ANDA Approval Dynamics and the Paragraph IV Market

-Part II: The Impact of Increased ANDA Activity on Approvals-

by Gregory Glass

Abstract: As detailed in *Part I: ANDA Filing Dynamics and the Paragraph IV Market*, the dramatic increase in the number of Paragraph IV patent cases filed has had minor impact on filing dynamics in the PIV Market. In fact, the data demonstrate that only a small number of brand products have been directly affected. Upon examining certified products and the timing of PIV cases, *Part I* showed that a small number of brand products (between 8-15%) had 10 or more filers file their ANDA's at or near the the date of the first PIV certification. The concentration of a large number of ANDA filers clustered around a few brand products is more striking when juxtaposed to the facts that 4 out of 5 brand products had fewer than 5 ANDA filers file at or near the date of the first PIV certification and over 50% of brand products had only 1 ANDA filer present one year after the first PIV case was filed. While *Part I* showed that filing dynamics have become more competitive for a selected few products, it does not answer the question of whether these dynamics change during the course of PIV litigation: that is, do many ANDA filers appear for a brand product over the years of PIV litigation? How often do brand products see multiple ANDA filers approved on the first possible approval date? How often do generic markets emerge immediately as highly competitive (4 or more filers) or hypercompetitive (10 or more)? How often does the first-filer maintain exclusivity? This paper -- Part II -- examines PIV cases and products as they advance through the litigation process and through to the emergence of the generic markets.

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Author's Note: This paper is being made available exclusively to ParagraphFour.com subscribers. Of course, the source data come directly from ParagraphFour.com, FDAPetitions.com, and FDA.

Background and Summary of Part I

Over the past several years, there has been a steady and dramatic increase in the number of Paragraph IV cases filed. With the increase in cases and the ANDA filings they represent, the question naturally arises as to whether there are many ANDA filers present at the time the first ANDA is filed (or shortly thereafter).

The companion paper *ANDA Filing Dynamics and the Paragraph IV Market - Part I* answered this question by using two sets of data. The first data set included New Molecular Entity and New Dosage Form products receiving a Paragraph IV certification in 2013 and then checking up to two years later to determine how many ANDA filers had filed at or around the time of first filing.

The second data set checked all PIV cases filed in 2012-2013 (regardless of product type and first-filing date) one year after the first case was filed to determine how many ANDA filers had filed at or around the time of first filing. Though different, both data sets produced similar results and conclusions and are summarized:

(1) 599 PIV cases were filed in the last two years (2013-2014), a 32% increase from the prior two years.

(2) A vast majority of PIV products will have 1-4 ANDA filers at the time of first-filing (82%, across both data sets) with nearly half of all products having only a single filer.

(3) About 10% of all products will be "hypercompetitive," having 10 or more ANDA filers file at or around the time of first filing.

While Part I provides insight of ANDA filing dynamics, these data do not provide information as to how the generic market emerges at the time of ANDA approval and launch. In other words, if there are typically only 1-4 filers at the time of first filing, do these figures change when the ANDA filers are finally approved and reach the market? This paper -- Part II -- examines these data and seeks to answer the following questions:

(1) What is the timing sequence of ANDA approvals involved for PIV-certified products?

(2) How often does FDA grant exclusivity to the first-filer(s)?

(3) Do generic products launch with many other products at the time of first approval or after exclusivity has expired?

Mythology Surrounding PIV Launch Dynamics

Certainly, three factors in the Paragraph IV Market can lead to plausible conclusions about launch dynamics. These factors are: an increase in the number of PIV cases and ANDA filers entering the market; more than 10 ANDA filers appearing on certain products; and the forfeiture provisions of the Medicare Modernization Act which can remove the first-filer exclusivity.

These factors lead to plausible conclusions: that many, if not most of, ANDA first-filers lose exclusivity at some point. If there is no exclusive ANDA filer, and there are many other ANDA filers present, then FDA will approve many ANDA's at one time, leading to a highly competitive or hypercompetitive generic launch.

