/07)
Ability ODT	10, 15, 20, 30 mg	Barr	3/16/07	3:07-cv-01267	NJ	Mary L. Cooper	Pending	Barr (3/07), Zydus (6/08)	
Ability Oral Solution	1 mg/ml	Teva	2/15/08	3:08-cv-01583	NJ	Mary L. Cooper	Pending	Teva (3/08, 10/08)	
Accolate	10mg, 20mg	Dr. Reddy	5/14/08	3:08-cv-02327	NJ	Mary L. Cooper	Pending	Dr. Reddy (6/08)	
Aciphex	20 mg	Teva, Dr. Reddy	11/20/03	1:03-cv-02123	SD of NY	Garard E. Lynch	Settled 5/08	Lost 5/07; Upheld 7/08	Dr. Reddy (1/03), Teva (11/03), Mylan (1/04)
Acicon	2, 4, 8 mg	Cobalt Pharma	8/23/06	1:03-cv-01855	ND of GA	Marvin H. Shoop	Settled 5/08	Lost 8/06; 5-9/08	Cobalt (8/06, 5-9/08)
Actonel	5, 30, 35 mg	Teva	7/2/04	1:03-cv-00940	DE	Joseph L. Farnam, Jr.	Lost 2/08; Upheld 5/09	Teva (8/04)	
Actonel	75 mg	Teva	12/19/07	1:03-cv-00066	DE	Joseph L. Farnam, Jr.	Lost 2/08; Upheld 5/09	Teva (2/08)	
Actonel With Calcium	35/500 mg	Teva	2/19/08	1:03-cv-00191	DE	Joseph L. Farnam, Jr.	Lost 2/08; Upheld 5/09	Teva (4/08)	
Actonel	150 mg	Teva	8/12/08	08-cv-00627	DE	Joseph L. Farnam, Jr.	Pending	Teva (9/08), Sun (1/09, D-4/09), Apotex (3/09)	
Actos	15, 30, 45 mg	Mylan	9/6/03	1:03-cv-08253	SD of NY	Denise L. Cote	Lost 2/06; Upheld 6/07	Mylan (10/03), Watson (10/03), Ranbaxy (10/03), Alphapharm (3/04), Sandoz (5/07), Torrent (7/09)	
Actopus Met	15/500, 15/850 mg	Mylan	6/23/08	1:03-cv-06999	SD of NY	Denise L. Cote	Pending	Mylan (8/08), Teva (5/09), Sandoz (6/09)	
Admoscan	3 mg/ml	Teva	4/18/05	1:05-cv-00337	DE	Sue L. Robinson	Settled 10/07; Launch 9/12	Teva (5/05, 5-10/07), Wockhardt (9/09)	
Adrenal XR	5, 10, 15, 20, 25, 30 mg	Barr	2/24/03	1:03-cv-01219	SD of NY	P. Kevin Castel	Settled 8/06; Launch 4/09	Barr (2/03, 5-8/06), Impax (12/03, 5-1/06), Colony (1/05, NS), Teva (3/05, 5-3/08), Andrx (11/06, 5-11/07), Sandoz (1/07, 5-10/09), Actavis/Colony (3/07, 5-4/08)	
Advicor	20/1000 mg	Filed 5/22/08	NA	NA	NA	NA	Pending	NA	
Advicor	20/500 mg	Filed 9/22/08	NA	NA	NA	NA	Pending	NA	
Advicor	20/750 mg	Filed 12/17/08	NA	NA	NA	NA	Pending	NA	
Aggrenox	25/200 mg	Barr	7/11/07	1:07-cv-00432	DE	Gregory M. Sleet	Settled 8/08; Launch 7/15	Barr (7/07, 5-8/08)	
Albion cream	5% cream	Filed 10/17/05	NA	NA	NA	NA	Pending	NA	
Alimta	500 mg/vial	Teva	6/5/08	08-cv-00315	DE	Gregory M. Sleet	Pending	Teva (6/08), APP Pharma (6/08), Barr (4/09)	
Alimta	100 mg/vial	Teva	11/19/08	08-cv-00860	DE	Gregory M. Sleet	Pending	Teva (11/08), Barr (4/09)	
Allegria tabs	30, 60, 180 mg	Barr	6/1/01	2:03-cv-03637 (lead case) 2:03-cv-04801 (consolidated with 2:01-cv-03627)	NJ	Joseph A. Greenaway, Jr.	At risk 9/05; Settled 11/08	Barr (9/01), Impax (3/02), Teva (2/03), Dr. Reddy (3/03), Sandoz (1/04, 8/04), Ranbaxy (4/04), Mylan (5/04, 8/05, 10/07), Wockhardt (11/07, WD-12/07), Sun (10/09)	
Allegria D-12	60/120 mg	Barr	3/28/02	2:07-cv-05180	NJ	Joseph A. Greenaway, Jr.	Settled 11/08; Launch 11/09	Barr (1/03), Impax (4/02, 3/04), Mylan (3/03, 3/04), Dr. Reddy (12/03), Sandoz (3/06, 5/07), Wockhardt (11/07, WD-12/07), Sun (10/09)	
Allegria tabs	30, 60, 180 mg	Dr. Reddy	10/26/07	2:07-cv-05180	NJ	Joseph A. Greenaway, Jr.	Pending	Dr. Reddy (10/07)	
Allegria D-12	60/120 mg	Dr. Reddy (505(b)2)	9/26/03	2:03-cv-05108	NJ	Joseph A. Greenaway, Jr.	Pending	Dr. Reddy (7/04)	
Alphagan P	0.15% solution	Exelis/Paddock	7/12/07	1:07-cv-00516	DE	Gregory M. Sleet	Lost 10/23/09	Exelis (3/07), Apotex (5/07)	
Alphagan P	0.10% solution	Filed 12/20/06	NA	NA	NA	NA	Pending	NA	
Ambien CR	12.5 mg	Anchen	Not sued	P IV filed 1/19/06	NA	NA	NA	Anchen (1/06, NS), Actavis, Synthron (2/07), Barr (4/07), Mutual (5/07), Sandoz (3/08)	
Ambien CR	6.25 mg	Actavis	Not sued	P IV filed 2/2/06	NA	NA	NA	Actavis (2/06, NS), Anchen, Watson (1/07), Synthron (2/07), Barr (4/07), Mutual (5/07)	
AndroGel	1% 0.5 mg/1 mg	Watson	10/20/08	1:03-cv-02501	ND of GA	Sue L. Robinson	Settled 9/06; Launch 8/15	Watson (8/03, 5-9/05), Paddock/Par (8/03, 5-9/06)	
AndroGel	250 mg/vial	Filed 12/26/07	NA	NA	NA	NA	NA	NA	
Angelox	43mg, 130mg	Lupin	9/1/09	1:09-cv-00751	DE	Eduardo C. Robreno	NA	Teva (10/09), APP (10/09)	
Angelox	43mg, 130mg	Lupin	12/2/08	1:09-cv-00083	MD	Richard D. Bennett	Dropped 10/2009	Lupin (1/09), Paddock (7/09-D)	
Angiotroban Injection	100 mg/ml	Barr	11/19/07	1:07-cv-11614	SD of NY	John G. Koeltl	Pending	Barr (12/07)	
Aricept	5, 10 mg	Teva, Ranbaxy	10/27/05	2:05-cv-05727	NJ	Garrett E. Brown, Jr.	Pending	Teva (12/05), Apotex (7/09-D)	
Aricept ODT	5, 10 mg	URV/Mutual	8/5/06	2:05-cv-03613	NJ	Garrett E. Brown, Jr.	Dismissed 12/07	Mutual/URV (8/06, D-12/07)	
Arthrocare	75/0.2, 50/0.2 mg	Teva	3/19/09	09-cv-03985	SD of NY	Richard J. Sullivan	Settled 12/09	Teva (4/09)	
Asacol	400 mg	Roxane	9/14/07	3:07-cv-05185	NJ	Freda L. Wolfson	Pending	Roxane (10/07)	
Astellin	EQ 0.125 mg base	Apotex	7/27/05	1:06-cv-00164	DE	Sue L. Robinson	Settled 4/08; Launch 3/10	Apotex (3/05, 4/08-S), Sun Pharma (6/07), Cobalt (8/07, 8/08-S)	
Atacand	4, 8, 16, and 32 mg	Sandoz	Not sued	NA	NA	NA	NA	Sandoz (4/07, NS), Teva (3/08, 4/08, NS), Mylan (7/08, NS)	
Atacand HCT	16/12.5, 32/12.5 mg	Mylan	Not sued	NA	NA	NA	NA	Mylan (9/08, NS)	
Atipria	600/200/300 mg	Teva	3/30/09	1:08-cv-10838	SD of NY	Richard J. Sullivan	Pending	Teva (5/09)	
Axid oral sol.	15 mg/ml	Filed 5/14/08	NA	NA	NA	NA	Pending	NA	
Availde	150/12.5, 300/12.5 mg	Filed 11/10/04	NA	NA	NA	NA	Pending	NA	
Availde	300/25 mg	Filed 6/6/05	NA	NA	NA	NA	Pending	NA	
Avandamet	1/500, 2/500, 4/500, 2/1000, 4/1000 mg	Teva	12/20/04	1:05-cv-00536	NJ	Noel L. Hillman	Settled 9/07; Launch 1Q12	Teva (1/05, 5-9/07)	
Avandia	1/4, 2/4, 4/4, 8/2, 8/4mg	Teva	3/29/07	5/11/07 1:07-cv-02238	NJ	Noel L. Hillman	Settled 9/07; Launch 1Q12	Teva (5/07, 5-9/07)	
Avandia	2, 4, 8 mg	Teva or Dr. Reddy	7/14/03	9/6/03 (TEVA) 1:03-cv-04037 (TEVA)	NJ	Noel L. Hillman	Settled 9/07; Launch 1Q12	Teva (8/03, 5-9/07), Dr. Reddy (9/03)	
Avapro	75, 150, 300 mg	Teva	NA	NA	NA	NA	Pending	Teva	
Axibac	400 mg	Dr. Reddy's	2/10/04	1:04-cv-00179	DE	Sue L. Robinson	Lost 10/07	Dr. Reddy (3/04), Teva (4/07)	



