Dueling Forums for Invalidating Pharmaceutical Patents

-- Has the Inter Partes Review Overtaken Hatch-Waxman Litigation? --

by Gregory Glass

Abstract: In 1984, Congress passed the Hatch-Waxman Act which created a mechanism for generic drug manufacturers to enter the market by challenging patents of branded pharmaceutical products in federal courts. In 2011, The Leahy-Smith America Invents Act was passed into Law which enabled anyone to petition the Patent Trial and Appeal Board (of the U.S. Patent and Trademark Office) to cancel one or more claims of a patent through an Inter Partes Review. 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. However, filing an Inter Partes Review has become a tactic generic drug manufacturers have employed to challenge the same patents disputed in their Hatch-Waxman cases in federal court. The Inter Partes Review has reached the six-year mark, and this paper analyzes and considers the viability of the Inter Partes Review as a strategic alternative for generic drug manufacturers.

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Background of the Hatch-Waxman Act

In 1984, the Hatch-Waxman Act was enacted which created a process for drug approvals. The Act created a method for a generic drug manufacturer to enter the market by filing an Abbreviated New Drug Application (ANDA).[1]

The ANDA process allows a generic manufacturer to reference a branded pharmaceutical product (the one it seeks to "copy") by conducting certain studies to demonstrate bioequivalence and interchangeability at the pharmacy.

As part of the ANDA process, the ANDA filer has to certify against patents the brand company has listed in the Orange Book, published by the US Food and Drug Administration.[2] The most important certification is the Paragraph IV (PIV) certification which instructs FDA to approve of the ANDA as soon as possible (that is, before the patent(s) expire) as the ANDA filer does not believe its product infringes the patent or otherwise the patent is invalid or cannot be enforced.

When an ANDA with a PIV certification is filed, the brand company may file a patent infringement action in the appropriate federal court. After the court decision, the case can be appealed to the Court of Appeals for the Federal Circuit in Washington, DC.

Background of the Inter Partes Review

In 2011, the Leahy-Smith America Invents Act[3] was enacted to thwart a perceived, growing problem. Over the past two decades, companies have been created to 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, and 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. As such, a company such as Samsung or Apple can petition the Board to cancel a patent issued to a non-practicing entity.

If the Board believes that the petition has a reasonable likelihood of canceling at least one of the patent's claims, it then "institutes" an Inter Partes Review.[4] If not, it denies the petition without further review, a non-appealable decision. If instituted, the Board conducts an administrative trial and issues a Final Written Decision either upholding the patent as valid or invalidating the claim(s) of the patent.[5] The Decision can be appealed to the same Court of Appeals for the Federal Circuit.

The Act was put into practice in September 2012 and effectively created a second forum where patents can be challenged and invalidated. Since its enactment, ANDA filers have recognized the IPR as a possible strategic alternative to bringing their products to market. At the six-year mark of IPRs, it is now an appropriate time to analyze the data and how the IPR process interacts with corresponding Hatch-Waxman litigation and to consider whether the IPR process is a viable alternative.

Advantages of the IPR Process

Since 2003, there have been over 4,000 PIV cases filed which cover over 800 branded products.[6] The reasons for the sheer number of these cases and PIV activity are numerous. However, the most important reason is that the PIV mechanism has become the primary pathway to the generic market for an ANDA filer.

In other words, instead of waiting for all Orange Book patents to expire before entering the market, the ANDA filer can reach the market sooner if the PIV litigation settles (as the brand gives up patent term in return for a known outcome) or the ANDA filer wins its PIV case (invalidating the patent for all ANDA filers or receiving a declaration of non-infringement for its own product.)

However, PIV litigation in a federal court can be a lengthy and expensive process. For example, the average PIV case takes about 31 months to resolve in a district court then an additional 13 months in the Court of Appeals. So, the typical time frame for a PIV case -- from the filing of the Complaint to the Court of Appeals decision -- is about 43 months, a few months shy of four years.