In "Generic-Drug Firms Go Beyond Knockoffs," *The Wall Street Journal* promotes this plausible conclusion.[1] The article examines why many generic drug firms expand into brand products. Part of the reason, the piece describes, is the loss of first-filer exclusivity through forfeiture, and by quoting a generic firm CEO, "that whole business model disappeared," concludes that a first-filer ANDA strategy is no longer viable.

This information leads to the statement from a PIV Attorney in New York concluding, "multiple generic companies could sell rival generics as soon as patent protection expired" which then leads to, "today, four or more generic-drug makers may launch a new generic at the same time, damping prices."

In other words, the plausible conclusions are clear: no ANDA filer gets exclusivity anymore, and just about every time the generic market emerges, it emerges as highly competitive with four or more ANDA filers approved and launched at the same time.

While the conclusions seem plausible, the data show that these conclusions are indeed myth.

Methodology

Part II answers the questions surrounding approval and launch dynamics, and in essence, tests the plausible conclusions that could be reached by some in the market and perpretrated by the business press. In order to do so, the methodology is as follows.

Over the past six years, 239 lead PIV cases have been resolved in a federal district court. Of these, 126 of them (52.7%) were settled, and 113 of them (47.3%) were the subject of a court decision and final judgment.[2]

These 113 cases, representing 113 distinct district court decisions, are the starting point of the data analysis. The 113 cases represent 104 brand products (as there may be multiple decisions in different district courts over the same product or different outcomes for different ANDA filers in one district court.)

Then, of the 104 brand products, the methodology is simple: using the data provided by FDA at *Drugs@FDA*, determine which of these brand drugs have designated "therapeutic equivalents," that is, which of the brand drugs have at least one corresponding ANDA product with final approval.

Of the approved ANDA products, record how many ANDA products were approved through December 31, 2014 and their dates of approval. Next, determine whether the FDA has included for review the approval letter for the ANDA product first approved. If FDA did include the approval letter, check the letter to determine whether FDA granted exclusivity or otherwise stated anything regarding exclusivity and/or forfeiture.[3]

These data should provide insight into approval and launch dynamics and answer the questions posed. Note that these data start with court cases that have been adjudicated (decided), regardless of the decision. So, these data include all resolved PIV cases regardless of whether the judgment favored the brand (upholding the litigated, last-patent-to-expire) or generic (invalidating the litigated, last-patent-to-expire and/or finding non-infringement.) Including both sides of win/loss eliminates potential bias regarding approval of ANDA's in either cohort.

Moreover, settled cases are not included.[4] Settled cases could easily skew data for the primary reason that an ANDA filer settling a PIV case could subsequently launch a product as a licensee of the brand and not under its own approved ANDA. In addition, the Court of Appeals was also not a factor in the data collection as at that point in the litigation, the 30-month stay would have expired, enabling an at-risk launch of the first filer and additional approvals.

While the data set offers insight and can help answer the questions posed, there is one important limitation. Approvals do not necessarily equate with product launches. While many ANDA filers eagerly launch upon receiving approval, the first approved ANDA product often will not need or want to launch, especially if its underlying PIV case is pending.

While a limitation, the approvals nonetheless offer unbiased and great insight, particularly when approval letters are available to review. Launch data were not included as these data are not always readily available or necessarily reliable.

Findings and Discussion

Of the 104 Brand products identified, 64 of them had approved therapeutic equivalents through December 31, 2014. Presumably, the 40 products that did not have therapeutic equivalents represent cases that either the brand won (and is still patent protected); where the ANDA filer(s) won but are waiting for other patents to expire before gaining approval; or perhaps the first ANDA filer is not yet approvable.

Figure 1 depicts the data. Of the 64 brand products that have therapeutic equivalents, 21 of them had only one corresponding, "therapeutically equivalent" ANDA approved and 20 additional products had two such ANDA's approved. In other words, 64% of brand products only had 1-2 ANDA's approved.