Drug	Dose	Estimated First Filer	Date Notified	Date Sued	Case Number	Court	Judge	Outcome for Generic	Other Paragraph IV Filers (Date Sued)
Avizor	30, 45, 60, 75, 90, 120 mg	Acavis	9/14/07	10/18/07	2:07-cv-05041	DE	Susan D. W. Genton	Pending	Actavis (10/07), Sandoz (7/09)
Avizor	0.05 mg	Barr	1/11/08	2/25/08	1:08-cv-00112	NI	Sue L. Robinson	Pending	Barr (1/08)
Avort	6.25, 12.5 mg	Teva	2/8/06	3/24/06	1:06-cv-02293	SD of NY	Loretta A. Presta	Settled 12/07	Teva (2/06)
Azor	5/20, 10/40 mg	Mylan	4/18/08	6/3/08	2:06-cv-03462	NI	William J. Martini	Lost 7/09	Mylan (6/08)
Benicar	5, 20, 40 mg	Mylan	6/19/06	7/31/06	2:06-cv-03462	NI	William J. Martini	Lost 7/09	Mylan (7/06)
Benicar HCT	20/12.5, 40/12.5, 40/25 mg	Mylan	5/19/07	9/22/07	2:07-cv-03039	NI	William J. Martini	Lost 7/09	Mylan (6/07)
Boniva	2.5 and 1.50 mg	Shared	7/27/07	9/7/07	2:07-cv-04284	NI	Stanley R. Chesler	Pending	Teva (9/07), Mutual (9/07), Apotex (9/07), Dr. Reddy's (9/07), Cobalt (9/07), Orchid (9/07), Mylan (9/07), Actavis (5/08), 6/08-D)
Boniva	1 mg/ml, 3 ml vial	Filed 9/31/07	NA	NA	NA	NA	NA	NA	NA
Brovina	0.015mg base/2mL	Filed 10/1/09	NA	NA	NA	NA	NA	NA	NA
Caleq	2.5/50, 5/10, 5/20, 5/40, 10/10, 10/20, 10/40	Ranbaxy	1/24/07	3/9/07	1:07-cv-00138	DE	Joseph J. Farnam, Jr.	Lost 11/07	Ranbaxy (3/07, 3/08-DJ), Sandoz (10/09)
Candice (ini)	50 mg/vial and 70 mg/vial	Teva	10/22/09	11/25/09	2:09-cv-06026	NI	Stanley R. Chesler	Pending	Teva (11/09)
Carbatrol	300 mg	Nostrum Pharma	7/29/03	9/18/03	3:03-cv-04436	NI	Mary L. Cooper	SI denied 7/05	Nostrum (9/03), Core Pharma (5/06), Teva (5/07, 5-9/09), Actavis (7/08, L-3/09), Core Pharma (5/06), Teva (5/07, 5-9/09), Nostrum (7/08), Apotex (7/08), Actavis (7/07), L-3/09)
Carbatrol	100, 200 mg	Core Pharma	3/30/06	5/17/06	2:06-cv-02266	NI	Stanley R. Chesler	SI granted 11/08	
Cardiem LA	120, 180, 240, 300, 360, 420 mg	Andrx	9/2/05 (other doses)	8/10/05	1:05-cv-00586	DE	Kent A. Jordan	Settled 12/07; Launch 4/09	Andrx (8/05, 10/05, 10/06, 5-12/07)
Celebrex	100, 200, 400 mg	Teva	1/6/04	2/19/04	2:04-cv-00754	NI	John C. Liffand	Lost 3/07; Upheld in part; Reversed in part 3/08	Teva (2/04)
Celebrex	50 mg	Filed 3/21/08	NA	NA	NA	NA	NA	Pending	
Cenestin	1.25, 0.625mg	Paddeck	1/15/09	3/2/09	1:09-cv-1905	SD of NY	NA	Pending	Paddeck (3/09)
Clialis	5, 10, 20 mg	Filed 11/21/07	NA	NA	NA	NA	NA	Pending	
Clialis	2.5 mg	Filed 10/14/08	NA	NA	NA	NA	NA	Pending	
Clarithrex	5 mg	Shared	8/17-8/31/06	9/29/06	3:06-cv-04715	NI	Mary L. Cooper	Pending	Zyus; Sandoz (5-9/09); Mylan (5-9/09); Orchid (5-9/09); Perrigo (5-12/08); Glenmark, GeoPharma, Lupin (5-12/08); Ranbaxy, Sun Pharm, Watson (all 9/06), Anchen (11/07), Zydis (9/05), Dr. Reddy's (9/06, 5-12/08), Orchid (5-8/09)
Clarithrex	2.5, 5 mg	Zyus, Dr. Reddy's	8/17-8/31/06	9/29/06	3:06-cv-04715	NI	Mary L. Cooper	Settled 12/08	Dr. Reddy (9/06, 5-12/08), Anchen (10/07), Sandoz (3/08)
Clarithrex	2.5/120, 5/240 mg	Filed 5/9/08	NA	NA	NA	NA	NA	Pending	
Clarithrex syrup	0.5 mg/ml	Filed 5/9/08	NA	NA	NA	NA	NA	Pending	
Globex lotion	0.05%	Actavis	5/22/06	7/5/06	4:06-cv-00471	ND of TX	Terry R. Means	Pending	Actavis (7/06)
Globex shampoo	0.05%	Actavis	1/18/08	2/21/08	4:08-cv-00115	ND of TX	John McBrady	Pending	Actavis (2/08)
Globex spray	0.05%	Paddeck	11/24/08	1/7/09	4:09-cv-00002	ND of TX	Terry R. Means	Pending	Paddeck (1/09)
Combigan	0.2%/0.5%	Sandoz	2/20/09	4/7/09	2:09-cv-00097	DE	John T. Ward	Pending	Sandoz (4/09), Hi-Tech (6/09), Alcon (11/09)
Combin	150/500 mg	Teva	9/20/07	11/2/07	1:07-cv-00713	DE	Joseph J. Farnam, Jr.	Settled 4/09; Launch 9/12	Teva (11/07), Lupin (8/08)
Comtan	200 mg	Wockhard	8/3/07	9/13/07	1:07-cv-00550	DE	Gregory M. Sleat	Dismissed 10/06	Wockhard (9/07), Sun Pharm (11/08)
Concerta	18, 27, 36, 54 mg	Impax	7/20/05	9/1/05	1:05-cv-00662	DE	Joseph J. Farnam, Jr.	Dismissed 10/06	Impax (9/05, D-10/06), Andrx (9/05)
Copaxone	20 mg/mL, 3mL	Momenta/Sandoz	7/14/08	8/28/08	1:08-cv-07611	SD of NY	Barbara S. Jones	Pending	Momenta/Sandoz (8/08), Mylan (11/09)
Coquat	28/10.5%	Hi-Tech Pharmaceutical	12/5/05	1/18/06	3:06-cv-00256	NI	Mary L. Cooper	Lost 4/08; Upheld 4/07	Hi-Tech (1/06), Apotex (12/06)
Covert HS	240 mg	Filed 12/03	NA	NA	NA	NA	NA	Pending	
Coreg CR	40, 80, 10, 20 mg	URL/Mutual	12/14/07	2/4/08	2:08-cv-00549	ED of PA	Bridley Surrick	Dismissed 11/08	URL/Mutual (2/08)
Crestor	5, 10, 20, 40 mg	Shared	10/31-11/19/07	12/11/07	Multiple	Multiple	Joseph J. Farnam, Jr.	Pending	Aurobindo (12/07), Apotex (12/07), D-1/08), Cobalt (12/07), Par (12/07), Sandoz (12/07), Mylan (12/07), Sun (12/07), Teva (12/07-NS), Glenmark (12/07-NS)
Cubicin	250, 500mg/vial	Teva	2/6/09	3/23/09	09-cv-00189	DE	Gregory M. Sleat	Pending	Teva (3/09)
Culivate	0.05%	Glenmark	10/27/08	10/27/08	08-cv-05023	ED of NY	Carol B. Amoh	Pending	Glenmark (10/08), Perrigo (11/2009)
Symbelta	20, 30, 60 mg	Shared	10/28-11/06/08	11/14/08	Multiple	Multiple	Larry J. McKinney	Pending	Impax (11/08), Actavis (11/08), Sandoz (11/08), Wockhard (11/08), Cobalt (11/08), Lupin (11/08), Aurobindo (11/08), Sun (12/08), Anchen (6/09)
Delsym	30mg/5mL	Tris Pharma	5/14/09	6/26/09	3:09-cv-03125	NI	Freda L. Wolfson	Pending	Tris (6/09)
Detrol	1, 2 mg	Teva	2/23/04	3/26/04	2:04-cv-01418	NI	Dennis M. Cavanaugh	Dismissed 3/07	Teva (3/04)
Detrol LA	2, 4 mg	Teva	10/30/07	12/12/07	2:08-cv-01331	NI	Dennis M. Cavanaugh	Pending	Teva (12/07), Impax (3/08, 8/08)
Dilatol	2.5/0.5, 5/1, 10/2, 15/3, 20/4 mg/ml	Kall/Par	5/28/04	7/8/04	2:04-cv-03238	NI	John C. Liffand	Settled 7/07; Launch 9/10	Par (7/04, 5-7/07)
Dilatol acudial	5 mg/mL, 4mL	Filed 12/23/06	NA	NA	NA	NA	NA	Pending	
Differin	0.3%	Filed 9/15/09	NA	NA	NA	NA	NA	Pending	
Diovan	40, 80, 160, 320 mg	Ranbaxy	6/28/07	8/9/07	3:07-cv-03755	NI	Mary L. Cooper	Settled 9/07; Launch 9/12	Ranbaxy (8/07, 5-9/07)
Diovan HCT	80/12.5, 160/12.5, 160/25 mg	Mylan (7)	NA	NA	NA	NA	NA	Pending	
Diovan HCT	320/12.5, 320/25 mg	Filed 2/7/07	NA	NA	NA	NA	NA	Pending	
Dorzex	75, 100 mg	Shared	12/23/08	2:08-cv-08304	NI	NA	NA	Pending	
Dorzex	150 mg	Impax	3/19/09	2:09-cv-01283	NI	William J. Martini	William J. Martini	Pending	Mutual (12/08), Mylan (12/08), Impax (12/08), Sandoz (1/09), Actavis (1/09)
Dovonex solution	0.0005%	Hi-Tech Pharmaceutical	NA	Not Sued	P.I.V filed 5/19/06	DE	NA	Dismissed 10/19/09	Hi-Tech (8/06, NS), Altana (9/06, NS)
Duac	1%/5%	Perrigo	4/19/09	5/28/09	09-cv-00376	DE	Sue L. Robinson	Dismissed 10/19/09	Perrigo (5/09, D-10/09)
Effexor XR caps	37.5, 75, 150 mg	Teva	2/26/03	3/24/03	2:03-cv-01293	NI	William J. Martini	Settled 10/05; Launch 7/10	Teva (3/03, 5-10/05), Impax (4/06, 5-7/08), Anchen (4/06, 5-11/08), Lupin (3/07, 5-4/09), Osmolca (4/07, 5-1/08), Sandoz (6/07), Mylan (7/07, 5-12/09), Wockhard (8/07, 5-5/09), Apotex (8/08), Torrent (1/09), Zydis (4/09), Orchid (7/09)
Effexor XR tabs	37.5, 75, 150 mg	Sun Pharm	8/29/07	Not Sued	Convenient Not NA	DC	NA	Pending	Sun Pharm (NS)
Flestat	0.05%	Sandoz	1/16/09	Not Sued	1:09-cv-01444	DC	NA	Pending	Sandoz (7/09-D)
Flocon cream	0.1%	Filed 4/03	NA	NA	NA	NA	NA	Pending	
Flocon lotion	0.1%	Filed 6/10/04	NA	NA	NA	NA	NA	Pending	



