The Paragraph IV Market and the Forfeiture of Exclusivity

-- The Impact of the Forfeiture Provisions Ten Years Later-- by Gregory Glass

Abstract: In December 2003, the Congress enacted the Medicare Modernization Act which introduced the forfeiture provisions to the Hatch-Waxman process. In an attempt to prevent first-to-file ANDA filers from creating a bottleneck to approval for later ANDA filers, the forfeiture provisions enumerated several circumstances which would strip the first-to-file ANDA holder of its exclusivity rights. As such, if a certain event were to occur, the first-to-file ANDA holder would forfeit its right to 180 days market exclusivity which would then allow subsequent ANDA filers to gain approval without having to wait for an exclusivity period to expire. Now that the Paragraph IV Market has reached the 10 year mark managing first-to-file ANDAs with the threat of forfeiture present, it is an appropriate time to examine the questions of how has FDA applied the forfeiture provisions and how have the forfeiture events impacted first-filers and the Paragraph IV marketplace. This paper examines these questions by surveying and analyzing data from citizen petitions and the past five years of Paragraph IV cases and their related ANDA approvals.

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Background

In December 2003, Congress enacted certain amendments to the Hatch-Waxman Act. Referred to as the Medicare Modernization Act, these amendments sought to improve the process through which generic pharmaceutical companies gain product approval and reach the market.[1]

Passed in 1984, the Hatch-Waxman Act created a system that rewarded first-to-file ANDA filers. Upon successfully moving through the process (usually through a Paragraph IV patent case), FDA would reward the first applicant with market exclusivity for 180 days, enabling it to be the only therapeutic equivalent (that is, generic) product on the market for six months.

However, during the late 1990's and into the early 2000's, there had been growing concern about the 180-days exclusivity provision. In the marketplace, there had been several instances where the first-filer ANDA would either move through the approval process very slowly or not enter the market due to a settlement or for other reasons. As such, the first-filer could in effect create a bottleneck in the ANDA approval process for later ANDA filers as FDA could not approve of their applications until the exclusivity time period had been invoked (by marketing or court decision) and exhausted.

In part, the Medicare Modernization Act (MMA) sought to rectify this problem with the ultimate goals of preventing a first-filer ANDA from becoming a bottleneck for approvals and thus enable a freer flow of ANDAs to the market.

The MMA hoped to acheive these goals by adding forfeiture provisions to the Hatch-Waxman scheme. In sum, it created six events which would strip exclusivity from the first-filer ANDA, thus allowing FDA to approve subsequent ANDAs without them having to wait for the exclusivity period to be invoked and expire.[2] These are:

(1) Failure to Market: if the first applicant **fails to market** its product under a variety of circumstances and time frames.

(2) Withdrawal of Application: If the first applicant **withdraws its application** or it is **deemed to have been incomplete.**

(3) Amendment of Certification: if the first applicant **amends or withdraws its patent certifications.**

(4) Failure to Obtain Tentative Approval: if the first applicant **fails to obtain tentative approval for its ANDA within 30 months** after it was filed.[3]

(5) Agreement: if the first applicant **enters into an agreement that is adjudicated to have violated antitrust law.**

(6) Expiration of Patents: if **the relevant patents expire.**

By delineating the six forfeiture events, the MMA clearly sought to address the most common reasons why first-filer ANDAs created bottlenecks. With the forfeiture events in place, FDA was then empowered to declare a forfeiture event where appropriate and thus to allow subsequent filed ANDAs to be approved without the obstacle of an exclusivity period.

The Forfeiture Provisions -- 10 years later

However, with these new rules in place, the Paragraph IV Market would need time to digest them and determine how FDA would interpret and apply them. Moreover, both brands and generics would then need to manage their products and litigate and resolve PIV patent cases while considering the implications of forfeiture.