The resolution of an IPR proceeding is much quicker. By statute and regulation, the Board must decide whether to institute an IPR within 6 months after the filing of the IPR Petition.[7] The Board then has 12 months to make its decision over the instituted proceeding though the decision can be delayed for certain reasons such as

joinder of an additional party.[8] So, this timeline typically gives a petitioner in an IPR proceeding a decision about 18 months after filing the petition.

As the Court of Appeals process is the same, the IPR process is about a year shorter -- 18 months versus 31 months (often more) -- than a federal court.

Of course, with a shorter duration of proceeding, the IPR process becomes less expensive than litigating a PIV case in a federal court. Moreover, with a quicker decision and resolution to its patent challenge, the IPR process can provide certainty to the ANDA filer sooner which enables it to be more cost and time efficient in its operations as the product nears the market.

However, the quicker and less expensive resolution to its patent challenge is only one reason why the IPR process is an attractive alternative to litigating a PIV case in federal court.

Over the years, the jurisprudence of the dueling forums evolved to the setting a lower standard of proof for invalidating claims of a patent in an IPR proceeding. In the case of Novartis AG v. Noven Pharmaceuticals, the Court of Appeals considered the legal issue of differing proof standards: the federal district courts require an ANDA filer in a PIV case to establish a patent's invalidity through "clear and convincing" evidence while the Board only requires a petitioner to establish a patent's invalidity through "a preponderance" of the evidence standard.[9]

Of course, these differing standards in different forums can lead to different results which is what happened in the Novartis AG v. Noven Pharmaceuticals case. There, the IPR Board concluded that a patent covering Exelon©(rivastigmine) patch was invalid while a district court had previously concluded that the same patent was valid.

Instead of reconciling and aligning the two proof standards, the Court of Appeals decided not to, concluding that the two proof standards were acceptable. As such, proving a patent is invalid is essentially easier in an IPR proceeding than in a PIV case.

More ANDA Filers file IPR Petitions

With an option for a less expensive, quicker forum with a lower proof standard, it is not a surprise that ANDA filers began to adopt a strategy of filing IPRs while engaged in PIV litigation in federal courts.

Of course, as the IPR process was not really designed for ANDA filers, there was little IPR activity in the first year. During the first year the IPR process was in place (2013), only 10 IPRs were filed involving a patent that was involved with a PIV certification.[10]

However, over time, ANDA filers began to adopt the IPR filing as a parallel strategy of challenging patents. For example, two years later, in 2015, ANDA filers filed 130 IPR petitions (a 13-fold increase) and an additional 109 proceedings the following year in 2016.[11]

Clearly, by filing these IPR petitions, ANDA filers viewed the IPR process as an important component of their strategy to enter the market. While an attractive option, the IPR process cannot supplant the ANDA process -- under the Hatch-Waxman act, the generic company must file its ANDA, certify against (and challenge) the patent(s), and run through the court process (or settle) before obtaining approval to enter the market.[12]

In addition, the IPR process also has a few limitations and disadvantages. For example, the petition can be filed "only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications."[13] This limitation leaves out some legal arguments open to the ANDA filer in a PIV case.

Moreover, when the ANDA filer submits an IPR petition, the petition is a public record. So, the petition essentially lays out the ANDA filer's entire legal argument whereas in a PIV case, many of these documents and arguments are sealed or not printed.

Finally, the IPR filer takes the risk that the Patent Trial and Appeal Board rejects its petition outright (ie does not institute it) or rejects the ANDA filer's case after a Board trial. In either event, particularly where the ANDA filer failed to invalidate claims under a lower proof standard and though not binding on a federal court, the brand company/patent owner will take this result back to the district court where its PIV case is pending and submit it as persuasive evidence in its favor.

Analysis and Discussion

After six years of IPR filings and data, it is worth analyzing how well these IPR petitioners have fared and whether the IPR filing remains an attractive option for ANDA filers.

