Inter Partes Reviews and Paragraph IV Patent Cases

-- Inter Partes Reviews Three Years Later --
by Gregory Glass

Abstract: In 2011, The America Invents Act was passed into Law which enabled anyone to petition the Patent Trial and Appeal Board (of the US Patent and Trademark Office) to cancel one or more claims of a patent through an Inter Partes Review. While the ostensible purpose of the Act was to provide companies in the tech sector a less expensive forum to challenge patents from non-practicing entities, filing an Inter Partes Review has become a tactic ANDA filers have employed to challenge patents in Paragraph IV cases. The Inter Partes Review was put into practice in September 2012 with the filing of the first petitions for Inter Partes Review, and 148 of them have since been filed over Paragraph IV products. Now that the Inter Partes Review has reached the three-year mark, it is a good time to analyze the success of Inter Partes Reviews filed over patents covering brand products involved in Paragraph IV patent litigation. This paper analyzes the three years of data including the outcomes and success rates of Inter Partes Review petitions and considers the viability of the Inter Partes Review as a strategic alternative for ANDA filers.

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Background of the Inter Partes Review

In 2011, the America Invents Act was enacted to thwart a perceived, growing problem in the U.S. Over the past decade, companies have been created to identifiy and patent open areas of intellectual property, typically in the high tech sector. With patents in hand, these companies then file patent infringement suits in the hopes of garnering royalties or winning verdicts.

As these companies typically produce nothing, and are solely created to own intellectual property and file infringement cases, these entities are politely referred to as "non-practicing entities," or derisively called "patent trolls."

As one might imagine, the cost to a target company of these non-practicing entities can be enormous: from defending multiple cases in federal court to managing the interruption to its business and potential damage to its stock price.

In response, the Act created a process called the Inter Partes Review (IPR). It enabled anyone to file an IPR with the Patent Trial and Appeal Board (of the U.S. Patent and Trademark Office) to cancel one or more claims of a patent.[1] As such, a company such as Samsung or Apple can petition the Board to cancel a patent issued to a non-practicing entity.

Compared to a federal court, the IPR process is designed to be quicker and less expensive. The process is quite simple: a petitioner files the petition, the patent owner can file an initial response (but does not have to), and the Board then conducts an initial review.

If the Board believes that the petition has a reasonable likelihood of canceling at least one of the patent's claims, it then "initiates" an Inter Partes Review. If not, it denies the petition without further review. If initiated, the Board conducts an administrative hearing and issues a Final Written Decision either upholding the patent as valid or invalidating the claim(s) of the patent.

Though not really designed to contest pharmaceutical patents listed in the Orange Book, IPR filings have become commonplace in the pharmaceutical sector. Specifically, ANDA filers have decided that the IPR is a viable strategy to pursue in parallel to defending their Paragraph IV patent cases.

The Act was put into practice three years ago in September 2012. At the three-year mark of IPRs, it is now an appropriate time to analyze the data.

The Findings

Starting on October 1, 2012 and going through September 30, 2015, there have been 36 months (three annual cycles) of IPR petitions. The U.S. Patent Trademark Office assigns annual numbers on a 12 month cycle starting on October 1. So, for example, the USPTO will designate IPRs filed between October 1, 2012 to September 30, 2013 as "2013" petitions, and the "2014" petitions for the 12 months starting October 1, 2013, and so forth.

Over the past 3 years, there have been 148 IPRs filed over patents involved in Paragraph IV cases. ANDA filers have filed a vast majority (91%) of these IPRs which are always connected to a patent involved in a Paragraph IV case.[2] (To note, 20 additional IPRs have been filed on Orange Book patents that are not involved in Paragraph IV cases. This paper will not focus or further consider these petitions.)

As the graph below indicates, the number of IPRs has been increasing over this time period.