The 10 year anniversary of the passage of the MMA offers an appropriate time to examine how the market has reacted to forfeiture events; how FDA has applied forfeiture events to ANDAs; and how the forfeiture provisions have impacted ANDA approvals.

The Research

When developing a research methodolgy, it is important to consider the available data in the context of timing. Of course, the forfeiture provisions are events exclusively tied to ANDAs that include Paragraph IV certifications. Because the forfeiture provisions apply to ANDAs filed after the passage of the MMA, the research can only consider ANDAs filed after its passage in December 2003.

Because forfeiture events are tied to an ANDA with a Paragraph IV certification, it is important to note that it often takes 3-5 years from filing to final approval because the filing typically leads to a PIV patent case in federal district court and then appeal. As such, the market would rarely experience a forfeiture event for the the first 3-5 years after the passage of the MMA (say, from 2004 to 2006 or 2007).

Then, in order to answer these questions, the research methodology covers two separate sets of data.

First, the research examines all citizen petitions filed since 2004 dealing with the forfeiture events. The petition process offers market players an opportunity to establish clarity as to when FDA deems a forfeiture event to have occurred. In addition, these petitions can be filed while ANDAs are pending which can offer some insight during the early part of the time period.

The research protocol for these data is a rather simple search and review of petitions filed over forfeiture. These can be found in FDAPetitions.com which covers all pharmaceutical citizens petitions filed since January 1, 2004.

Second, the research examines Paragraph IV patent cases completed over the past five years and match these data with approval data from FDA. For this part of the research, the research protocol is to:

(1) identify all of the PIV cases that have resolved through the US District Courts in the past five years. These data offer a good starting point for two reasons: (a) as the cases have resolved and are years through the litigation process, they are nearer to generic approval and remove the 30 month stay as a factor and (b) there is a public record of how a court ruled, either invalidating patents or declaring non-infringement which can then influence the timing of approvals.

(2) of the resolved cases, identify those where the district courts have rendered decisions and those that have settled. Eliminate the settled cases.

(3) focusing on the cases (and products) that have court decisions, determine which brand products have "therapeutic equivalents." If the product has a therapeutic equivalent, then FDA has approved at least one ANDA for that product.

(4) record all of the approved ANDAs, including dates of approval. The FDA site (drugs@FDA) contain these data. Along with this, the approval letters can also be reviewed for any additional information including whether exclusivity has been granted or possibly forfeited. However, as anyone familiar with the FDA site knows, there is a limit to this information: sometimes FDA includes approval letters for ANDAs, sometimes it does not, yielding no further information.

Note the rationale for excluding certain data. The research excludes approval data for products whose cases have settled. While most PIV cases settle, these data may not be reliable to some degree because the settling first-filer ANDA may enter the market through a license. If the ultimate point of the research is to understand market dynamics and forfeiture, the approvals of ANDAs in settled cases may not provide the most reliable picture.

The Findings -- Citizen Petitions

Six citizens petitions were filed regarding the forfeiture provisions since the passage of the MMA. These came in two varieties. First, in four petitions, the petitioner was an ANDA filer seeking to have FDA declare that a forfeiture event had occurred to the first-filer ANDA. The FDA declared forfeiture had occurred in one of them; denied the petition in two others; and the fourth is still pending.[4]

Second, two Notices sought clarity regarding the interpretation of certain forfeiture events. The first stemmed from a petition from Teva and focused on the Failure to Market event.[5] When enacted, the provision could have been read to strip exclusivity from a commonly used ANDA filing strategy: filing a PIII against the first-to-expire patent (usually a molecule patent) and PIV(s) against patents that were years from expiration (sometimes more than 10 years). The advantages of this strategy were two-fold. First, it increased the filer's odds of being the first applicant as these ANDAs are filed very early in the cycle. Second, if no PIV suit were filed, it guaranteed the filer exclusivity as soon as the first patent expired.