There are two methods to count and analyze the IPR

process. Both have merit but are slightly different. First, the petitions themselves can be counted and analyzed which would inform volume and success rate.

Second, the patents themselves can also be counted and analyzed. In some situations, several IPRs are filed over one patent and consolidated into one proceeding, and depending on result, can thus skew or weight data. Counting challenged patents and results of their associated IPRs can also be instructive and can inform strength of patents and success rate.

The Board has two decision points. At the outset, it needs to determine whether to "institute" the petition for trial which it will do if there is "a reasonable likelihood that the petitioner would prevail...."[14] If it does not institute the petition for trial, the proceeding is over (and thus validates the challenged claim(s)), and the IPR petitioner cannot appeal this decision.[15] If the instituted proceeding goes through trial, the Board will make the substantive decision over the claim(s), either validating the claims or invalidating them.

Of course, IPR proceedings can settle at anytime, leaving essentially three outcomes of the IPR proceeding: settlement, patent validated (either by not being instituted or being found valid after the Board trial), or patent invalidated (after the Board trial.)

Over the past six years, 420 IPR petitions have been filed involving a patent that has been the subject of a PIV certification.[16] Of these, the Board issued its initial decision on 348 of them (the others settled before initial Board decision or are still awaiting decision.) [17]

Of the 348 petitions, the Board denied review 114 times (or 33% of the time). As such, the IPR petition, through its initial decision, was found to not have a reasonable likelihood of success, and the Board essentially validated the patent claim(s).[18] Of those 150 IPR proceedings that completed trial with decision, the Board validated the patent 54% of the time.

To analyze the success rate of an ANDA filer which submits an IPR petition, we should consider all of the following outcomes over the past six years. For this analysis, an IPR petitioner can have success by reducing patent term by a settlement (94 of them) coupled with invalidating claims by a favorable Board trial decision (69 of them, or 163 total). However, an IPR petitioner would have an unfavorable outcome when the patent goes to full term through validation by a denial of institution (114 times) together with a Board trial decision favoring the Brand company/patent holder (81 of them, or 195 total).

Of the 358 proceedings that resolved, the ANDA filer is successful in 163 of them, or 45% of the time.[19] Compared to a PIV case, using similar criteria, **the ANDA filer fared much worse in the IPR process**. Roughly half of PIV cases settle while the ANDA filer goes onto win an additional 44% of cases tried. In other words, an ANDA filer will succeed by reducing patent term through settlement or court victory about 75% of the time.

However, we should consider the more germane metric of outcomes over individual patents. The chart below shows the patents that have been challenged through the IPR process and their outcomes.

Outcomes of Resolved IPRs by Patent
• October 1, 2012-September 30, 2018 •

Patents: 218
Settled: 77 (35%)
Validated: 114 (53%)
Invalidated: 27 (12%)

As a note, these data differ slightly than those previously discussed -- the chart above presents the number of *patents* that have resolved completely through the IPR process (including the Court of Appeals (but only reflects Board decisions)) while the previous data represent the number of *IPR proceedings* that have resolved through the IPR process before the USPTO.

Either way the data are presented or analyzed, the data reflect the USPTO Board results are reasonably the same. As the chart above suggests, the IPR petitioner succeeds in reducing patent term about 47% of the time (adding settled and invalidated at trial) while the patent is protected through patent term 53% of the time (a figure which includes proceedings not initiated and those where the Board upheld the patent after trial.) So, counting patents yields an ANDA filer success of 47% while counting petitions yields 45%.

Again comparing these data to the PIV action, ANDA filers tend to fare much worse in the IPR process. As mentioned, ANDA filers are able to reduce patent term through a PIV case about 75% of the time either through settlement or by winning in the district court.[20] Moreover, even if settlements and institution denials are removed from the analysis, and only PIV court decisions are compared with IPR Board decisions (that

is, substantive decisions on the merits), the rate of an ANDA filer invalidating a patent is 46% in both venues.[21]

Conclusion

The results of these data are a bit counter intuitive in a legal sense. With a lower standard of proof, a practicing attorney would reasonably conclude that an ANDA filer would fare far better in an IPR proceeding.