Moreover, only 14 of them had more than 4 approved ANDA filers. As discussed below, these data are a bit unexpected, and it is also worth noting that they represent cases that were resolved as early as 2009. So, roughly half of the products resolved in the district court between 4-6 years ago which suggests that many generic markets do not see a bunch of ANDA filers enter the market during or after PIV litigation resolves.

64 Brand Products having "therapeutic equivalents" and the number of approved ANDA's

1 ANDA Approved	**21 (33%)**
2 ANDA's Approved	**20 (31%)**
3 ANDA's Approved	**9 (14%)**
4+ ANDA's Approved	**14 (22%)**

Figure 1: Between 2009-2014, 113 cases were decided in a federal court, representing 104 products. Of these, only 64 had a "therapeutic equivalent" by December 31, 2014

The data depicted in Figure 1 are not intuitive in the sense that one might expect different results knowing the PIV market is growing in terms of cases filed and ANDA filers entering it. If nothing else, they contradict the mythology that many ANDA filers enter the market at the first possible moment, "damping prices."

Morever, an examination of the timing of ANDA approvals and a review of available approval letters is also insightful of ANDA approval dynamics. Of the same 64 products, and their 64 first-filed corresponding ANDA filers, FDA explicitly granted exclusivity 23 times (or 36% of the time.)

While the 36% figure may not appear to be significant, it is important to consider that 28 of the 64 products did not include FDA letters for the first approved ANDA filer (or, if there was a posted approval letter, the FDA letter was silent as to exclusivity.)

When analyzing the timing of these 28 products, there was a measurable phenomena: FDA approved the first ANDA product, and either FDA did not approve the second ANDA filer for 180 days or more or FDA did not approve a subsequent ANDA filer at all. In a sense, the first-approved filer of these 28 products enjoyed a "de facto" exclusivity by not having any additional ANDA competition for 6 months or more.

When considering the 23 first-filers explicity granted exclusivity, plus an additional 28 first-approved ANDA filers that nonetheless enjoyed 6 months of market time without a second ANDA approval, the result is that 51 of the 64 first-approved ANDA filers (80%) enjoyed some form of exclusivity.

Of the 64 Brand Products, emergence of corresponding ANDA approvals...	
FDA Granted Exclusivity (Approval Letter Available)	**23 (36%)**
"**De Facto**" **Exclusivity** (Second ANDA not approved for more than 6 months after the first)	**28 (44%)**
4+ ANDA's Approved at the first approval	**6 (9%)**

Figure 2: Rates and numbers of ANDA approvals through December 31, 2014

Reviewing the rate of ANDA approvals offers one more insight. Only 6 of the 64 products had an approval rate where 4 or more ANDA filers were approved at the same time. In other words, only 10% of these generic markets emerged with a "mulitple simultaneous approval" where a bunch of ANDA filers are approved at the first opportunity.[5]

Figure 2 depicts the data involving ANDA approval rates, and all of the data are available in Appendix 1.

Conclusion

In spite of the growth of the Paragraph IV Market in terms of PIV cases and the ANDA filings behind them, *Part I* showed that very few brand products receive a massive number (10 or more) of filings at the time of the first-filed ANDA with a PIV certification.

The data presented and analyzed in Part II demonstrate similar results. While there are indeed brand products that receive a very a large number (10 or more) of ANDA filings, there are still very few products that will have many (4 or more) ANDA approvals when FDA approves the first ANDA.

Over the past 6 years of resolved district court cases, only a small fraction of them (less than 10%) have seen more than 4 ANDA's approved at the first possible moment. On the contrary, a vast majority of the first-approved ANDA filers will enjoy exclusivity, either granted or "de facto," and as Appendix 1 suggests, several first-approved ANDA filers were approved years before the second ANDA approval.

While the data do have limitations -- in terms of recording approvals rather than actual launches and also do not account for the presence of an authorized generic -- they nonetheless offer some hard conclusions.