In the petition, Teva filed such an ANDA, certifying under Paragraph IV on patents that were years from expiration. There was no case filed, and Teva dissected the Failure to Market provision and argued that because a PIV court case could still be filed, the forfeiture event had not yet taken place. FDA agreed with Teva and two supporting commenters, opting to grant exclusivity and avoiding a declaration of forfeiture in these situations.

In the second Notice, FDA sought comments on a situation involving a failure to gain a timely tentative approval or final approval which was coupled with the brand company's request to de-list the patent. After considering several comments, FDA concluded that a forfeiture had occurred.[6]

Of these six filings, four of them focused on the issue of failure to gain tentative approval, and in sum, FDA declared forfeiture in only 2 of the 6 petitions. Also, one of the petitions cited two prior occasions where

FDA declared forfeiture, but only one of the two could be verified.

The petitions also covered ANDAs filed early in the time period (2004-2008) and provide some conclusion that perhaps FDA was reluctant to declare a forfeiture event during the initial stages of applying the forfeiture provisions. However, the data from PIV cases resolved over the past 5 years and their corresponding ANDA approvals provide more data and insight.

The Findings -- PIV Cases

Over the past five years -- between January 1, 2009 to December 31, 2013 -- approximately 198 PIV cases have been completed in a US District Court.[7] The breakdown of the outcomes of the PIV cases is provided in Figure 1 below.[8]

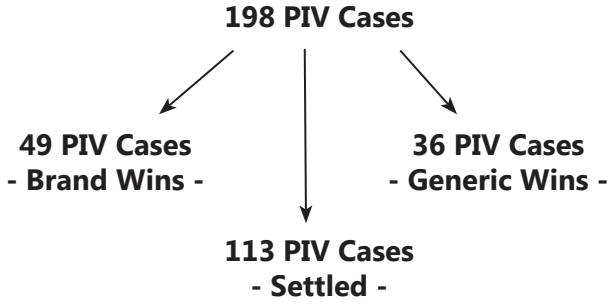

Figure 1: PIV District Court Outcomes 2009-2013

As Figure 1 shows, of the 198 PIV cases to resolve in the federal courts, 113 of them (57%) settled, and 85 cases were actually tried with the district court issuing a final judgment either from summary judgment or after trial. The list of these 85 cases are contained in the Table in Appendix 1.

The 85 cases cover 81 brand products, as four products had two different court decisions rendered. From this point, the research then considered the 81 products and compared them, at the end of the time period, with the number of corresponding ANDA approvals and any other possible information that FDA provides as mentioned in the fourth research step above.

In other words, of these 81 products, how many of them had therapeutic equivalents as of December 31, 2013, and of the products that did have a therapeutic equivalent, how often did FDA declare that the first-filer ANDA forfeited its exclusivity?

The answer to the first question is simple. Of the 81 products that resolved by district court decisions, 44 of them had at least one ANDA approved as of December 31, 2013 (as highlighted in Appendix 1.) Of course, this means that 37 of these brand products were most likely still patent protected or possibly that, for some reason, the ANDA(s) were not approvable.

The answer to the second question gets slightly more complicated. When reviewing approval letters, it is important to note how FDA has been handling forfeiture events. In the approval letters, FDA does one of four things: (1) grants sole (or shared) exclusivity to the ANDA first-filer; (2) omits information regarding exclusivity -- thus neither granting exclusivity nor declaring forfeiture; (3) notes that the ANDA filer was eligible for exclusivity but that a forfeiture event has occurred. However, FDA does not declare a forfeiture, delaying the decision unless necessitated by possible future events;[9] and (4) declares a forfeiture.

Of the 44 brand products, FDA posted approval letters for 33 corresponding ANDA products. These letters reveal that FDA declared forfeiture only once and granted exclusivity 18 times (including shared exclusivities but only counting them once). The remainder of the posted letters were either silent (and thus not granting exclusivity) or made no decision, though noting that a forfeiture event had taken place.