However, this seemingly logical conclusion does not hold up under data scrutiny. Moreover, ANDA filers submitting IPR petitions may have sensed this in actual practice. In 2015, the number of IPR filings involving a patent that had a PIV certification peaked at 130 petitions filed. However, over the past two years, the numbers have declined dramatically.

In 2017, the number of IPRs filed declined to 78, and in 2018, the number of IPRs declined further to 62, less than half of the peak year filings. For the first 4 months in 2019, the number of IPRs filed is only 6 petitions. In parallel, the number of PIV cases filed over the same time period remained steady.

The answer to the question in the subtitle is certainly clear. No, the Inter Partes Review process has not overtaken the PIV case. In fact, it appears that ANDA filers have considered the IPR a less valuable strategy as the experience of the IPR proceedings have not met expectations.

ENDNOTES

[1] The Hatch Waxman Act, formally known as the Drug Price Competition and Patent Term Restoration Act, is contained in 21 U.S.C. § 355 et seq. However, practitioners often refer to pertinent sections by citing the Federal Food, Drug, and Cosmetic Act § 505 et seq. Thus, for example, an Abbreviated New Drug Application is cited by practitioners as 21 U.S.C. § 355(j) as well as § 505(j) of the Federal Food, Drug, and Cosmetic Act. The general rules regarding the ANDA approval process described in this paper are contained in these sections.

[2] The Orange Book is more formally known as "Approved Drug Products with Therapeutic Equivalence Evaluations." FDA publishes this Book periodically and can be found at FDA.gov.

[3] The portion of the America Invents Act pertaining to the Inter Partes Review are contained in 35 U.S.C. § 311 et seq. The general rules regarding the IPR process described in this paper are contained in these sections.

[4] The provision allowing for an institution of an Inter Partes Review (if the petitioner has a reasonable likelihood of prevailing on at least one of the claims) is described in 35 U.S.C. § 314(a). However, the U.S. Supreme Court has recently interpreted this provision coupled with the Board's issuance of its Final Written Decision (§ 318). In SAS Institute Inc. v Iancu, 584 U.S.___(2018), Case #16-969, the U.S. Supreme Court concluded that the Board must consider and render a decision on all of the patent claims the petitioner challenges.

[5] Technically, the Patent Trial and Appeal Board will render claims of a patent "unpatentable" rather than "invalid." However, for the purposes of this paper, the terms are used interchangeably.

[6] All data cited in this paper regarding Paragraph IV cases, filings, outcomes, duration of court proceedings, statistics, etc, as well as commentary about the Paragraph IV Market, are sourced from the author's original research started in 2003 and contained in ParagraphFour.com.

[7] See, 35 U.S.C. § 314(b) and 37 C.F.R. § 42.107.

[8] 35 U.S.C. § 316(a)(11).

[9] Novartis AG v. Noven Pharmaceuticals, Court of Appeals for the Federal Circuit, Case #16-1678. In the Novartis v. Noven case, the Patent Trial and Appeal Board (in IPR #14-00549) found claims in a Novartis unpatentable (or invalid) even though a prior district court (actually two) had considered the same legal argument and found the same claims valid. Although the Court of Appeals cited additional evidence in the IPR proceeding, it nonetheless accepted that a district court and the Patent Trial and Appeal Board may reach different results. The Court of Appeals cited a previous U.S. Supreme Court case of Cuozzo Speed Technologies LLC v. Lee, 579 U.S. ____ (2016), Case # 15-446 which also considered an IPR proceeding and noted that the IPR Board uses a "preponderance of the evidence" standard per the code (35 U.S.C. § 316(e)) while a district court in a patent infringement case uses "clear and convincing evidence" to invalidate patent claims (Slip, page 7).