First, a vast majority of generic markets will emerge with an exclusive ANDA. Second, very few generic markets will emerge as highly competitive (4 or more competitors) or hypercompetitive (10 or more). Third, a first-filer ANDA filing strategy is still viable, contrary to perpetrated mythology.

Of course, with the large number of PIV filers and cases, it is certainly possible that filing and approval dynamics may change. However, for now, the data from both Parts I and II show that there is a high concentration of filers around a small number of products (that is, many filers tend to cluster around a few products) both in terms of filing ANDA's and their approvals.

Footnotes

[1] Jonathon Rockoff, Generic-Drug Firms Go Beyond Knockoffs," *The Wall Street Journal*, June 15, 2013.

[2] Of the 113 cases, brands won 62 while generics won 51. The time frame of the data is 2009-2014.

[3] The subject of forfeiture was detailed in the prior PIV paper "The Paragraph IV Market and the Forfeiture of Exclusivity" which is also a paper made available exclusively for subscribers of ParagraphFour.com. This paper uses the first five years (2009-2013) of the very same data set as this paper and found that FDA declared forfeiture only one time. The conclusion is that while forfeiture events do occur, their occurrence is very infrequent.

[4] While settled lead cases are not included, a case would be included in the counts if the first case settled but a court ruled on a subsequent case.

[5] Some readers may be quick to calculate that not all 64 brand products are accounted for in this analysis. Of the 64 brand products, FDA granted 23 first-filer ANDA's with exclusivity in letters available for review, 28 products had first-approved ANDA's that enjoyed de facto exclusivity, and 6 had multiple simultaneous approvals for a total of 57. The remaining 7 products simply did not fall into any category and instead typically FDA approved an ANDA which was followed by a second (or more) approvals within 6 months.

Appendix 1
PIV District Court Cases Decided January 1, 2009 – December 31, 2014
- With Final ANDA Approvals as of December 31, 2014 -

CASES BRAND COMPANIES WON

Product	Juris	Case #	# ANDAs Approved	1st ANDA Approved	2nd ANDA Approved	FDA Exclusivity Granted?
Abilify®(aripiprazole)	NJ	3:2007cv01000	0			
Alimta®(pemetrexed)	DE	1:2008cv00335	0			
Alimta®(pemetrexed)	INS	1:2010cv01376	see above			
Alphagan P®(brimo..)	DE	1:2007md01866	1	5/22/06		No
Angiomax®(bivalirudin)	ILN	1:2011cv01285	0			
Aplenzin®(bupropion)	FLS	1:2010cv20526	0			
Argatroban®(argatro..)	NYS	1:2007cv11614	3	1/5/12	6/30/14	No
Avodart®(dutasteride)	DE	1:2011cv00046	1	12/21/10		Yes*
AzaSite®(azithromy..)	NJ	3:2011cv003080	0			
Azilect®(rasagiline)	NJ	2:2010cv05078	2	7/1/13	9/12/13	No Letter
Benicar®(olmesartan)	NJ	2:2006cv03462	0			
Combigan®(brimo···)	TXE	2:2009cv00097	0			
Copaxone®(glatiramer)	NYS	1:2008cv07611	0			
Crestor®(rosuvastatin)	DE	1:2007cv00805	0			
Cymbalta®(duloxetine)	INS	1:2008CV01547	11	12/11/13	12/17/13	Yes
Detrol®(tolterodine)	NJ	2:2007cv00174	2	9/5/12	11/27/12	No Letter
Differin®(adapalene)	DE	1:2012cv00045	2	6/14/12	10/27/14	No Letter
Epzicom®(abacavir...)	DE	1:2011cv00576	0			
Exelon®(rivastigmine)	DE	1:2011cv01077	0			
Famvir®(famciclovir)	NJ	2:2005cv01887	8	8/24/07	3/21/11	Yes
Fentora®(fentanyl)	DE	1:2011cv00164	see below			
Fortical®(calcitonin...)	NYS	1:2006cv05571	0			
Frova®(frovatriptan)	DE	1:2011cv00717	1	8/28/14		No Letter
Gemzar®(gemcitabine)	INS	1:2006cv00238	8	1/25/11	7/26/11	Yes
Gralise®(gabapentin)	NJ	3:2012cv01358	0			
Hectorol®(doxercalciferol)	DE	1:2009cv00285	2	8/30/13	2/4/14	No
Hectorol®(doxercalciferol)	ILN	1:2008cv01083	see above			
Latisse®(bimatoprost)	NCM	1:2010cv00681	1	12/1/14		No Letter
Lescol®(fluvastatin)	NJ	2:2008cv05042	2	4/11/12	6/12/12	No Letter
Lialda®(mesalamine)	FLS	0:2012cv60862	0			
Lo Loestrin FE®(norethin...)	NJ	3:2011cv05048	0			
Lovaza®(omega 3 acid....)	DE	1:2009cv00286	3	4/7/14	6/24/14	No Letter
Lumigan®(bimataprost)	DE	1:2009cv00333	0			
Lumigan®(bimataprost)	TXE	6:2011cv00441	see above			
Lyrica®(pregabalin)	DE	1:2009cv00307	3	7/3/12	N/A	Yes/Yes*
Lysteda®(tranexamic)	NV	3:2011cv00481	see below			
Naropin®(ropivacaine)	NJ	3:2007cv1251	3	7/17/14	9/23/14	No Letter
Nuedexta®(dextromorh...)	DE	1:2011cv00704	0			
Nuvigil®(armodafanil)	DE	1:2010md2200	2	6/1/12	8/29/12	Yes