Drug	Dose	Estimated First Filer	Date Notified	Date Sued	Case Number	Court	Judge	Outcome for Generic	Other Paragraph IV Filers (Date Sued)
Eloacin	50 mg/vial, 100 mg per vial	Shared	May 2007	June/July 2007	3:07-cv-02782	NJ	Freda L. Wolfson	Won 6/09; RKO 8/09; Remanded 9/09	Sandoz (6/07), Dabur (6/07), Par (10/07), Teva (7/07), Abraxis (7/07), Ebewe (7/07), S-7/09), Actavis (7/07), Sun/Caraco (7/07), Mayne (7/07), Barr (11/07), Barr (1/08), Apotex (8/08)
Eloacin XR	200 mg per vial	Par, Ebewe	5/24/07	7/6/07	3:07-cv-03183	NJ	Freda L. Wolfson	Pending	Par (7/07), Ebewe (7/07), Mayne (9/07), Teva (11/07), Barr (1/08)
Emend	40, 80, 125 mg	Sandoz	1/19/09	2/27/09	3:09-cv-00890	NJ	Mary L. Wolfson	Pending	Sandoz (2/09)
Enblex	7.5, 15 mg	Teva, Watson, Anchen	3/19/09	4/24/09	1:09-cv-00291	DE	Sue L. Robinson	Pending	Teva (4/09), Watson (4/09), Anchen (4/09)
Enblex XR	3 mg	Barr	4/19/08	5/22/08	1:08-cv-00305	DE	Gregory M. Sleet	Pending	Barr (5/08), Mylan (7/08)
Epipen	0.15, 0.3 mg	Teva	7/20/09		1:09-cv-00652	DE	Gregory M. Sleet	Pending	Teva (9/09)
Epwlr	150 mg	Filed 10/1/07	NA	NA	NA	NA	NA	NA	NA
Epwlr HBV	100 mg	Filed 10/31/07	NA	NA	NA	NA	NA	NA	NA
Ediroom	600/300 mg	Aurobindo (?)	NA	NA	NA	NA	NA	NA	NA
Efedrone	200, 300 mg	Actavis (?)	12/4/07	1/12/08	1:08-cv-00336	DE	Gregory M. Sleet	Pending	Actavis (1/08)
Ethylol	500 mg/vial	Sun Pharm	6/29/04	8/12/04	1:08-cv-02832	MD	Marvin J. Garbis	Settled 7/09	Sun Pharm (8/04)
Evista	60 mg	Barr	10/9/02	1/12/02	1:02-cv-01844	SD of IN	Sarah Evans Barker	Lost 9/09	Barr (12/02), Teva (6/06), Invagen (1/09)
Evoclin	30mg	Perrigo/Cobtek	1/29/09	3/13/09	1:09-cv-00187	DE	Sue L. Robinson	Pending	Cobtek (3/09)
Evoclin XR	30mg	Par	1/29/09	6/28/09	1:09-cv-00470	DE	Jerome B. Simandle	Pending	Apotex (6/09), Sandoz (11/09)
Exforge	10/160 mg	Par	NA	Not Sued	NA	NA	NA	NA	Par (10/07, NS)
Exforge XR	5/160 mg	Par	NA	Not Sued	NA	NA	NA	NA	Par (11/07, NS)
Exforge XR	10/320 mg	Par	NA	Not Sued	NA	NA	NA	NA	Par (11/07, NS)
Exforge XR	5/320 mg	Par	NA	Not Sued	NA	NA	NA	NA	Par (11/07, NS)
Exelon caps	1.5, 3, 4.5, 6 mg	Dr. Reddy's, Sun Pharm	NA	8/5/04	1:04-cv-06045	SD of NY	Harold Baer	Settled 12/07, 1/08	Dr. Reddy's (8/04, 5-1/08), Sun Pharm (8/04, 5-12/07), Ranbaxy (3/05), Watson (5/05, D-12/07)
Exelon solution	2 mg/ml	Ranbaxy	NA	NA	NA	NA	NA	Pending	Ranbaxy
Factive	320 mg	Orchid	5/30/08	NA	NA	NA	NA	Pending	Orchid
Famvir	125, 250, 500 mg	Teva	7/22/05	4/8/05	2:05-cv-01887	NJ	Dennis M. Cavanaugh	NA	Teva (9/05), Roxane (3/08)
Fasodex (inj)	50 mg/ml, 2.5 mL, 5 mL	Filed 10/1/09	NA	NA	NA	NA	NA	NA	NA
Fentanyl	25, 100 mg	Barr	7/14/08	8/21/08	1:08-cv-00531	DE	Joseph J. Farnan, Jr.	Case closed 8/09	Barr (8/08), Novel (11/08)
Femara	2.5 mg	Mylan	5/10/06	6/28/06	3:06-cv-02885	NJ	Mary L. Cooper	Settled 12/08	Mylan (6/06)
Femcon Fe	0.035 mg, 0.04 mg	Barr	8/13/07	9/24/07	2:07-cv-04550	NJ	William J. Martini	Settled 12/08	Barr (9/07, 5-12/08), Watson (9/07, 5-1/09), Lupin (8/09)
Femora	1, 2, 3, 4, 6, 8 mg	Ranbaxy	4/21/08	6/2/08	3:08-cv-00330	DE	Sue L. Robinson	Pending	Watson (6/08), Barr (7/08, 10/08, 5-11/09)
Floxam	0.4 mg	Ranbaxy	4/6/05	5/13/05	3:05-cv-02583	NJ	Mary L. Cooper	Lost 2/07; Settled 11/07	Ranbaxy (5/05, 5-11/07), Impax (7/08, 5-10/09)
Floxam	7/9/04 (5, 10 mg)								
Focalin daily	2.5, 5, 10 mg	Teva	7/28/04 (2, 5 mg)	8/19/04	3:04-cv-04030	NJ	Freda L. Wolfson	Pending	Teva (8/04), Par (10/07)
Focalin XR	5, 10, 20 mg	Teva	8/3/07	9/14/07	1:07-cv-00552	DE	Sue L. Wolfson	Pending	Teva (9/07), Par (10/07), Actavis (10/07), Barr (11/07)
Focalin XR	15 mg	Par	8/23/07	10/9/07	1:07-cv-00603	DE	Sue L. Robinson	Pending	Lupin (1/09)
Fortamet	500, 1000 mg	Lupin	12/3/08	1/15/09	09-cv-00037	DE	Joseph J. Farnan, Jr.	Pending	Apotex (7/06)
Fortical	200 mcg	Apotex	6/12/06	7/29/06	1:06-cv-05571	SD of NY	Robert P. Patterson	Pending	Apotex (7/06)
Forenol	500, 750, 1000 mg	Mylan, Barr, Natco	7/2/09	3/16/09	1:09-cv-02380	SD of NY	Paul G. Gardephe	Pending	Mylan (3/09), Barr (3/09), Natco (3/09)
Gabtril	2, 4 mg	Sun Pharm	NA	Not Sued	P. IV filed 2/1/05	NA	NA	Pending	Sun (5/05)
Gemzar	200 mg/vial	Teva	1/17/06	2/15/06	1:06-cv-00238	SD of IN	Sarah Evans Barker	Won 8/09	Teva (2/06), Mayne (8/06), Sun Pharm (12/06, D-9/07), Sandoz (10/09)
Gemzar	2 g/vial	Hospira/Mayne	12/5/07	1/10/08	1:08-cv-00037	SD of IN	Sarah Evans Barker	Won 8/09	Hospira (1/08), Mayne (1/08), Teva (9/08)
Geodon	20, 40, 60, 80 mg	Lupin	NA	NA	NA	NA	NA	Pending	Lupin
Gleevec	100, 400 mg	Sun Pharm	NA	NA	NA	NA	NA	Pending	NA
Glimezide	500, 1000 mg	Lupin	11/6/09	11/25/09	09-cv-05587	ND of CA	NA	Pending	NA
Glimezide (inj)	2 mg/ml, 2 ml ampules	Perrigo/Pentech	NA	2/21/08	1:08-cv-01083	ND of IL	Robert M. Dow, Jr	Pending	Pentech (2/08), Eagle (4/09), Sandoz (7/09), Roxane (8/09)
Integrilin	2 mg/mL, 10 mL vial	Teva	1/8/09	2/18/09	09-cv-00105	DE	J. Curtis Joyner	NA	Teva (2/09)
Kaletra	100/25, 200/50 mg	Mylan	1/30/09	3/13/09	1:09-cv-01586	ND of IL	Robert M. Dow, Jr.	Pending	Mylan (3/09)
Lescor XL	80 mg	Par	NA	Not Sued	NA	NA	NA	Pending	Par (3/07, NS)
Lescor	20, 40 mg base	Mylan	8/27/08	10/10/08	2:08-cv-05042	NJ	Peter G. Sheridan	Pending	Mylan (10/08)
Lexapro	5, 10, 20 mg	Ivax	NA	9/23/03	1:03-cv-00891	DE	Joseph J. Farnan Jr.	Lost 7/06; Upheld 9/07	Ivax (9/03), Alphapharm (5/04, 5-10/05), Caraco (7/05, 5-7/09)
Levitra	5, 10, 20 mg	Teva	5/19/09	7/1/09	1:09-cv-00480	DE	Gregory M. Sleet	Pending	Teva (7/08)
Lipitor	10, 20, 40, 80 mg	Ranbaxy	1/10/03	2/25/03	1:03-cv-00209	DE	Joseph J. Farnan Jr.	Lost 12/05; Upheld 8/05	Ranbaxy (2/03, D1-3/08), Teva (6/07, 4/08), Cobalt (10/07), Apotex (12/08), Mylan (6/09), KDDCO (11/09), Kremers-Urban (12/09), Dr. Reddy's (12/09)
Loestrin 24 Fe	1 mg, 0.02 mg and 75 mg	Watson	6/19/06	7/28/06	2:06-cv-03451	NJ	Harold A. Ackerman	Settled 7/09	Watson (7/06, 5-3/09), Lupin (8/09, D-10/09)
Loprox.gel	0.7% gel	Paddock	5/8/06	6/22/06	0:06-cv-02588	MI	Michael J Davis	Settled 8/07	Paddock (6/06, 5-8/07), Glenmark (10/09, 5-11/09)
Lotrel	2.5/10, 5/10, 5/20, 10/20 mg	Teva	8/6/04	9/16/04	2:04-cv-04473	NJ	Garrett E. Brown, Jr.	At risk 5/07; PI denied 6/07	Teva (9/04), Watson (3/08), Par (10/06, 5-2/09), Lupin (12/06, 5-9/09), Dr. Reddy (17/07, 5/08, 5-9/09), Mylan (10/07), Cobalt (12/08, 5-9/09)
Lotrel	5/40, 10/40 mg	Par	11/17/06	12/29/06	2:06-cv-04788	NJ	Garrett E. Brown, Jr.	Pending	Par (12/06), Lupin (12/06, 5-9/09), Teva (2/08), Cobalt (6/08)
Lovaza	1g	Par, Teva, Apotex	3/17/09	4/23/09	1:09-cv-00286	DE	Sue L. Robinson	Won 5/16/05; Overturned 4/05	Teva (4/09), Par (4/09), Apotex (4/09)
Lovenox	Multiple	Amphastar Pharma	NA	8/4/03	5:03-cv-00887	CD of CA	Mariana R. Pfeister	(Remanded), Won 2/07, Under appeal	Amphastar (8/03), Teva, Moments/Sandoz, Eon (8/06), Hospira (12/07)