[10] In addition to collecting and analyzing Paragraph IV data per endnote 6, the author also collects data

regarding the universe of petitions for Inter Partes Review connected with Paragraph IV cases and Orange Book patents. As such, all data cited regarding the number of IPRs filed, outcomes, statistics, etc, as well as commentary about IPR filing dynamics, are sourced from the author's original research and contained in ParagraphFour.com.

[11] Note also that the United States Patent & Trademark Office uses the following nomenclature for numbering IPR petitions. The official numbered year of petitions begins on October 1 and ends on September 30. For example, it numbers as year 2013 the petitions filed between October 1, 2012 - September 30, 2013 as in petition "2013-00072." For the purposes of this paper, the author has adopted the same annual structure for data presentation and analysis. So, for example, petitions filed in 2015 are those filed in the twelve months between October 1, 2014 - September 30, 2015 and begin with the year 2015 as its petition number. As such, there have been 6 years (or 6 twelve-month cycles) between the start of the IPR filings on October 1, 2012 and September 30, 2018.

[12] Technically speaking, under the Hatch-Waxman Act, the ANDA filer may not have to "run through the court process" as stated. After filing its ANDA with a PIV certification, the ANDA filer notifies the brand company (and/or patent owner) of its application. While there are certain benefits for the brand company to file a patent infringement action over the PIV filing, it is not required to. Sometimes, about 10-15% of the time by the author's estimate, no case is filed at all so the ANDA filer never goes through the court process. Nonetheless, it must still file its ANDA to gain approval and market access.

[13] 35 U.S.C. § 311(b).

[14] 35 U.S.C. § 314(a).

[15] 35 U.S.C. § 314(d).

[16] ANDA filers involved in a PIV patent infringement case pending in a federal court file nearly all of the IPR petitions over patents that have received a PIV certification. However, there are occasions where non-ANDA filers (or ANDA filers not sued in a PIV case) file petitions. The most noteworthy of these would be hedge funds seeking to invalidate a patent and benefit by shorting the patent holder's stock. While these particular IPRs account for fewer than a dozen filings, all of the IPR filings associated with a patent that has received a Paragraph IV certification are included in the data presented in this paper.

[17] As mentioned in endnote 11, all data are taken through September 30, 2018 so 72 IPRs were awaiting the initial Board decision as of that date or settled before the initial Board decision.

[18] A Board decision not to institute an IPR proceeding is not the end for an ANDA filer. Theoretically, it can proceed through its PIV case. However, if the Board has determined its argument does not have a reasonable likelihood of success -- using a lower proof standard than the PIV case -- a federal district court will likely consider this persuasive and rule in a similar fashion by upholding the patent claims. So, while not technically the end, an adverse ruling in the IPR process is realistically the end of the ANDA filer's attempt to invalidate the patent.

[19] For those readers who like to triangulate data, this is another presentation. Of the 420 IPR proceedings filed, 20 of them were still pending initial review as of the end date September 30, 2018, leaving 400. Of those 400 petitions, 42 petitions were initiated for trial but were also pending as of September 30, 2018 leaving 358 proceedings that were either settled (94), not initiated (114), or completed trial before the Board (150).

[20] As for comparisons, the PIV data presented are outcomes from the lead PIV case resulting in a settlement or unique court decisions. In many situations, there are several PIV cases filed over one product and a certain patent(s) which are consolidated into one case (yielding one settlement or one court decision), similar to multiple IPR proceedings filed over one patent. So, the PIV case outcomes data presented are comparable to the patents outcome data through the IPR process.

[21] For the six-year time period, as presented in the paper, the Board rendered decisions in 150 petitions, finding the patent valid 81 times (54%) and invalid 69 times (46%). In PIV cases filed since 2003 through September 1, 2018, 279 lead cases have received a ruling on the merits (by trial or summary judgment). Of these, the district court upheld the patent(s) 156 times (56%) and invalidated the patent(s) 123 times (46%).