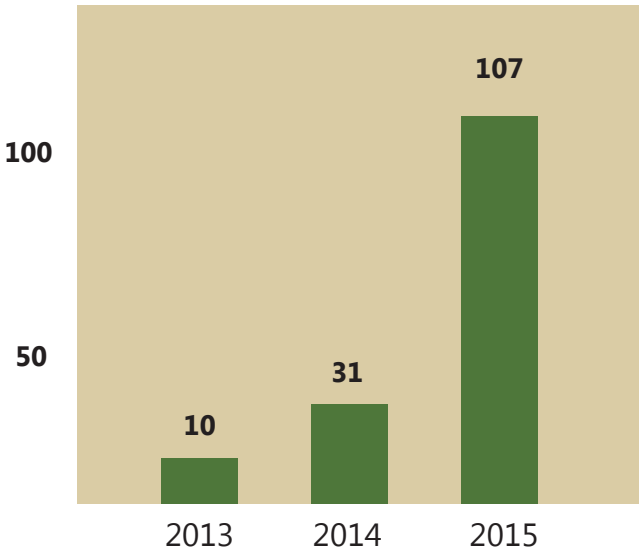

Figure 1: Number of Inter Partes Reviews Filed over Patents Involved in a Paragraph IV Case -- Last 3 years, by 12 month cycle --

Figure 1 illustrates the number of IPRs file per 12 month cycle. In other words, between October 1, 2012 to September 30, 2013 (the IPRs assigned as a "2013" petition by the USPTO), only 10 IPRs were filed. However, over the past 12 months (Oct. 1, 2014 to Sept. 30, 2015), 107 IPRs have been filed.

The number of IPRs filed over the three years is understandable in the context of the ANDA filer. Simply put, an ANDA filer is always trying to gain approval and reach the market as soon as possible. Of course, the

primary obstacle to approval and market entry is the brand's patent(s). Typically, after the generic company files its ANDA, the brand company will file its Paragraph IV patent infringment action against it.

In addition to defending its pending PIV case, the ANDA filer can also file an IPR petition. The more than 10-fold increase in IPR filings from Year 1 to Year 3 suggests that ANDA filers consider IPRs a viable, alternative method to invalidating a patent. ANDA filers likely see the IPR as a dual strategy to either gain leverage if settlement negotiations are possible or as a chance to invalidate a patent in a less expensive, quicker fashion.

The Outcomes of IPRs

However, the viability of the IPR as a strategy for ANDA filers will ultimately depend on its success. From three years of data, the PIV Market can now make some initial determinations. Appendix 1 contains a flow diagram of the 148 IPRs filed over Paragraph IV products.

Here is the summary. Of 148 IPRs filed:

- The Board made its initial decision in 75 IPRs
- ... instituting 52 IPRs (69%) for review and
- ... and denying 23 IPRs (31%)

As for the other IPRs, 61 of them are still pending as of September 30, 2015, and 12 of them settled before the Board made its initial review decision.

Of the 52 IPRs the Board instituted for a full trial:

- The Board has made decisions in 19 of them
- ... upholding the patent 11 times (58%)
- ... and invalidating the patent 8 times (42%)

A synopsis of each of the 19 Board decisions is below in Appendix 2. As for the other instituted IPRs, 22 of them are still pending as of September 30, 2015, and 11 of them settled before trial.

The Patent Breakdown

As mulitple IPRs can be filed over one patent, the data can also be broken out by patents. The 148 IPRs filed covered 91 patents. While all of these patents are at issue with a Paragraph IV case and brand product, only one IPR was filed over a non-Orange Book patent.

The outcomes data over the patents considered is identical to the data over IPRs. Of the 19 IPRs the Board considered after trial and issued a Final Written Decision, these IPRs covered 12 patents. The Board upheld the claims in 7 of these patents (58%) and invalidated claims in the remaining 5 patents (42%).

Discussion -- Data Comparison

Before considering the viability of the IPR to ANDA filers as a means to invalidate a patent, it is important to compare these data with others. The first data set comes from a paper published in *The University of Chicago Law Review Dialogue*.[3]

In this paper, two authors compiled all IPR data at the two-year mark. These data included all IPRs filed, regardless of industry type, and thus includes the few pharmaceutical IPRs filed. (Note, per Figure 1, only 41 IPRs associated with a Paragraph IV product had been filed by the end of the two-year mark, and none had gone through the entire Board process.)