Table continued on next page.....

Appendix 1 (Continued)
PIV District Court Cases Decided January 1, 2009 – December 31, 2014
- With Final ANDA Approvals as of December 31, 2014 -

CASES BRAND COMPANIES WON (Continued)

Product	Juris	Case #	# ANDAs Approved	1st ANDA Approved	2nd ANDA Approved	FDA Exclusivity Granted?
Ofirmev®(acetamino...)	DE	1:2011cv00733	0			
Oracea®(doxycycline)	DE	1:2009cv00184	0			
Ortho Tri-cyclen Lo®(nor...)	NJ	2:2008cv05103	2	3/9/11	6/25/12	No Letter
Patanol®(olopatadine)	INS	1:2006cv01642	0			
Perforomist®(formoterol)	WVN	1:2009cv00087	0			
Rapamune®(sirolimus)	DE	1:2010cv00357	2	1/8/14	10/27/14	No Letter
Seasonique®(levonorge⋯)	NV	3:2008cv00016	see below			
Sensipar®(cinacalcet)	DE	1:2008cv00464	0			
Seroquel XR®(quetiapine)	NJ	3:2010cv01835	0			
Singulair®(montelukast)	NJ	3:2007cv01596	15	8/3/12	8/6/12	No
Suprep Bowel Kit®	NJ	3:2011cv01341	0			
Sutent®(sunitinib)	DE	1:2010cv00528	1	1/30/14		Yes*
Sustiva®(efavirenz)	DE	1:2009cv00651	0			
Tamiflu®(oseltamivir)	NJ	1:2011cv01455	0			
Tarceva®(erlotinib)	DE	1:2009cv00185	1	6/11/14		No Letter
Tarka®(trandolapril⋯)	NJ	2:2007cv05855	1	8/30/10		Yes
Treximet®(sumatriptan⋯)	TXE	6:2008cv00437	0			
Uroxatral®(alfuzosin)	DE	1:2007cv00572	8	7/18/11	1/17/12	Yes
Viagra®(sildenafil)	VAE	2:2010cv00128	0			
Vigamox®(moxifloxacin)	DE	1:2006cv00234	1	9/4/14		No
Vytorin®(ezetimibe⋯)	NJ	2:2009cv06383	0			
Vyvanse®(lisdexamfetam...)	NJ	2:2011cv03781	0			
Xopenex®(levalbuterol)	DE	1:2006cv00113	4	4/9/08	3/15/13	No Letter

For Table on Cases Generic Companies won, see next page

Appendix 1 Notes:

1. All approval data from Drugs@FDA. Approvals are Final ANDA (or 505(b)(2) NDA) approvals.
2. All approval data through December 31, 2014. ANDAs include PIV 505(b)(2) NDAs per ParagraphFour.com research protocol.