The summary of these data are in the following Figure 2. In sum, 44 brand products had therapeutic equivalents. Of these, the corresponding ANDA final approvals were as follows:

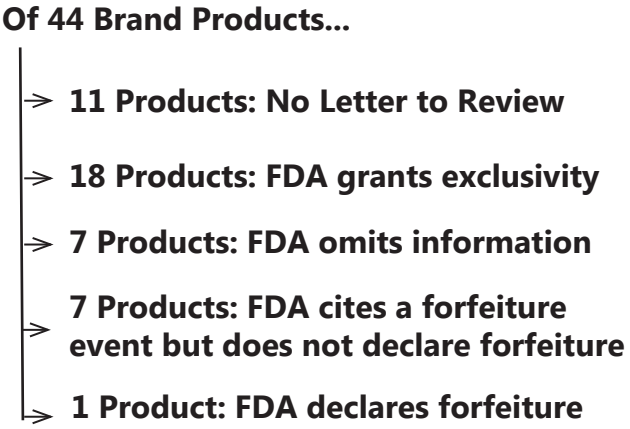

Figure 2: ANDAs Approved as of December 31, 2013

As Figure 2 suggests, of the 33 ANDA products that had approval letters available for review, FDA declared a forfeiture only 1 time and exclusivity 18 times. However, that still leaves the research with two queries.

First, what happened to those 7 products which FDA posted letters, citing a forfeiture event but not declaring a forfeiture? Second, what happened in the market to the 11 ANDA products that did not have a letter to review? Can we tell if forfeiture event occur for these 18 products?

By researching the approvals of all ANDAs for these products including number of approvals and dates, we can get closer to the answers regarding forfeiture. Appendix 1 offers these data as well.

Of the 7 products that FDA stated a forfeiture event took place but did not declare forfeiture, 6 of the ANDA products were either the only ANDA approved or the second ANDA was approved more than 180 days after the first. The approval timing suggests that the forfeiture contingencies outlined in the FDA letters (see footnote 9 for an example) were not met and that FDA did not end up declaring forfeiture for these 6 ANDAs.

The seventh product (Boniva®(ibandronate) had its second ANDA approved one day after the first. While it might suggest a forfeiture was declared, it is not likely as there was more than one first-filer, suggesting that there was shared exclusivity and no forfeiture.

Of the 44 products, FDA declared a forfeiture only one time.

Of the 11 ANDA products that did not have a letter to review, 8 of them either were the only ANDA approved or the second ANDA was approved after 180 days from the first ANDA approval. Of course, these data do not completely rule out that a forfeiture event did not take place (for example, the second filer may have filed much later than the first), but they nonethless suggest that the likelihood is that FDA did not declare forfeiture.

As for the other 3 products, each of these had at least two ANDAs approved with the second ANDA approved within three months of the first. Again, these data are not conclusive. It is possible that the first ANDA approved forfeited, enabling the second ANDA approval. However, it is also possible that both were first-filers with the second simply not yet ready for approval.

While the approval data can be insightful and reasonably conclusive for the 7 products where FDA cited a forfeiture event but did not declare one, the approval data for the 11 "No Letter" products are best viewed as directional and not conclusive. The obvious limitation is that the 180 days exclusivity begins on commercial marketing, not approval. This fact opens up the possibilities that other market dynamics are at issue regarding the approval sequence.

Conclusion

After forfeiture provisions were inserted into the Hatch Waxman scheme in 2003, it likely raised a bit of angst among both generic and brand companies. With the new rules in place, it would have been easy to envision a marketplace where forfeiture and multiple simultaneous generic approvals were commonplace.

Such a market would have deflated two commonly used strategies such as early filing (10+ years before patent expiry) for ANDA filers and authorized generic arrangements for brand companies which strategy depends upon the exclusivity period.