The Patent Board invalidates an Orange Book patent associated with a Paragraph IV case at nearly half the rate of the "average" IPR (42% v. 77%)

The authors recorded similar data as presented here, and in a sense, their data created what can be considered the "average" IPR. Specifically, they found that the Board instituted an IPR 84% of the time and, after a full Board trial, all instituted claims were invalidated or disclaimed 77% of the time.

The data comparisons are presented in Figure 2.

	The "Average" IPR	The PIV-IPR
IPRs Instituted	**84%**	**69%**
Patents Invalidated	**77%**	**42%**

Figure 2: Comparison of Data Between the "Average" IPR from the UChicago Study and IPRs associated with PIV Cases

While a purist might point out that the two data sets do not cover the same time periods and weaken the comparison, they nonetheless offer a comparison which shows differences that are expected.

The average IPR will almost always consider and scrutinize a patent from a non-practicing entity which is the point of the IPR process. Typically, these patents stem from inventions which are rarely discovered during the course of business or in practice.

On the contrary, pharmaceutical patents are almost always the result of a business practice: discovering a molecule in a lab; discovering an effective formulation among many choices; or analyzing data from an *in vitro* or *in vivo* well-controlled, adequately powered study.

As such, in theory at least, a patent issued as a result of a non-practicing entity trolling for open spaces in intellectual property are likely going to be weaker (and more vulnerable to challenge) when compared to a pharmaceutical patent.

The data comparison supports this conclusion. It is really no suprise that the Board institutes more trials over the average patent in the average IPR than one associated with an Orange Book patent (84% v. 69%). It is also no surprise that the Board invalidates more of these as well (77% v. 42%).

These data are more striking when comparing the IPR associated with a PIV case to a second data set: the results of PIV cases. As reported in a prior paper made available to subscribers of ParagraphFour.com,in cases tried before a US District Court, the generic party (ANDA filer) wins about 42% of the time. [4]

In other words, over the past 5-6 years, ANDA filers have won 42% of its cases decided by a district court -- the same figure as they have won through the IPR procedure over the past three years.

While the similarity of the win/loss rate could fluctuate slightly over the years, the fact that they are so similar is likely not an anomaly or coincidence. Regardless of venue (court v. USPTO Board), it appears that when most judges review a pharmaceutical patent, they are more likely than not to uphold it.

If nothing else, the data regarding invalidating patents in a district court serve to provide strong support to the rate of invalidation in the IPR process and likely suggests that the rate of invalidation will be similar in the future.

Discussion -- Legal Issue

While this paper focuses on the PIV Market and is not intended to be a legal treatise, it would be remiss not to raise the legal question as it impacts ANDA strategy: which venue really controls the decision over whether claims in a patent are valid?

The answer appears to expose a conflict between the Hatch Waxman Act (the Paragraph IV process) and the IPR process. In a sense, a district court judge does not need to consider the opinion of the USPTO Trial Board and vice-versa.

Over the past three years, ANDA Filers have won 42% of its PIV cases tried -- the same rate of success of invalidating a patent through in the IPR process

The tension between the two venues was pronounced in the recent decisions over Exelon®(rivastigmine) Patch in September 2015. In the early part of the month, the District Court in Delaware in a PIV case concluded that claims 7 and 16 of the 6,335,031 patent were valid overcoming a defense of obvousness.

However, later in the month, the Trial Board at the USPTO concluded the same claims of the '031 patent (as well as others) were obvious and thus unpatentable. While the Trial Board acknowledged the district court decision (as well as prior similar decisions of both the district and Court of Appeals for the Federal Circuit), the Board noted that it was not bound by these decisions and that the legal standard was lower for the Board to invalidate claims in a patent.[5]

While this conflict exists between the two venues, the America Invents Act also leaves the losing party the option of appealing the Board decisions to the Court of Appeals for the Federal Circuit -- the same appellate court that serves as the appellate court for PIV cases.

As these dueling Exelon Patch decisions will likely reach the Court of Appeals at the same time, the Court of Appeals should sort out the legal question of which venue has more effective control over questions involving patent validity.

Discussion -- The IPR as a Strategy

When considering strategies to market, an ANDA filer has two options: (1) file an ANDA with PIII certifications only and wait for the brand's patents to expire. As presented in the last two papers made available to subscribers regarding ANDA filing and launch dynamics, Option (1) has become a strategy that is more difficult to achieve and sustain success.