Drug	Dose	Estimated First Filer	Date Notified	Date Sued	Case Number	Court	Judge	Outcome for Generic	Other Paragraph IV Filers (Date Sued)
Lumigan	0.03%	Barr	3/28/09	5/7/09	09-cv-00333	DE	Sue L. Robinson	Pending	Barr (5/09), Wockhardt (3/09), Reedy's (3/09), Novane (3/09), Cobalt (3/09), Glenmark (3/09), Orchid (3/09), Origenuis (3/09), Lupin (3/09), Sun Pharm (3/09),
Lunesta	1, 2, 3 mg	Shared	Multiple	3/20/09	2:09-cv-01302	NJ	Dennis M. Cavanaugh	Pending	Actavis (10/09), Anchen (10/09), Pentech (11/07)
Luvox CR	100, 150 mg	Actavis, Anchen, Perrigo/Pentech	8/24/09	10/16/09	1:09-cv-00744	DE	Gregory M. Sleet	Pending	Watson (3/08, D-4/09), Sandoz (5/08, D-9/09)
Ludix	0.12%	Watson	9/24/07	11/6/07	1:07-cv-00297	ND of IL	Jean B. Gottschall	Pending	Teva (4/09), Sun (4/09), Cobalt (4/09), Glenmark (8/09)
Lybrel	0.02 mg/0.09 mg	Watson	2/1/08	3/12/08	1:08-cv-00145	DE	Joseph J. Farnan, Jr.	Dismissed 4/09; Launch 5/10	
Lyrica	25, 50, 75, 100, 150, 200, 225, 300mg	Shared	3/17/09	4/29/09	Multiple	DE	Gregory M. Sleet	Pending	
Mefenone	250/100mg	Glenmark	8/10/09	8/14/09	1:09-cv-00608	DE	Joseph J. Farnan, Jr.	Pending	
Mefenone	5, 10 mg	Filed 9/2/04	NA	NA	NA	NA	NA	Pending	
Mefenone	5, 10 mg	Mylan (7)	NA	NA	NA	NA	NA	Pending	
Mefenone	10, 15 mg	Meridia	11/9/09	12/23/09	1:09-cv-07968	ND of IL	Rebecca R. Palmeyer	Pending	
Mefenone	10, 20, 30 mg	Filed 5/13/05	NA	NA	NA	NA	NA	Pending	
Mefenone	40 mg	KV Pharm	4/18/08	NA	1:08-cv-00223	DE	Joseph J. Farnan, Jr.	Pending	KV (4/08)
Mefenone (topical)	0.75%	Tolmar	3/19/09	3/3/09	3:09-cv-0400	ND of TX	David C. Godbey	Dismissed 4/09	Tolmar (3/09, D-4/09)
Mifedrisol	20, 40, 80 mg	Watson (?)	NA	NA	NA	NA	NA	Pending	
Mifedrisol HCT	80/112.5, 80/25mg	Filed 12/31/08	NA	NA	NA	NA	NA	Pending	
Mirapex	0.25, 0.125, 0.5, 1.0, 1.5 mg	Barr	8/10/05	9/26/05	1:05-cv-00700	DE	Joseph J. Farnan, Jr.	Won 6/08; Settled 8/08; Launch 1/10	Barr (9/05, 5-9/08), Mylan (12/05)
Moxonidine	2% and 1.2 g	Perrigo	3/7/08	4/19/08	3:08-cv-01909	NJ	Freda L. Wolfson	Dismissed 9/08	Perrigo (4/08)
Moviprep oral soln	100 g, 7.5 g, 2.691 g, 1.015 g, 5.9 g and 4.2 g per pouch	Novel Labs	NA	5/14/08	3:08-cv-02311	NJ	Freda L. Wolfson	Pending	Novel (5/08)
Mucinex SE	600, 1200 mg	URL/Mutual	8/22/06	10/2/06	2:06-cv-04418	ED of PA	Paul S. Diamond	Settled 3/07; Launch 7/12	Mutual/URL (10/06, 5-3/07), Perrigo (9/07), Watson (4/09)
Mucinex DM	600/30, 1200/60 mg	Watson	3/11/09	4/24/09	1:09-cv-03933	SD of NY	Barbara S. Jones	Pending	Watson (4/09)
Mucinex D	600/60, 1200/120 mg	Watson	4/21/09	6/5/09	1:09-cv-04455	SD of NY	Barbara S. Jones	Pending	Watson (4/09)
Myfortic	180, 360 mg	Apotex	9/20/09	11/4/09	1:09-cv-06950	ND of IL	David H. Coar	Pending	Apotex (11/09)
Namea	5, 10 mg	Shared	Multiple	1/10/08	1:08-cv-00021	DE	Multiple	Pending	
Namea	15, 20 mg	Usher-Smith	12/14/07	1/10/08	1:08-cv-00021	DE	Gregory M. Sleet	Pending	
Nasacort AQ	0.05% mist/spray	Barr/Perrigo	3/20/06	5/2/06	1:06-cv-00286	DE	Gregory M. Sleet	Settled 11/08; Launch 6/11	Usher-Smith (1/08), Barr (5/06)
Nasacort	20mg spray	Apotex	NA	12/18/09	3:09-cv-08373	NJ	Garrett E. Brown, Jr.	Pending	Apotex (12/09)
Nexium	20, 40 mg	Ranbaxy	10/14/05	11/21/05	3:05-cv-05553	NJ	Garrett E. Brown, Jr.	Settled 4/05; Launch 5/27/14	Ranbaxy (11/05), Wax (3/06, 10/08), Dr. Reddy's (7/07), Mylan (NS), Sandoz (4/08)
Nexium (lin)	20, 40 mg/vial	Teva	4/25/08	NA	08-cv-00238	SD of NY	Jaei A. Pianos	Pending	Barr (3/02, 5-4/05), Lupin (3/09)
Niaspan	1000 mg	Barr	NA	3/4/02	1:02-cv-01683	SD of NY	Victor Marrero	Settled 4/05; Launch 9/13	Barr (3/02, 5-4/05), Lupin (3/09)
Niaspan	500, 750 mg	Barr	NA	8/12/02	1:02-cv-08995	SD of NY	Victor Marrero	Settled 4/05; Launch 9/13	Barr (3/02, 5-4/05), Lupin (3/09)
Nimbex (inj)	2mg/mL, 5mL vial, 10 mg/mL, 20mL vial, 2mg/mL, 10 mL vial	Sandoz	11/6/09	12/18/09	1:09-cv-00972	DE	Gregory M. Sleet	Pending	Sandoz (12/09)
Nitroxam	0.25, 0.5, 1.0, 2 mg	Par	3/17/06	4/28/06	2:06-cv-01970	NJ	Dickinson R. DeBevoise	At risk 3/09	Par (4/06), Actavis (2/07)
Nitroxam	0.3, 0.4, 0.6 mg	Filed 10/19/05	NA	NA	NA	NA	NA	Pending	
Nuvigil	250mg	Teva	10/19/09	12/2/09	1:09-cv-00918	DE	Gregory M. Sleet	Pending	Teva (12/2/09), Actavis (12/8/09), Mylan (12/11/09), Watson (1/10)
Nuvigil	200mg	Mylan	11/2/09	12/11/09	1:09-cv-00954	DE	Gregory M. Sleet	Pending	Teva (12/2/09), Actavis (12/8/09), Mylan (12/11/09), Watson (1/10)
Cluz	0.05% foam	Perrigo	9/7/05	10/19/05	2:05-cv-05038	NJ	Garrett E. Brown, Jr.	Pending	Perrigo (10/05), Pentech (4/08)
Opana ER	5, 10, 20, 40 mg	Impax	10/3/07	11/15/07	2:09-cv-00831	NJ	Katharine S. Hayden	Pending	Impax (11/07), Actavis (3/08-5-2/09), Sandoz (8/08), Barr (10/08)
Opana ER	30 mg	Actavis	6/30/08	7/11/08	2:08-cv-01563	NJ	Katharine S. Hayden	Pending	Actavis (7/08-5-2/09), Impax (7/08), Teva (7/09)
Optivar	7.5, 15mg	Actavis	5/29/08	7/11/08	2:08-cv-01563	NJ	Katharine S. Hayden	Pending	Actavis (7/08-5-2/09), Impax (7/08), Teva (7/09)
Optivar	0.05% solution	Apotex	3/6/07	4/17/07	1:07-cv-00204	DE	Sue L. Robinson	Settled 4/08; Launch 12/09	Apotex (3/07), Sun Pharm (6/07)
Oracea	40 mg	Mylan	2/4/09	3/19/09	1:09-cv-00184	DE	Joseph J. Farnan, Jr.	Pending	Mylan (3/09), Lupin (7/09), Impax (9/09)
Ortho Evra	0.15 mg/0.02 mg	Filed 3/22/07	NA	NA	NA	NA	NA	Pending	
Ortho Tri-Cyclen Lo	0.18/0.025, 0.215/0.025, 0.25/0.025 mg/mg	Barr	8/20/03	10/1/03	2:03-cv-04678	NJ	Stanley R. Chesler	At Risk 6/09; Settled 7/09; Launch 12/15	Barr (10/03, 5-7/09), Watson (10/08), Sandoz (6/09)
Oxytrol	1.02 g and 0.398 g	Novel Labs	7/25/08	9/8/08	3:08-cv-04628	NJ	Freda L. Wolfson	Launch 12/15	Novel (9/08)
Palanol	3-mg/2-mins	Barr	9/11/08	10/23/08	1:08-cv-00793	DE	Gregory M. Sleet	Settled 10/09; Launch 4/15	Barr (10/08, 5-10/09)
Palanol	0.1%	Apotex	10/2/06	11/15/06	1:06-cv-01642	SD of IL	Richard L. Young	Pending	Apotex (11/06), Barr (10/07), Sandoz (2/09)
Palanol	0.2%	Barr	11/29/08	1/8/09	1:09-cv-00026	SD of IL	Jane Magnus-Stinson	Pending	Barr (11/09), Apotex (2/09)
Palanol CR	37.5 mg	Filed 5/19/09	NA	NA	NA	NA	NA	Pending	
Perforomist	0.2mg/2mL	Teva	5/12/09	6/23/09	1:09-cv-00087	ND of WV	Irene M. Keeley	Pending	Teva (6/09)
Plavix	75 mg	Apotex	3/14/02	3/21/02	2:02-cv-02255	SD of NY	Sidney H. Stein	Settled 3/02 (Rejected 7/06); Lost 6/07	Apotex (3/02, 5-3/06), Dr. Reddy (5/02), Teva (9/04), Watson (8/04, 5-8/09), Mylan, Sandoz, Cobalt (9/05), Sun (7/08)
Prandin	1/500, 2/500 mg	Apotex	9/10/09	10/22/09	1:09-cv-08639	SD of NY	Paul G. Gardaphie	Pending	Actavis (10/09), Sandoz (11/09)
Prandin	0.5, 1.0, 2 mg	Caraco	4/26/05	6/9/05	4:05-cv-00188	ED of MI	Donald A. Schier	Lost 6/22/09	Caraco (6/05), Mylan (5/09)
Precedex	100mcg/mL	Sandoz	7/27/09	9/4/09	3:09-cv-04591	NJ	Mary L. Cooper	Pending	Sandoz (9/09)
Prevacid	15, 30 mg	Teva	11/15/05	1/17/06	1:06-cv-00033	DE	Sue L. Robinson	Won 3/1/08	Teva (1/06)
Prevacid SoluTabs	15, 30 mg	Teva	4/12/07	5/25/07	1:07-cv-00331	DE	Sue L. Robinson	Won 3/1/08	Teva (1/06)
Primaxin IM	500, 750 mg	Ranbaxy	1/12/07	4/30/07	1:07-cv-00229	DE	Gregory M. Sleet	Dismissed 7/08	Ranbaxy (4/07)