During the first half of the decade with forfeiture, forfeiture events were uncommon for operational reasons: because PIV cases take about 3-5 years to resolve, their approvals would necessarily lag along with the cases.

Nonetheless, several market players tested the application of the provisions through citizen petitions. By granting only a couple of them, FDA did not appear too eager to interpret fact patterns to declare forfeiture, and FDA also kept intact the early filer ANDA strategy.

While there are a few forfeiture events cited and the research does not cover every ANDA approval, it appears that forfeiture events were certainly not a common occurrence during 2003-2008.

Paragraph IV case data from the second half of the time period provides firmer insights as to forfeiture. The resolved cases from 2009-2013 provide a researchable time frame for generic approvals, and offer the universe of data for ANDA products that incurred a Paragraph IV case and resolved by judgment.

When reviewing the actual approvals, it is reasonably clear that FDA has rarely declared a forfeiture. Of the 44 products, FDA declared forfeiture only one time as stated in the 33 letters available for review. The other products, while not entirely conclusive, nonetheless point to the conclusion that forfeiture is best described as an uncommon occurrence, perhaps even a rare event.

The fact that FDA has noted a forfeiture event has

occurred yet refused to declare a forfeiture also reveals FDA's reluctance to declare forfeiture.

The impact of forfeiture, for now, appears to be minimal. While it can be devastating to an ANDA filer if forfeiture occurs, as well as a brand now faced with multiple generic approvals, it just does not appear to occur that often, and a vast majority of ANDA filings appear to be unaffected. Brands as well can expect a generic marketplace to evolve as it has in the past, leaving an authorized generic strategy as a viable option.

Footnotes

[1] The Hatch-Waxman Act is formally known as Section 505, Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and the Medicare Modernization Act is the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173).

[2] The forfeiture provisions can be found at 21 U.S.C. §355(j)(5)(D).

[3] Subsequent amendments to the statute allows for additional time for tentative approval if delayed by a citizens petition (21 U.S.C. §355(q)(1)(G)). Also, on July 9, 2012, Congress enacted The Food and Drug Administration Safety and Innovation Act (Pub Law 112-144) which expands the 30 month time period to 36 and 40 months for ANDAs filed during certain time periods and under certain conditions. The section is cited as Section 1133 of the FDASIA and is relegated to a Note in 21 U.S.C. §355.

[4] These petitions include: (1) 2010P-0632 (Hectorol®doxercalciferol) (no forfeiture); (2) 2011P-0486 Antara®(fenofibrate) (forfeiture); (3) 2012P-0279 Avapro®(irbesartan) (no forfeiture); and (4) 2012P-0661 Nexium®(esomeprazole) (pending). While these four petitions all considered the failure to get timely tentative approval, the Hectoral petition also included the withdrawal of application forfeiture event. It is also interesting to note that a recently filed petition (2014P-0594) is requesting that Ranbaxy forfeit exclusivity on several products due to delays in approval and marketing stemming from its reported manufacturing and quality control issues.

[5] Teva filed a petition which FDA turned into a Notice (2007N-0389) over granisetron injection (no forfeiture).

[6] FDA issued Notice (2007N-0417) involving Precose®(acarbose) (forfeiture).

[7] "Case" typically means the result of the the lead PIV case or a court decision. For example, if the lead case settles, along with the others for a given product, it is counted as one case, and the subsequent cases that settle are not included. For cases where a court renders a decision (and represents a lead case with others rolled into it), that is also counted as one case. However, some products may have two distinct court decisions which would then count as two cases. Another way to think of a "case" is to equate it with a court decision (as one court decision equals one case.) As such, while there were 198 decided and settled cases over the past five years, the raw number of actual PIV cases is much higher.