Thus Option (2) -- file an ANDA with PIV certification(s) and challenge the brand's patents -- has become the most viable strategy for an ANDA filer.

But the IPR process has opened another alternative. While in PIV litigation (or even before it, as what occurred over Gilenya®(fingolimod)), the ANDA filer can choose either to roll through the Hatch Waxman process or file an IPR petition in parallel to the PIV case, if one is indeed filed.

The IPR option has a few advantages, the primary one being that it is a lot faster than a PIV case. Typically, a PIV case in the district court will run about 36 months from filing to district court decision. However, an IPR associated with PIV cases takes only about 18 months (the process also has certain time limits embedded into the statute.)

For an ANDA filer, the IPR does not appear to have an inherent advantage over simply defending its PIV case. As such, while the IPR can be a useful tactic, it will not likely displace the PIV case of its importance.

Along with a quicker route to possibly invalidating a patent comes the cost savings associated with the trial process before the Patent Board. The cost savings can be substantial given the limited discovery and quicker time to resolution.

While some might consider the Patent Board a more favorable venue for an IPR petitioner, the identical success rates between the IPR and PIV case do not support this rationale.

But the IPR process is not without its downsides. First, the process limits the legal arguments an ANDA filer can raise compared to a federal court. Second, it limits discovery. Third, in cases where an ANDA filer has a potentially non-infringing product, the IPR process becomes less desirable as an ANDA filer is better off having an approved, non-infringing product rather than invalidating a patent for the benefit of all ANDA filers. Fourth, if it were to lose its IPR, the winning brand company will no doubt use the Board opinion as persuasive evidence for the district court judge to consider.

Moreover, when an ANDA filer files an IPR petition, it must also expose its legal argument whereas in federal court, some, most, or all of the arguments can be sealed from others to examine. In addition, as the Hatch Waxman Act connects the legal process to the ANDA approval process, a federal court will have more power to decide other legal issues and control outcomes through injunction, orders to FDA, or settlements.

One final consideration is the first-to-file status. In theory, at least, if a patent is found to be invalid in an IPR, it might strip the first ANDA filer of the benefits of being a first-filer.[6] Thus, the strategy is really only attractive to later filers.[7]

However, even for a first-filer ANDA, the IPR process may also prove to be an efficient method to clear out late-issued patents. In other words, after the first PIV case is filed, some brand companies will add patents to the Orange Book, often ones that were issued after the PIV case was filed.

With these considerations, using the IPR process as a strategy to market will ultimately come down to the ANDA itself. The data suggest that an IPR petitioner will fare about the same as it will in federal court winning at a 42% rate. Given the limited use of the IPR and the perceptions of the individual ANDA filer, it may prove to be an attractive strategy in some situations.

For example, if the ANDA filer is one of the later filers to a particular brand product and its sole argument to invalidate the patent is the obviousness defense, then the IPR strategy might indeed be an attractive alterative to lengthy and expensive PIV litigation. If successful, it may disrupt the exclusive status of the first-filer ANDA.

However, the same filer, filing a different ANDA, might feel differently if it were in the first-to-file position, wanted to raise different arguments than allowed in the IPR process, or prefers the power of the federal court to issue favorable orders rather than the limited powers of the USPTO Board.

Conclusion

While many ANDA filers have embraced the IPR as a parallel strategy to defending their PIV cases, the data suggest that they fare no better than a district court decision. As their IPR filings end up in the Court of Appeals, possibly along with their PIV cases, it appears that the IPR provides no inherent advantage.

Without an inherent advantage, the IPR will not likely displace the PIV case of its importance. Nonetheless, the PIV Market can expect to see IPRs deployed by later ANDA filers and in the circumstances where these filers have mitigated downside risk.

Footnotes

[1] Formally known as the Leahy-Smith America Invents Act. September 16, 2011, Public Law 112-29. It can also be referenced as 35 U.S.C. 311 et seq. Note also that some sources prefer to italicize the term Inter Partes. I have declined to do so here.