Drug	Dose	Estimated First Filer	Date Notified	Date Sued	Case Number	Court	Judge	Outcome for Generic	Other Paragraph IV Filers (Date Sued)
Protonix	20, 40 mg	Teva, Sun Pharm	4/6/04	5/20/04	2:06-cv-02355	NJ	Jose L. Linares	At risk 12/07	Teva (4/04), Sandoz (4/04-Pill on compound patent, PIV on formulation patents), Sun Pharm (4/04, 5/05), Kudos (8/06), Apotex (8/09)
Protonix IV	40 mg/100 ml	Sun Pharm	3/1/05	5/5/05	2:05-cv-02391	NJ	Jose L. Linares	Pending	Sun Pharm (6/05), Teva (NS), Apotex (2/08), Sandoz (5/08), Teva (6/08)
Provigil	100, 200 mg	Teva, Mylan, Barr, Ranbaxy	3/28/03	3/31/03	2:03-cv-01394	NJ	John C. Liffand	Settled 12/05, 1/06, 2/06; Launch 4/12	Teva (3/03-S), Mylan (3/03-S), Ranbaxy (3/03-S), Barr (3/03-S), Sandoz (5/04-DR 5/05), Carlsbad (2/05-S), Caraco (11/05-NS), Apotex (1/06-NS), Hikma (8/08-NS)
Pulmicort Respules	0.25/2 ml, 0.5/2 ml	ivax	9/14/05	10/26/05	1:05-cv-05142	NJ	Renee Marie Rumb	Settled 11/08	ivax (10/05), Breatb (3/08), Apotex (4/09)
Quin	0.5% solution	Hi-Tech Pharms	11/7/03	12/19/03	1:03-cv-01151	DE	Kent A. Jordan	Dismissed 2/04	Hi-Tech (10/03)
Recid (Inj)	0.05 mg/ml, 100 ml vial	Teva	11/7/08	12/19/08	08-cv-00952	DE	Sue L. Robinson	NA	Teva (12/08)
Renage	400, 800 mg	Mylan (?)	NA	Not Sued	NA	NA	NA	Pending	Mylan 2 (Not Sued), Lupin (3/09), Impax (3/09), Sandoz (7/09), Endo (10/09)
Remela	800 mg	Impax	2/23/09	4/23/09	1:09-cv-00846	MD	J. Frederick Mozt	Pending	Impax (4/09), Lupin (5/09)
Resquip XL	2, 3, 4, 8, 12 mg	Impax, Actavis	Jan 2009	Not Sued	NA	NA	NA	Pending	NA
Reyataz	100, 150, 200, 300 mg	Teva	10/19/09	12/2/09	1:09-cv-00919	DE	Sue L. Robinson	Pending	NA
Rhinocort spray	0.032 mg (32 mcg)/spray	Apotex	Not Sued	Not Sued	NA	NA	NA	Not sued	NA
Ritalin LA	20, 30, 40 mg	Abrika	10/23/06	12/6/06	2:06-cv-05818	NJ	Fred L. Wolfson	Pending	Abrika (12/06), KV (10/07), Barr (10/07)
Rogaine Foam	5%	Perrigo	8/26/09	10/9/09	1:09-cv-00758	DE	Gregory M. Sleet	Pending	Perrigo (10/09)
Rozem	225, 325, 425 mg	Teva	7/22/09	11/6/09	1:09-cv-00841	DE	Sue L. Robinson	Pending	Teva (11/09), Watson (12/09)
Rythmol SR	100, 200, 300 mg	Par	11/8/06	12/19/06	1:08-cv-00774	DE	Joseph J. Ferman, Jr.	Settled 4/09	Par (12/06, 5-4/09)
Ryzolt	100, 200, 300 mg	Watson	9/29/09	11/5/09	1:09-cv-00833	DE	Kent A. Jordan	Pending	Watson (11/09)
Sandocor XR	60 mg	Watson	6/2/09	7/13/09	09-cv-00511	DE	NA	Pending	Watson (7/09), Sandoz (11/09)
Sandostatin	Multiple	Sun Pharm (?)	NA	Not Sued	NA	NA	NA	Pending	KV (10/07), Barr (10/07)
Seasonale	0.03 mg/0.15 mg	Watson	1/22/08	3/6/08	3:07-cv-05941	NJ	Mary L. Cooper	Pending	Watson (12/07), Sandoz (12/07), Lupin (9/09)
Seasonique	0.03 mg/0.15 mg	Watson	6/13/08	7/31/08	1:09-cv-00454	DE	Harvey Bartle, III	Dismissed 3/08	Watson (3/08, 7-3/08)
Sensipar	30, 60, 90 mg	Barr, Teva	9/28/2005 (25 mg)	11/8/2005 (25 mg)	3:09-cv-03333 (25 mg)	DE	NA	Pending	Barr (7/08), Teva (7/08)
Seroquel	25, 50, 100, 150, 200, 300, 400 mg	Teva	2/21/06 (100, 200, 300 mg)	3/31/06 (100, 200, 300 mg)	2:06-cv-01528 (100, 200, 300 mg)	NJ	Joel A. Pisano	Lost SJ 7/08; Upheld 9/09	Teva (11/05, 25 mg, 3/06, 100, 200, 300 mg, 7/07, 50, 150, 400 mg), Sandoz (4/07)
Seroquel XR	150, 200, 300, 400 mg	Pharmaceuticals	7/23/08 (400 mg)	7/28/08	3:08-cv-03773	NJ	Joel A. Pisano	Pending	Handa (7/08, 10/08), Accord/ntas (9/08), Biowall (1/09)
Sincor	20/100 mg	Teva	NA	NA	NA	NA	NA	Pending	NA
Singular tablets	4, 5, 10 mg	Teva	2/23/07	4/3/07	3:07-cv-01596	NJ	Garrett E. Brown, Jr.	Lost 9/09	Teva (4/07)
Singular chewables	4, 5 mg	Teva	4/4/07	5/14/07	3:07-cv-02264	NJ	Garrett E. Brown, Jr.	Lost 9/09	Teva (5/07)
Singular granules	4 mg	Teva	12/8/08	1/16/09	09-cv-00233	NJ	Garrett E. Brown, Jr.	Lost 9/09	Teva (1/09)
Stelkin	800 mg	Eon	11/3/04	12/17/04	1:04-cv-05540	ED of NY	David G. Trager	Won SJ 1/09	Eon (12/04)
Sobrate	3% topical	Novartis Consumer	3/20/07	5/3/07	2:07-cv-02075	NJ	Dennis M. Cavanaugh	Pending	Novartis (9/07)
Solodyn	45, 90, 135 mg	Impax	1/15/08	1/15/08	3:08-cv-00253	NB of CA	Maxine M. Chesney	Dismissed 4/08	Impax (1/08, 5-12/08)
Solodyn	45, 90, 135 mg	Mylan, Barr, Sandoz	12/8/08	1/13/09	1:09-cv-00033	DE	Joseph J. Ferman, Jr.	Pending	Mylan (1/09), Sandoz (1/09, 5-8/09), Barr (1/09, 5-3/09), Ranbaxy (6/09), Lupin (11/09)
Solodyn	65, 115 mg	Teva	11/7/09	12/28/09	1:09-cv-00464	MD	Marvin J. Garbis	Pending	Teva (12/09), Lupin (1/10)
Stalevo 100, 150	25, 100/200, 37.5/150/200 mg	Sun Pharm	10/1/07	11/13/07	3:07-cv-05436	NJ	Mary L. Cooper	Pending	Sun (11/07)
Stalevo 50, 200	12.5, 50, 200 mg	Wockhardt	10/29/08	12/8/08	08-cv-00917	DE	Gregory M. Sleet	Settled 4/09; Launch 9/12	Wockhardt (12/08)
Stalevo 75, 125	18.75 mg/75 mg/200 mg and 60, 120 mg	Par, Teva, Watson	NA	NA	NA	NA	NA	Pending	NA
Strattera	10, 18, 25, 40, 60, 80, 100 mg	Shared	6/28-8/16/07	8/8-9/5/2007	2:07-cv-03770	NJ	Dennis M. Cavanaugh	Pending	Par (NS), Teva (NS), Watson (NS), Actavis (8/07), Sandoz (8/07-10/07), Sun (9/07), Genmark (9/07, 7/08-5), Mylan (9/07), Teva (9/07), Apotex (9/07), Aurbindo (9/07), Symbion (9/07, 8/08-)
Sular	25.5, 34 mg	Filed 11/28/08	NA	NA	NA	NA	NA	Pending	NA
Suprane	99.9%	Minrad	12/12/08	1/23/09	09-cv-00054	DE	Unassigned	Pending	Minrad (1/09)
Sustiva	600 mg	Mylan	7/16/09	8/28/09	09-cv-00651	DE	Unassigned	Pending	NA
Symbax	6/25, 12/25, 6/50, 12/50 mg	Teva	3/11/05	4/22/05	1:05-cv-00595	SD of IN	Richard L. Young	Dismissed 10/07	Teva (4/05)
Tarceva	25, 100, 150 mg base	Teva, Mylan	2/6/09	3/19/09	1:09-cv-00185	DE	Sue L. Robinson	Pending	Teva (3/09), Mylan (3/09)
Tarka	4/240, 2/240, 2/180, 1/240 mg	Genmark	10/29/07	12/7/07	2:08-cv-01658 (1 mg/240 mg dose)	NJ	Dennis M. Cavanaugh	Pending	Genmark (12/07, 4/08 for 1 mg/240 mg)
Tarka	1/240 mg	Filed 2/20/08	NA	NA	NA	NA	NA	Pending	NA
Taxotere	20/2, 80/8, 160mg/16ml	Hospira	9/28/07	11/9/07	1:07-cv-00721	DE	Gregory M. Sleet	Pending	Hospira b2 (11/07), Apotex b2 (8/08), Sun b2 (8/09)
Taxotere	40/1, 20/0.5, 80mg/2ml	Apotex	6/27/08	8/8/08	1:08-cv-00496	DE	Gregory M. Sleet	Pending	Hospira b2 (11/07), Apotex b2 (8/08), Sun b2 (8/09)
Taxotere	40 mg/ml, 0.5 mL and 2 mL	Sandoz	9/15/09	10/29/09	1:09-cv-00810	DE	Gregory M. Sleet	Pending	Sandoz (10/09)
Temodar	5, 20, 100, 250 mg	Barr	6/8/07	7/20/07	1:07-cv-00457	DE	Sue L. Robinson	Pending	Barr (7/07)
Temodar	140, 180 mg	Filed 3/24/08	NA	NA	NA	NA	NA	Pending	NA
Testim	1%	Upsher-Smith	10/22/08	12/4/08	1:08-cv-00908	DE	Sue L. Robinson	Pending	Upsher-Smith (12/08)
Thalomid	50, 100, 150, 200 mg/vial	Barr	12/6/06	1/18/07	2:07-cv-00286 (lead case)	NJ	Susan D. Wieston	Pending	Barr (1/07, 8/07 on new 912 patent, 11/07 on 150 mg dose)
Tobi	300mg/5ml	Teva	10/27/09	11/10/09	1:09-cv-00949	DE	Noel L. Killoran	Pending	Teva (12/09)
Trawatan	0.004%	Teva	3/17/09	4/30/09	1:09-cv-00318	DE	Lorraine D. Davis	Pending	Teva (4/09), Barr (7/09), Apotex (10/09)
Trawatan Z	0.004%	Par	6/1/09	7/1/09	1:09-cv-00481	DE	Lorraine D. Davis	Pending	Par (7/09), Teva (7/09)