For the "FDA Exclusivity Granted?" Column

3. A "No Letter" entry means that FDA did not attach the approval letter to the product. FDA Approval Letters were searched for every first approved product.
4. A "Yes" means that FDA explicitly granted the ANDA product 180-days exclusivity either solely or shared.
5. A "Yes*" means that FDA recognized that the ANDA filer was the first-to-file ANDA, making it eligible for 180-days exclusivity but that a forfeiture event occurred. However, FDA did not formally rule that the ANDA filer forfeited its exclusivity but instead delayed the decision based on certain possible future events. An example of this approval letter can be found for the Approval letter of December 21, 2010 for Barr for dutasteride which can be found at Drugs@fda.
6. A "No" means that the FDA letter is silent or otherwise omits any information regarding the ANDAs eligibility for 180-day exclusivity. It appears that the FDA Letters omit this information for 505(b)(2) products and when it approves the product while the court case is still pending and no judgment has been entered.
7. A "Forfeit" means that FDA explicity declared that the ANDA applicant forfeited the 180-days exclusivity.

Product Notes

8. While the question of "who wins?" a PIV case is usually a simple question to answer, it sometimes is quite complicated. For both Exelon®(rivastigmine) and Lysteda®(tranexamic) cases, one court decided each case under one case number (DE 1:2011cv01077 and NV 3:2011cv00481, respectively). Each case involved two different defendants. While patents were found to be valid in each case, one defendant in each case was found to have not infringed while the other defendant was found to have infringed. Hence, these cases were placed in both as a Brand and Generic win.

9. Concerta®(methlyphenidate) Extended Relase Tablets is BX rated and hence is not "therapeutically equivalent" but was nonetheless included in the research due to likely market practices of interchangeability.

Appendix 1 (Continued)
PIV District Court Cases Decided January 1, 2009 – December 31, 2014
- With Final ANDA Approvals as of December 31, 2014 -