[2] The other 9% of filers have come from the financial sector, typically a hedge fund seeking to invalidate a patent to profit from stock positions.

[3] Brian J. Love and Shawn Ambwani, "Inter Partes Review: An Early Look at the Numbers," *The University of Chicago Law Review Dialogue*, 81:93.

[4] See the paper "The Paragraph IV Market and the Forfeiture of Exclusivity" (page 4) which is available for subscribers on ParagraphFour.com. Note that these data are from from 2009-2013 showing an ANDA success rate of 42% in PIV cases. However, the addition of 2014 data yields the same result.

[5] See the Exelon®(rivastigmine) Patch product topic in ParagraphFour.com. The referenced case is Novartis v. Noven, Delaware District Court 1:2013cv00527 (on appeal) and the Inter Partes Review proceedings of IPR2014-00549 and IPR2014-00550.

[6] This is an area of unsettled legal arguments. Over the decades, courts have had to intepret many of the provisions of the Hatch-Waxman Act. The IPR process will also likely raise additional legal questions. The section here raises possible scenarios. For example, if the Board invalidates a patent in an IPR proceeding before a district court decision, what impact would that have, if any, on the pending PIV cases and the first-filer? If the first-filer ANDA settles its case (or still has a pending case) and a later-filed ANDA filer is able to invalidate the key patent in an IPR proceeding, does this affect the exclusivity rights of the first-filer?

[7] The data also support the conclusion that a later filer is the most likely party to file an IPR. Of the IPRs involved in the 19 Board decisions, it appears that all 19 IPR petitions were filed by later (not first-filer) ANDA filers.

Summary of Outcomes of Inter Partes Review Board Decisions

1. IPR 2013-00368: Oracea®(doxycycline) Capsules -- Amneal filed three IPRs (this and the following two) over three patents involved in its PIV case. In this IPR, the Patent Trial and Appeal Board issued its Final Written Decision on December 9, 2014 finding claims 1, 2, 5-15, and 19-22 of the 8,206,740 valid, overcoming an obviousness challenge.

2. IPR 2013-00371: Oracea®(doxycycline) Capsules -- On the same day as (1) above, the Board issued a Final Written Decision finding claims 1-13 and 17-20 of the 8,394,405 valid.

3. IPR 2013-00372: Oracea®(doxycycline) Capsules -- On the same day as (1) above, the Board issued a Final Written Decision finding claims 1-12 and 16-21 of the 8,394,406 valid.

4. IPR 2014-00115: Tygacil®(tigecycline) For Injection -- The Patent Trial and Appeal Board issued its Final Written Decision on April 20, 2015 concluding that claims 1-23 of the 7,879,828 patent were not obvious and thus patentable (ie, valid). Petition filer Apotex has appealed this decision which is currently pending.

5. IPR 2014-00325: Suboxone®(buprenorphine and naloxone) Sublingual Film -- In its first invalidation of claims in an Orange Book patent, the Patent Trial and Appeal Board issued its Final Written Decision on June 30, 2015 where it concluded that prior art anticipated claims 15-19 of the 8,475,832 patent and thus were unpatentable (ie, invalid). Patent holder RB Pharmaceuticals Limited has appealed this decision which is pending.

6. IPR 2014-00360: Opana®(oxymorphone) ER Tablets -- On July 22, 2015, the Board upheld claims 1, 2, 6, 12-14, 17, 21-51, and 54-71 of the 8,329,216 patent. This IPR had been joined by a second petition over different claims in the same patent (IPR 2014-01365).

7. IPR 2014-01365 Opana®(oxymorphone) ER Tablets -- This IPR was joined to the IPR above (reference 6) with the Board upholding claims 1, 2, 6, 12-14, 17, 21-51, and 54-71 of the 8,329,216 patent on July 22, 2015.

8. IPR 2014-00377: Glumetza®(metformin) Extended-release Tablets -- Endo filed six IPR proceedings which affected this product and a few others as they shared patents. Endo did not have a PIV case pending. In this IPR, the Board issued its Decision on July 8, 2015 and found that claims 1, 8-10, 13-15, 43, 45, and 46 of the 6,635,280 patent were valid, overcoming obviousness. Endo appealed this decision (and the next two) which is pending.