[8] In just about all cases, it is simple to determine whether the brand or generic company "wins" the PIV case. Usually, of the patent(s) litigated, the decision is clear -- either the patent(s) in dispute is upheld (infringed, valid and enforceable) or is not (finding non-infringement, invalidity, and/or unenforceability). However if a court concludes that one patent is valid but the other is not, the expiration dates are then considered as to who won the case by using the last-patent-to-expire as the one that controls. For example, if a court rules two patents invalid but the third valid and the third patent is last-to-expire, then the brand wins.

[9] The approval letter to Barr for its dutasteride capsules (ANDA 090095) provides a typical example. FDA states, after establishing eligibility of Barr for the 180-day exclusivity, "The agency notes that Barr failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed....The agency is not, however, making a formal determination at this time of Barr' s eligibility for 180-day generic drug exclusivity. It will do so only if another paragraph IV applicant becomes eligible for full approval (a) within 180 days after Barr begins commercial marketing of Dutasteride Capsules, 0.5mg, or (b) at any time prior to the expiration of the last listed patent if Barr has not begun commercial marketing."

Appendix 1
PIV District Court Cases Decided January 1, 2009 – December 31, 2013
- With Final ANDA Approvals as of December 31, 2013 -

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			
Alphagan P®(brimo..)	DE	1:2007md01866	1	5/22/06		No
Aplenzin®(bupropion)	FLS	1:2010cv20526	0			
Argatroban®(argatro..)	NYS	1:2007cv11614	1	1/5/12		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	7	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	1	6/14/12		No Letter
Famvir®(famciclovir)	NJ	2:2005cv01887	7	8/24/07	3/21/11	Yes
Fentora®(fentanyl)	DE	1:2011cv00164	see below			
Fortical®(calcitonin...)	NYS	1:2006cv05571	0			
Gemzar®(gemcitabine)	INS	1:2006cv00238	8	1/25/11	7/26/11	Yes
Hectoral®(doxercalciferol)	DE	1:2009cv00285	1	8/30/13		No
Hectoral®(doxercalciferol)	ILN	1:2008cv01083	see above			
Latisse®(bimatoprost)	NCM	1:2010cv00681	0			
Lescol®(fluvastatin)	NJ	2:2008cv05042	2	4/11/12	6/12/12	No Letter
Lialda®(mesalamine)	FLS	0:2012cv60862	0			
Lovaza®(omega 3 acid....)	DE	1:2009cv00286	0			
Lumigan®(bimataprost)	DE	1:2009cv00333	0			
Lyrica®(pregabalin)	DE	1:2009cv00307	3	7/3/12	N/A	Yes/Yes*
Naropin®(ropivacaine)	NJ	3:2007cv1251	0			
Nuvigil®(armodafanil)	DE	1:2010md2200	2	6/1/12	8/29/12	Yes
Ofirmev®(acetamino...)	DE	1:2011cv00733	0			
Oracea®(doxycycline)	DE	1:2009cv00184	1	7/1/10		Yes
Ortho Tri-cyclen Lo®(nor...)	NJ	2:2008cv05103	2	3/9/11	6/25/12	No Letter
Patanol®(olopatadine)	INS	1:2006cv01642	0			
Rapamune®(sirolimus)	DE	1:2010cv00357	0			
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	12	8/3/12	8/6/12	No

Table continued on next page.....

Appendix 1 (Continued)
PIV District Court Cases Decided January 1, 2009 – December 31, 2013
- With Final ANDA Approvals as of December 31, 2013 -

CASES BRAND COMPANIES WON (Continued)

Product	Juris	Case #	# ANDAs Approved	1st ANDA Approved	2nd ANDA Approved	FDA Exclusivity Granted?
Suprep Bowel Kit®	NJ	3:2011cv01341	0			
Sustiva®(efavirenz)	DE	1:2009cv00651	0			
Tamiflu®(oseltamivir)	NJ	1:2011cv01455	0			
Tarceva®(erlotinib)	DE	1:2009cv00185	0			
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	0			
Vytorin®(ezetimibe…)	NJ	2:2009cv06383	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, 2013. ANDAs include PIV 505(b)(2) NDAs per ParagraphFour.com research protocol.
3. Note also that for two ANDAs, FDA recognized that a forfeiture event took place (failure to receive timely tentative approval), but FDA granted exclusivity as the delayed tentative approvals were due to filing of citizens petitions. (Sandoz, ANDA 40445 for metaxalone and IMPAX Labs, ANDA 90505 for doxycycline.)