Drug	Dose	Estimated First Filer	Date Notified	Date Sued	Case Number	Court	Judge	Outcome for Generic	Other Paragraph IV Filers (Date Sued)
Tricor tab	160 mg	Teva	NA	10/4/02	1:02-cv-01512	DE	Kent A. Jordan	Settled 6/05	Teva (11/02, 5-6/05), Impax (1/03), Par (2/03), Ranbaxy (1/04)
Tricor tab	54 mg	Teva	NA	10/4/02	1:02-cv-01512	DE	Kent A. Jordan	Settled 6/05	Teva (11/02, 5-6/05), Impax (1/03), Par (2/03), Ranbaxy (1/04)
Tricor tab	145 mg	Teva	1/16/08	2/29/08	2:08-cv-01085	NJ	Joseph A. Greenaway, Jr.	Settled 11/09	Teva (2/08, 5-11/09), Biovail (11/08), Lupin (3/09), Impax (10/09)
Tricor tab	48 mg	Biovail	9/19/08	11/3/08	1:08-cv-06274	ND of IL	Wayne R. Andersen	Pending	Biovail (11/08), Lupin (3/09), Impax (10/09)
Treximet	85/500 mg	Par	10/8/08	11/14/08	6:08-cv-00437	ED of TX	Leonard Davis	Pending	Par (11/08), Mylan (1/09), Teva (9/09), Dr. Reddy's (9/09)
Truvada	200/300 mg	Teva	11/3/08	12/12/08	1:08-cv-10838	SD of NY	Richard J. Sullivan	Pending	Teva (12/08)
Tygacl (inj)	50mg/vial	Sandoz	10/30/09	12/11/09	1:09-cv-08955	DE	Joseph J. Farnan, Jr.	Pending	Sandoz (12/09)
Uroaxtral	10 mg	Shared	Multiple	9/21/07	1:07-cv-00572	DE	Gregory M. Sleet	Pending	Actavis/Par (9/07), Aurbindo (9/07), Mylan (9/07), Teva (9/07), Sun (9/07), Torrent (9/07), Ranbaxy (9/07), Barr (9/07), Apotex (12/07), Wockhardt (3/08)
Valcyc	450 mg	Ranbaxy	3/17/05	4/28/06	3:06-cv-02003	NJ	Freda L. Wolfson	Won 9/09	Ranbaxy (4/06)
Valtrex	500, 1000 mg	Ranbaxy	4/1/03	5/9/03	3:03-cv-02158	NJ	Mary L. Cooper	Settled 7/07	Ranbaxy (5/03, 5-7/07), Apotex (7/09-D)
Valtrex	0.1% cream	Perrigo	4/29/08	6/6/08	1:08-cv-00539	WD of MI	Paul L. Maloney	Settled 4/09	Perrigo (6/08, 5-4/09), Glenmark (6/09, 5-11/09)
Veldio	3.5mg/vial	Teva	1/16/09	2/27/09	1:09-cv-00127	DE	Gregory M. Sleet	Pending	Teva (2/09)
Vereclin PM	100, 200, 300 mg	Mylan	7/19/06	9/1/06	1:06-cv-00133	ND of WV	Irene M. Kealey	Dismissed 8/07	Mylan (9/06, D-8/07)
Vesicare	5, 10 mg	Teva	8/11/09	9/22/09	1:09-cv-08100	SD of NY	Sidney H. Stein	Pending	Teva (9/09)
Vfend (tab)	50, 200 mg	Mylan	Not Sued	Not Sued	NA	NA	NA	Pending	Mylan (NS)
Vfend (inj)	200mg/vial	Sandoz	Not Sued	Not Sued	NA	NA	NA	Pending	Sandoz (NS)
Viagra	25, 50 mg	Filed 10/25/04	NA	NA	NA	NA	NA	Pending	NA
Viagra	100 mg	Filed 11/19/04	NA	NA	NA	NA	NA	Pending	NA
Vigamox	0.5% solution	Teva	2/21/06	4/5/06	1:06-cv-00234	DE	Sue L. Robinson	Lost 10/09	Teva (4/06)
Vitonin	10/10, 10/20, 10/40, 10/80mg	Mylan	11/5/09	12/18/09	1:09-cv-00167	ND of WV	Irene M. Kealey	Pending	Mylan (12/09)
Weichol	625mg	Filed 7/1/09	NA	NA	NA	NA	NA	Pending	NA
Xalatan	2.5 ml	Par/Arrow	12/18/01	12/21/01	3:01-cv-06011	DE	Stanley R. Chesler	Lost 7/04; Upheld 8/05; Mandate 10/05	Par/Arrow (12/01)
Xeloda	150, 500 mg	Mylan	3/11/09	4/8/09	2:09-cv-01692	NJ	William J. Martini	Pending	Mylan (4/09), Teva (10/09), Roxane (12/09)
Xopenex neb	0.003%, 0.021% and 0.042% solution	Breath Ltd	9/6/05	10/21/05	1:06-cv-10043	MA	Douglas P. Woodlock	Settled 5/08	Breath (10/05, 5-4/08), Dey (2/06), Watson (3/06, NS), Barr (7/07, 5-3/09)
Xopenex neb	0.25% solution	Dey	8/14/06	9/27/06	1:06-cv-00113	DE	Kent A. Jordan	Pending	Dey (9/06)
Xyzal tabs	5 mg	Perrigo/Synthon	2/28/08	4/10/08	1:08-cv-00207	DE	Gregory M. Sleet	Case Dropped 6/08	Synthon (4/08, D-6/08), Sun (5/08, D-5/09), Sandoz (6/08), Barr (7/08, D-4/09)
Xyzal oral sol.	0.5mg/ml	Perrigo/Synthon	5/5/09	6/17/09	5:09-cv-00264	ED of ND	W. Earl Britt	Pending	Synthon (6/09)
Yasmin	3 mg/0.03 mg	Barr	3/18/05	4/29/05	2:05-cv-02308	NJ	Peter G. Sheridan	Won on 3/3/08;	Barr (3/05), Watson (4/08), Sandoz (4/08)
Yaz	3 mg/0.02 mg	Barr	Not Sued	Not Sued	NA	NA	NA	Settled 6/08	BRL (9/06-NS, 5-6/08), WPI (11/07), Sandoz (7/08)
Zanaflex (caps)	2, 4, 6 mg	Apotex	8/31/07	10/11/07	2:07-cv-04937	NJ	Garrett E. Brown, Jr.	Pending	Apotex (10/07)
Zantac syrup	15 mg base/ml	Teva	2/5/04	3/18/04	1:04-cv-00171	DE	Kent A. Jordan	Pending	Teva (3/04), Cypress (6/07, D-1/08), Amneal Pharma (1/08)
Zegerid caps	mg	Par	8/2/07	9/13/07	1:07-cv-00551	DE	Gregory M. Sleet	Pending	Par (9/07)
Zegerid suspension	40 mg/1680 mg per packet	Par	11/13/07	12/20/07	1:07-cv-00827	DE	Gregory M. Sleet	Pending	Par (12/07)
Zemplar (caps)	1, 2, 4mcg	Teva	10/8/08	11/20/08	1:08-cv-06659	ND of IN	Charles P. Kocoras	Pending	Teva (10/08)
Zemplar (inj)	0.002mg/ml in 1 mL vial and 0.005mg/ml	Sandoz	2/19/09	4/1/09	09-cv-00215	DE	Gregory M. Sleet	Pending	Sandoz (4/09), Teva (11/09)
Zenita	10 mg	Glenmark	2/9/07	3/22/07	2:07-cv-01334	SD of NY	Jose L. Linares	Pending	Glenmark (3/07)
Zometax (inj)	4mg base/5ml; 5mg	Teva	6/10/08	7/24/08	1:08-cv-00459	DE	Sue L. Robinson	Pending	Teva (7/08)
Zymar	0.3% solution drops	Apotex	10/17/07	11/29/07	1:07-cv-00779	DE	Sue L. Robinson	Pending	Apotex (11/07)
Zyvox (inj)	2mg/ml, 300ml bag	Filed 9/1/09	NA	NA	NA	NA	NA	Pending	NA
Zyvox (susp.)	100mg/5ml	Filed 8/3/09	NA	NA	NA	NA	NA	Pending	NA
Zyvox (tab)	500 mg	Filed 12/21/05	NA	NA	NA	NA	NA	Pending	NA

Source: PACER, Company reports, RBC Capital Markets estimates.



Appendix D: Litigation Scorecard History 2000-2009 (Complete)

	Lost	%	Won	%	Settled	%	Dropped	%	TOTAL	Success %
Actavis (total)	1	17%	2	33%	3	50%	0	0%	6	83%
Alpharma	0	0%	1	100%	0	0%	0	0%	1	100%
Actavis	1	20%	1	20%	3	60%	0	0%	5	80%
Alcon	0	0%	0	0%	1	100%	0	0%	1	100%
Amneal	0	0%	0	0%	1	100%	0	0%	1	100%
Amphastar	0	0%	1	100%	0	0%	0	0%	1	100%
Anchen	0	0%	1	25%	3	75%	0	0%	4	100%
Apotex	12	57%	2	10%	7	33%	0	0%	21	43%
Baxter	0	0%	1	100%	0	0%	0	0%	1	100%
Bedford	0	0%	0	0%	1	100%	0	0%	1	100%
Breath	0	0%	0	0%	1	100%	0	0%	1	100%
Caraco	0	0%	1	100%	0	0%	0	0%	1	100%
Cheminor	1	100%	0	0%	0	0%	0	0%	1	0%
Corepharma	0	0%	1	50%	1	50%	0	0%	2	100%
Covidien	0	0%	0	0%	1	100%	0	0%	1	100%
Cypress Pharma	0	0%	0	0%	1	100%	0	0%	1	100%
Dr. Reddy's	7	39%	2	11%	9	50%	0	0%	18	61%
Endo	0	0%	1	50%	1	50%	0	0%	2	100%
Exela	1	100%	0	0%	0	0%	0	0%	1	0%
Glenmark	1	33%	0	0%	2	67%	0	0%	3	67%
Hi Tech	1	100%	0	0%	0	0%	0	0%	1	0%
Hospira	1	33%	2	67%	0	0%	0	0%	3	67%
Impax	2	14%	4	29%	7	50%	1	7%	14	86%
KV Pharm	1	14%	1	14%	3	43%	2	29%	7	86%
Lupin	2	25%	1	13%	4	50%	1	13%	8	75%
Mylan	9	36%	7	28%	9	36%	0	0%	25	64%
Nostrum	1	100%	0	0%	0	0%	0	0%	1	0%
Orchid	0	0%	0	0%	2	100%	0	0%	2	100%
Par	2	13%	4	27%	9	60%	0	0%	15	87%
Paddock	0	0%	1	50%	1	50%	0	0%	2	100%
Perrigo	0	0%	1	13%	4	50%	3	38%	8	100%
Prasco	1	100%	0	0%	0	0%	0	0%	1	0%
Ranbaxy	7	37%	2	11%	9	47%	1	5%	19	63%
Roxane	1	33%	0	0%	2	67%	0	0%	3	67%
Sandoz (total)	3	13%	11	46%	9	38%	1	4%	24	88%
Sandoz	3	18%	6	35%	7	41%	1	6%	17	82%
Eon Labs	0	0%	5	71%	2	29%	0	0%	7	100%
Schwarz	1	50%	1	50%	0	0%	0	0%	2	50%
Sun	3	33%	1	11%	4	44%	1	11%	9	67%
Teva (total)	24	22%	27	25%	51	46%	8	7%	110	78%
Teva	17	25%	16	23%	31	45%	5	7%	69	75%
Copley	0	0%	1	50%	1	50%	0	0%	2	100%
IVAX	4	80%	1	20%	0	0%	0	0%	5	20%
Barr	3	9%	9	26%	19	56%	3	9%	34	91%
Tolmar	0	0%	0	0%	1	100%	0	0%	1	100%
Upsher Smith	0	0%	0	0%	2	100%	0	0%	2	100%
URL Pharma	2	40%	1	20%	1	20%	1	20%	5	60%
Watson (total)	4	10%	6	15%	23	59%	6	15%	39	90%
Watson	2	13%	0	0%	9	56%	5	31%	16	88%
Andrx	2	13%	6	40%	7	47%	0	0%	15	87%
Cobalt	0	0%	0	0%	7	88%	1	13%	8	100%
Wockhardt	0	0%	0	0%	4	100%	0	0%	4	100%
Zydus	1	100%	0	0%	0	0%	0	0%	1	0%
Generics Total	89	24%	82	22%	177	47%	25	7%	373	76%