9. IPR 2014-00378: Glumetza®(metformin) Extended-release Tablets -- Tried with the Board proceeding in reference (7), the Board likewise upheld claims 1, 8-10, 13-15, 61, and 62 of the 6,340,475 patent.

10. IPR 2014-00379: Glumetza®(metformin) Extended-release Tablets -- Tried with the Board proceeding in reference (7), the Board likewise upheld claims 43, 54, 55, 57, 58, and 66 of the same 6,340,475 patent.

11. IPR 2014-00652: Glumetza®(metformin) Extended-release Tablets - In addition to the patents challenged by Endo in references 8-10 Endo also filed three additional IPR petitions that the Board instituted for review. In this IPR, the Board agreed with Endo, issuing an Final Written Decision on September 16, 2015 that claims 1, 3-5, and 10-13 of the 6,723,340 patent were unpatentable on obviousness grounds.

12. IPR 2014-00654: Glumetza®(metformin) Extended-release Tablets - Endo again challenged claims of tehe 6,340,475 patent (see references 9 and 10 above). Here the Board issued its Decision on September 21, 2015, again finding that claims 1, 2, 8-15, 43, 54, 55, 57, 58, 61, 62, and 66 were valid overcoming obviousness grounds.

13. IPR 2014-00656: Glumetza®(metformin) Extended-release Tablets - Endo again challenged claims in the 6,635,280 patent (see reference 8 above), On September 21, 2015, the Board again found claims 1, 2, 8, 9, 13-15, 43, 45, and 46 patentable.

14. IPR 2014-00784: Gilenya®(fingolimod) Capsules -- This IPR holds the distinction of being filed before the first PIV-ANDA was filed. Since then, Novartis brought several PIV cases againt ANDA filers except for Torrent which filed this IPR. The IPR proceeding consolidated with one filed later with the Decision issued for both on September 24, 2015. In this IPR, the Board found claims 1-32 of the 8,324,283 to be unpatentable (ie, invalid) for obviousness.

Summary of Outcomes of Inter Partes Review Board Decisions (Continued)

15. IPR 2014-00518: Gilenya®(fingolimod) Capsules -- Apotex and Mylan filed this IPR which was consolidated to the above (reference 14). On September 24, 2015, the Board found claims 1-32 of the 8,324,283 to be unpatentable (ie, invalid) for obviousness.

16. IPR 2014-00549: Exelon®(rivastigmine) Patch Transdermal System Extended-Release -- Noven filed this IPR over the 6,316,023 patent. While this patent had been upheld in proceeding PIV cases, the Patent Trial and Appeal Board issued its Final Written Decision on September 28, 2015. Citing additional evidence and not being bound by a recent Delaware District Court decision to the contrary, the Board concluded that claims 1, 2, 4, 5, 7, and 8 were unpatentable (ie, invalid) due to obviousness. This IPR joined IPR 2015-00265.

17. IPR 2014-00550: Exelon®(rivastigmine) Patch Transdermal System Extended-Release -- Noven filed this IPR over the 6,335,031 patent. While this patent had been upheld in proceeding PIV cases including the Court of Appeals, the Patent Trial and Appeal Board issued its Final Written Decision on September 28, 2015. Noting that it had conducted an independent analysis and not being bound by a recent court decisions to the contrary and as Noven provided additional evidence, the Board concluded that claims 1-3, 7, 15, 16, and 18 were unpatentable (ie, invalid) due to obviousness. This IPR joined IPR 2015-00268.

18. IPR 2015-00265: Exelon®(rivastigmine) Patch Transdermal System Extended-Release -- Mylan filed this IPR over the 6,316,023 patent which was consolidated to IPR 2014-00549 proceeding (reference 16 above) with the conclusion that claims 1, 2, 4, 5, 7, and 8 were unpatentable.

19. IPR 2015-00268: Exelon®(rivastigmine) Patch Transdermal System Extended-Release -- Mylan filed this IPR over the 6,335,031 patent which was consolidated to IPR 2014-00550) proceeding (reference 17 above) with the concluding that claims 1-3, 7, 15, 16, and 18 were unpatentable.