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.
6. A "No" means that the FDA letter is silent or otherwise omits any information regarding the ANDAs eligibility for 180-day exclusivity. ParagraphFour.com research protocol includes 505(b)(2) products which FDA approval letters omit this information as these products are not eligible for exclusivity. The Table includes three 505(b)(2) products. It also appears that FDA will omit this information when it approves the product while the court case is still pending and no judgment has been entered (but not not in every circumstance.)
7. A "Forfeit" means that FDA explicity declared that the ANDA applicant forfeited the 180-days exclusivity.

Appendix 1 (Continued)
PIV District Court Cases Decided January 1, 2009 – December 31, 2013
- With Final ANDA Approvals as of December 31, 2013 -

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
Amrix®(cyclobenzaprine)	DE	1:2008cv00889	1	1/31/13		No Letter
Antara®(fenofibrate)	NYS	1:2011md2241	3	3/1/12	1/10/13	No Letter
Boniva®(ibandronate)	NJ	2:2007cv04417	6	3/19/12	3/20/12	Yes*
Cenestin®(conj... estrogen)	NYS	1:2009cv01905	0			
Concerta®(methlyphen...)	DE	1:2005cv00642	2	12/28/12	7/9/13	Yes*
Dexilant®(dexlanso...)	CAN	5:2011cv00840	0			
Doryx®(doxycycline)	NJ	2:2008cv06304	4	12/28/10	12/14/11	Yes
Eloxatin®(oxaliplatin)	NJ	3:2007cv02762	6	8/7/09	N/A	Yes
Entocort®(budesonide)	DE	1:2008cv00453	1	5/16/11		No
Evista®(raloxifene)	INS	1:2006cv01017	0			
Fentora®(fentanyl)	DE	1:2008cv00330	1	1/7/11		Yes*
Gemzar®(gemcitabine)	MIE	2:2007cv15087	see above			
Lunesta®(eszopiclone)	NJ	1:2009cv01302	4	5/23/11	7/14/11	Yes
Mucinex®(guaifenesin)	FLS	0:2009cv60609	1	11/23/11		No Letter
Nasonex®(mometasone)	NJ	2:2009cv06367	0			
Prandin®(repaglinide)	MIE	4:2005cv40188	1	7/11/13		Yes
Precedex®(dexmedet...)	NJ	3:2009cv04591	0			
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
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
Skelaxin®(metaxalone)	NYE	1:2003cv00006	2	3/31/10	6/21/13	Yes
Strattera®(atomoxetine)	NJ	2:2007cv03770	0			
Taxotere®(docetaxel)	DE	1:2007cv00721	2	6/8/11	4/12/13	No
Temodar®(temozolomide)	DE	1:2007cv00457	1	3/1/10		Yes
Testim®(testosterone)	DE	1:2013cv00148	0			
Travatan®(travoprost)	DE	1:2009cv00318	0			
Ultram ER®(tramadol)	DE	1:2007cv00255	3	11/13/09	8/29/11	Yes
Valcyte®(valganciclovir)	NJ	3:2006cv00223	0			
Zanaflex®(tizanidine)	NJ	2:2007cv04937	2	2/3/12	11/9/12	Yes*
Zegerid®(omeprazole⋯.)	DE	1:2007cv00551	1	5/25/10		Yes
Zymar®(gatifloxacin)	DE	1:2007cv00779	1	8/19/11		No Letter
Zymaxid®(gatifloxacin)	DE	1:2011cv00271	1	8/28/13		Yes