Source: PACER, Company reports, RBC Capital Markets estimates.



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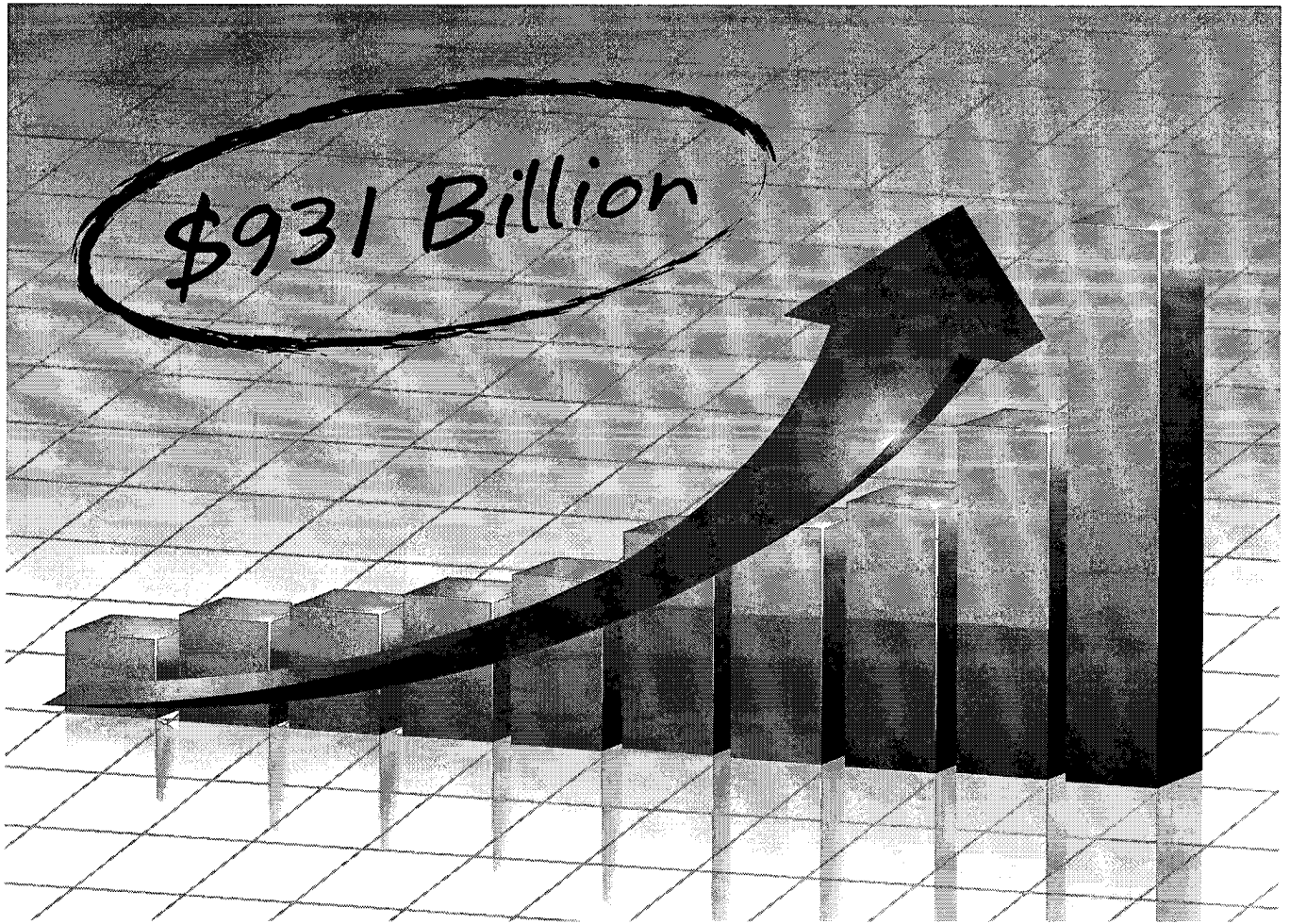
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September 2011



SAVINGS

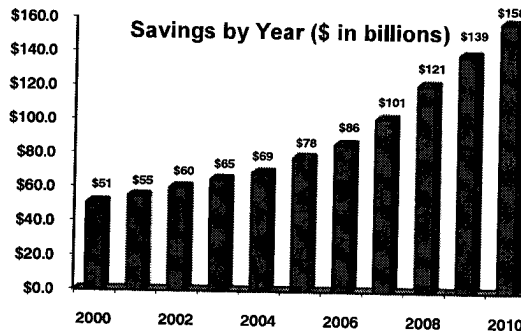
**An Economic Analysis of
Generic Drug Usage in the U.S.**

EXECUTIVE SUMMARY

As government leaders in Washington and across the country look for ways to cut health care costs, this new analysis details the remarkable savings achieved through the use of generic medications. Over the past 12 years (January 1999 through December 2010), the use of FDA-approved generic prescription drugs has saved the U.S. health care system an astounding \$1.031 trillion. And at the current generic utilization rate, more than \$3 billion is being saved every week as American consumers and patients rely on generic medicines to provide the quality care they need.

This independent analysis, conducted for GPhA by the IMS Institute for Healthcare Informatics and IMS Health, shows that:

- The use of generic prescription drugs in place of their brand name counterparts saved the U.S. health care system more than \$931 billion over the past decade (2001 through 2010).
- In 2010 alone, generic use generated more than \$157 billion in savings.
- Savings from newer generic medicines—those that have entered the market since 2001—continue to increase exponentially and account for more than one-third of the total savings.



With government leaders being forced every day to make difficult choices pertaining to spending and deficits, it is imperative that the savings available through generic use be recognized. Policies that encourage generic dispensing and steer clear of unwarranted restrictions on generic use can bring even greater savings as new requirements under the 2010 health care reform law are put in place. For instance:

- Data from the Centers for Medicare and Medicaid Services (CMS) show that increasing generic use in Medicaid by just two percentage points would save the program more than \$1.3 billion annually. These savings are critical to sustaining the viability of Medicaid, as studies have concluded that the program needlessly spends billions of dollars each year by reimbursing pharmacies for costly brand products when generics

with identical active ingredients, strengths, dosage forms and therapeutic benefits are available at lower costs.

- With more than a third of annual savings generated by generic medications coming from products that have entered the market since 2001, it would be misguided to enforce a ban on patent litigation settlements since most new generics get to market as the result of a settlement. In fact, of the 22 new, first-time generics launched this year, 16 will be launched prior to expiration of the brand drugs thanks to a patent settlement.
- Increasing funding to the FDA's Office of Generic Drugs (OGD) is also an essential component in ensuring the savings potential from generic medications is fully realized. Currently, more than 2,000 generic drug applications are awaiting OGD action, with as many as 365 of those for first-time generic drugs, according to the FDA. Savings are being left on the table each day this backlog continues to grow, as consumers and the government are forced to pay brand drug prices for prescriptions that could be available in affordable generic versions. With generic manufacturers on the verge of a historic agreement to provide the FDA with hundreds of millions of dollars in new user fee funding, it is critical that members of Congress follow suit to ensure that the savings generated by the use of generic medications will continue to grow.
- The forthcoming introduction of an approval pathway for biosimilars offers an additional opportunity to provide consumers and the government with enormous savings. Just as the introduction of generic versions of chemical drugs some quarter century ago ushered in a new era of access to safe and affordable medicines, biosimilars now hold the promise of providing consumers with the same benefit. In order for these benefits to be realized, however, it is critical that the FDA maintains its commitment to funding the biosimilars program, and ensures that a workable approval pathway is created that is free from obstacles that would serve only to delay the availability of these FDA-approved, safe, effective and lower-cost medications.

The analysis that follows clearly demonstrates that any effort to reduce health care costs — whether on Capitol Hill or in state legislatures — must recognize the billions of dollars in savings that can be achieved through the use of generic medicines. For more than 25 years, generic prescription drugs have allowed millions of Americans to get the medicine they need at an affordable cost. As new health care reform policies are implemented, the savings generated by generics will help make it possible to improve lives for less.

HIGHLIGHTS AND TRENDS

The IMS analysis shows that substituting generic prescription drugs in place of their brand-name counterparts saved the nation's health care system more than \$931 billion dollars from 2001 through 2010. In 2010 alone, the use of FDA-approved generics saved more than \$157 billion. That amounts to more than \$3 billion in savings every week.

In addition, the IMS analysis also shows that:

- Savings from generic medications that have entered the market since 2001 have continued to grow at an exponential rate, reaching more than \$360 billion by the end of 2010;
- Generic products for nervous system and cardiovascular treatments alone account for 62 percent of the cost savings;
- Despite having nearly seven times as many products on the market, generic medications still accounted for less drug spending than branded products with generic competition; and
- Over the past 10 years, patent settlements have resulted in billions of dollars in savings as dozens of first-time generics have come to market prior to patents expiring on the counterpart brand drugs.

This remarkable level of savings continues to dwarf the initial savings estimates that were made in 1984, when the Hatch-Waxman Act established the modern-day generic industry, and when it was projected that generics might save \$1 billion dollars over the first 10 years. The Congressional Budget Office (CBO) reported in 1998 that savings realized from the substitution of generic for brand-name drugs saved consumers between \$8 billion and \$10 billion in 1994, the 10th year after Hatch-Waxman was enacted. Since then, annual savings have grown exponentially.