CASES GENERIC COMPANIES WON

Product	Juris	Case #	# ANDAs Approved	1st ANDA Approved	2nd ANDA Approved	FDA Exclusivity Granted?
Accolate®(zafirlukast)	NJ	3:2008cv03237	1	11/18/10		Yes
Actonel®(risedronate)	DE	1:2008cv00627	4	6/10/14	6/13/14	No Letter
Amrix®(cyclobenzaprine)	DE	1:2008cv00889	1	1/31/13		No Letter
Angiomax®(bivalirudin)	DE	1:2009cv00750	see above			
Antara®(fenofibrate)	NYS	1:2011md2241	4	3/1/12	1/10/13	No Letter
Baraclude®(entecavir)	DE	1:2010cv00805	1	8/26/14		Yes
Boniva®(ibandronate)	NJ	2:2007cv04417	6	3/19/12	3/20/12	Yes*
Celebrex®(celecoxib)	VAE	2:2013cv00121	2	5/30/14	10/29/14	Yes
Cenestin®(conj... estrogen)	NYS	1:2009cv01905	0			
Concerta®(methlyphen...)	DE	1:2005cv00642	2	12/28/12	7/9/13	Yes*
Cubicin®(daptomycin)	DE	1:2012cv00367	1	9/12/14		No
Dexilant®(dexlanso...)	CAN	5:2011cv00840	0			
Diprivan®(propofol)	DE	1:2013cv00925	0			
Doryx®(doxycycline)	NJ	2:2008cv06304	4	12/28/10	12/14/11	Yes
Eloxatin®(oxaliplatin)	NJ	3:2007cv02762	8	8/7/09	N/A	Yes
Entocort®(budesonide)	DE	1:2008cv00453	2	5/16/11	4/2/14	No
Exelon®(rivastigmine)	DE	1:2011cv01077	0			
Evista®(raloxifene)	INS	1:2006cv01017	2	3/4/14	9/4/14	Yes
Fentora®(fentanyl)	DE	1:2008cv00330	1	1/7/11		Yes*
Generess FE®(norethin...)	NJ	3:2011cv07228	1	4/23/14		No Letter
Gemzar®(gemcitabine)	MIE	2:2007cv15087	see above			
Lotronex®(alosetron)	NJ	2:2011cv00230	0			
Lunesta®(eszopiclone)	NJ	1:2009cv01302	8	5/23/11	7/14/11	Yes
Lysteda®(tranexamic)	NV	3:2011cv00481	2	12/27/12	1/27/14	Yes
Megace ES®(megestrol)	MD	1:2011cv02466	1	8/27/14		No Letter
Mucinex®(guaifenesin)	FLS	0:2009cv60609	1	11/23/11		No Letter
Nasonex®(mometasone)	NJ	2:2009cv06367	0			
OxyContin®(oxycodone)	NYS	1:2011cv02037	0			
Prandin®(repaglinide)	MIE	4:2005cv40188	6	7/11/13	1/22/14	Yes
Precedex®(dexmedet...)	NJ	3:2009cv04591	3	8/18/14	11/15/14	No Letter
Prevacid®(lansoprazole)	DE	1:2007cv00331	1	10/15/10		Yes*
Prilosec OTC®(omepraz...)	NYS	1:2007cv06790	0			
Pulmicort Respules®(bud..)	NJ	1:2008cv01512	4	11/18/08	3/30/09	No
Remodulin®(trepostinil)	NJ	3:2014cv01617	0			
Restoril®(temazepam)	NJ	2:2007cv01299	3	9/8/09	5/21/10	No Letter
Sanctura XR®(trospium)	DE	1:2009cv00511	2	10/12/12	5/24/13	Yes*
Seasonique®(levonorge..)	NJ	3:2012cv00603	2	5/31/11	4/10/13	Forfeit

Appendix 1 (Continued)
PIV District Court Cases Decided January 1, 2009 – December 31, 2014
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CASES GENERIC COMPANIES WON (Continued)

Product	Juris	Case #	# ANDAs Approved	1st ANDA Approved	2nd ANDA Approved	FDA Exclusivity Granted?
Skelaxin®(metaxalone)	NYE	1:2003cv00006	2	3/31/10	6/21/13	Yes
Strattera®(atomoxetine)	NJ	2:2007cv03770	0			
Taxotere®(docetaxel)	DE	1:2007cv00721	3	6/8/11	4/12/13	No
Temodar®(temozolomide)	DE	1:2007cv00457	2	3/1/10	2/12/14	Yes
Testim®(testosterone)	DE	1:2013cv00148	1	6/4/14		No
Travatan®(travoprost)	DE	1:2009cv00318	0			
Trizivir®(abacavir, et al...)	DE	1:2011cv00576	1	12/5/13		Yes
Ultram ER®(tramadol)	DE	1:2007cv00255	3	11/13/09	8/29/11	Yes
Valcyte®(valganciclovir)	NJ	3:2006cv00223	2	11/4/14		No
Zanaflex®(tizanidine)	NJ	2:2007cv04937	2	2/3/12	11/9/12	Yes*
Zegerid®(omeprazole….)	DE	1:2007cv00551	1	5/25/10		Yes
Zemplar®(paricalcitol)	DE	1:2011cv00648	3	7/27/11	10/21/14	Yes
Zymar®(gatifloxacin)	DE	1:2007cv00779	1	8/19/11		No Letter
Zymaxid®(gatifloxacin)	DE	1:2011cv00271	2	8/28/13	9/3/14	Yes