Generic Versions of Blockbuster Drugs Continued to Provide Big Savings

This new analysis from IMS Health, based on brand and generic prescription drug sales and pricing data, shows that, in 2010, annual savings from the use of generic medications continued to be driven by the introduction of generic versions of well-known brand drugs. Generic versions of Flomax® and Aricept®, among several other big selling drugs, helped to continue the double-digit percentage growth in savings from 2009.

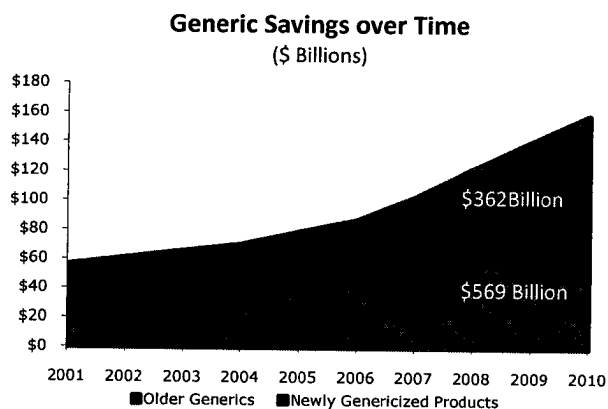
When combined with the phenomenal four-year growth in savings between 2005 and 2009 that was spurred by the launch of generic versions of several

blockbuster brand drugs, including Zocor®, Norvasc® and Zoloft®, generic medications are now saving the U.S. health care system more than \$3 billion every week. And with more than 20 new generic versions of blockbuster brand drugs entering the market this year—16 of which were made possible due to a pro-consumer patent settlement—2011 looks set to continue that trend.

Newer Generics Maintained Exponential Growth

The IMS analysis also found that the savings from generics introduced in the past 10 years has now reached approximately \$362 billion and accounts for more than 40 percent of the overall generic savings. In 2010 alone, the U.S. health care system saved nearly \$100 billion from these recently genericized products, or 63 percent of the savings for the entire year. Older generic medications, those approved prior to 2000, continued to provide a steady foundation of cost reduction as well, producing nearly \$60 billion in savings in 2010.

The savings generated by newer generics is expected to continue increasing over the next several years as many of the world's largest-selling brand drugs lose patent protection and face generic competition for the first time. That includes the two biggest-selling drugs: Pfizer's \$8 billion cholesterol fighter Lipitor® and the blood clot preventer Plavix®



by Bristol-Myers Squibb, both of which will lose patent protection in November 2011 thanks to the use of pro-consumer patent settlements.

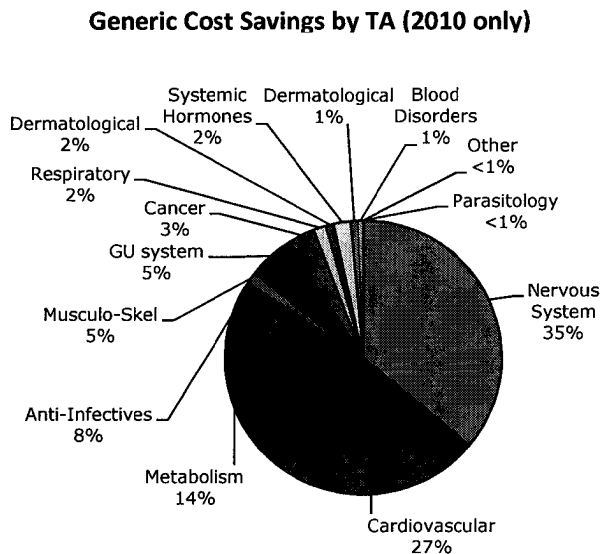
Among the other name-brand blockbusters that will lose patent protection between now and 2014 are Zyprexa®, Singulair® and Aricept®. Meanwhile, new reports continue to highlight the impact of generic medications for those suffering from chronic disease. These factors make it crystal clear that generic drugs are an integral part of the solution in reigning in U.S. health care costs.

Central Nervous System and Cardiovascular Drugs Lead the Way

Generic central nervous system (CNS) and cardiovascular drugs once again delivered the bulk of the savings generated by the generic industry in 2010. Combined, these two therapeutic areas alone provided the U.S. health care system more than \$100 billion in savings. Generic CNS medications also

continued their significant yearly growth in savings, growing 10 percent over the savings generated in 2009.

Generic metabolism drugs also continued to be a major source of health care savings in 2010, reducing costs by more than \$22 billion. Since 2001, the savings generated by these drugs has grown an astounding 500 percent from their initial level of more than \$4 billion. When added to the savings provided by generic nervous system and cardiovascular medicines, these three therapeutic categories account for nearly three-fourths of all savings generated by generic drugs in 2010.



Generic Savings Are an Integral Component in Reducing Health Care Costs

GPhA has long maintained that reducing government overspending in Medicare and Medicaid is an integral part of the solution to reducing U.S. health care costs. And one way states can control these growing costs is through a greater reliance on the use of generic drugs. Because the federal government pays states a portion of the cost of prescription drugs they purchase through Medicaid, the government can save hundreds of millions of dollars each year as the use of less costly generic drugs increases.

According to data from the Centers for Medicare and Medicaid Services, in 2010 Medicaid paid, on average, approximately \$200 for each monthly brand prescription, compared to just \$20 for a month's prescription in the generic version. By increasing generic utilization in Medicaid by just one percentage point, the government and taxpayers would save more than \$500 million. With Medicaid's generic utilization rate running nearly 10 percentage points lower than the 78 percent national rate, states have considerable opportunities to achieve added savings.

Generic Prescriptions Bring Patients Savings at the Pharmacy Counter

An additional IMS analysis has shown that generics are also bringing savings directly to patients at the pharmacy counter. In 2010 the average copayment for a generic drug was \$6.06 per prescription, compared to \$23.65 and \$34.77 for preferred and non-preferred brand drugs, respectively, according to the IMS Institute for Healthcare Informatics study entitled “The Use of Medicines in the United States: Review of 2010.”

Against this background, it is critical that new FDA-approved generics be introduced into the market sooner rather than later. American consumers and payors, including the federal government and the states, lose billions of dollars each week that generic access is delayed.

Inadequate funding of FDA’s Office of Generic Drugs (OGD) in past years has resulted in a backlog of more than 2,000 unapproved generic applications — as many as 365 of which are for first-time generic drugs — and a median approval time of nearly 30 months. As a result, consumers and the government are forced to pay brand drug prices for prescriptions that could be available in affordable generic versions if the FDA is adequately funded.

Pro-Consumer Patent Settlements Continued to be a Major Boost to Savings

Access to new, cost-saving generics also is facilitated through pro-consumer settlements of drug patent litigation. Over the past 10 years, patent settlements have enabled dozens of first-time generics to come to market many months before patents on the counterpart brand drugs expired. Of the 22 new generic drug launches expected in 2011, settlements made 16 of these possible where the generic will launch prior to patent expiry.

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Outside experts have also realized the savings pro-consumer settlements provide. An independent study by RBC Capital Markets, *Analyzing Litigation Success Rates*, found that generic companies are successful, thus able to market the generic product before patent expiration, in just 48 percent of cases, and that when factoring in settlements, generics are successful in bringing the generic product to market before patent expiration in 76 percent of cases.

While the settlement issue has engendered opposition from some who contend such generic-brand agreements are anticompetitive, the federal courts and

Congress have repeatedly recognized that settlements can be desirable options in patent litigation. The record is clear: settlements allow generic drugs to come to market long before patents on the counterpart brands expire, resulting in billions of dollars in annual savings. Year after year, settlements have proven to be pro-consumer and pro-competitive.

Generic Versions of Biologics Can Provide Comparable Savings

It is GPhA's position that the success of generics in achieving savings for consumers using traditional drugs can be duplicated in the biopharmaceutical market. Biogenerics and biosimilars would inject the competition needed in the biologic market to lower costs and provide significant savings for patients in need of these lifesaving treatments.

Estimates from various economic impact studies pin the projected savings from \$42 billion on the low end to as high as \$108 billion over the first 10 years of biogeneric market formation. Even stakeholders on the brand side of this issue—namely BIO and PhRMA—recognize that competition from biogenerics and biosimilars will significantly reduce health care costs.

In addition, the Congressional Budget Office (CBO) has estimated that the resulting increase in competition from biogenerics will yield substantially lower prices for certain drugs. CBO estimates that biogenerics will initially have prices about 25 percent below their brand-name counterparts and, after several years of competition, would have prices about 40 percent below those counterparts.

As the FDA continues to work toward implementing regulations on biogenerics, it is essential that the agency creates an approval process that is workable and free from obstacles that would serve only to delay the availability of FDA-approved, safe, effective and lower-cost biogeneric drugs.

For complete information on any of the topics discussed in this study, including Medicaid and Medicare generic utilization, funding for the Office of Generic Drugs, patent settlements and the cost trends for brand and generic prescription drugs, please contact the Generic Pharmaceutical Association at 202-249-7100, or visit gphaonline.org. This IMS analysis was commissioned by the Generic Pharmaceutical Association; 777 6th Street, NW, Suite 510; Washington, DC 20001. www.gphaonline.org

METHODOLOGY

This analysis conducted by IMS Health updates the previous analysis released in July 2010 on the total cost savings generic pharmaceuticals have provided to the U.S. health care system over the 10-year period of 2001 through 2010.

The analysis utilized IMS data on sales and unit volumes of brand and generic products, estimating potential savings at the molecule level. To ensure consistency of the analysis, branded products are defined as originator molecules that no longer are patent protected; generic drugs are those that were introduced after the patent protection had expired on the original reference product. The total savings was derived from a universe of 4,521 drugs, which are those products for which both brands and generics were available on the market.

Types	% of Molecules
1. Brands without Generic Competition	28%
2. Lost exclusivity after 2000	9%
3. Lost exclusivity 2000 and before	14%
4. No brand volume in the data set	49%
Total Number	4,521

Source: IMS Midas Data
Data Source includes: US Clinic, Drugstores, Fed Facilities, Food Stores, HMO, Home Healthcare, Long Term Health Care, Mail Service, Non-Fed Hospital and Misc.
Note: Because analysis was conducted across multiple TAs, some molecules can exist across multiple TAs.

As shown in the chart at right, excluded from the savings analysis were drug products for which: (1) there was no measurable generic competition, either because of an exclusivity or patents still in effect or because there was no generic version of the brand yet approved; and (2) only a generic drug was available for sale because the brand drug was no longer available on the market.

The overall methodology approach was to add 2010 generic volume to the 2009 Cost Savings Study data for each molecule. The average brand price in the last year of patent protection (for patent expirations before 2001) was estimated using the formula (Total sales of brand molecule) divided by (Total standard units of brand).

For year 2010 brands under generic competition, the estimated value of the replaced brand product with generics was calculated using the formula (Average brand price) multiplied by (Total standard units of generic). Finally, the generic cost savings was computed using the formula (Value of replaced brands with generics) minus the (Total sales of generic), with total savings equal to the sum total of all cost savings across all therapeutic areas. To obtain the most accurate savings estimate, "standard units" are used throughout the study. The standard unit is the "number of units" divided by "smallest common dose of a product form." Number of units refers to the number of tablets or capsules, ml or grams sold, multiplied by the number of packages sold, then multiplied by package size.

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