

## Intellectual Property - USA

### Property rights: a brave new world for patent owners

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#### Introduction

America Invents Act post-grant reviews at the US Patent and Trademark Office (USPTO) have garnered attention, if only because of a seemingly high number of patent claims being cancelled as a result. The first petition for *inter partes* review was filed on September 16 2012. As of May 22 2014, a total of 1,209 petitions for *inter partes* review have been filed, with 501 reviews instituted to date.<sup>(1)</sup> Parties in 141 of these reviews have since settled. Of the remainder, the USPTO has issued a final written decision on the merits of 71 claims, of which 61 were found unpatentable and cancelled.<sup>(2)</sup> So far, only one motion to amend claims in an *inter partes* review proceeding has been granted.<sup>(3)</sup>

As a result, America Invents Act post-grant reviews are an increasingly popular venue for parties to attempt to invalidate patents. This update looks at three reasons why *inter partes* reviews may represent a paradigm shift in the IP rights fight:

- The statutorily mandated short *inter partes* review timeframe may result in more frequent stays of litigation, thus effectively transferring validity defence adjudications from district courts to the USPTO.
- Challengers have a lower burden of proof to meet in cancelling patent claims in the USPTO when compared with proving invalidity during patent infringement litigation in federal courts (although unsuccessful challengers are estopped from raising the same arguments that were raised or "could have been raised" during the *inter partes* review).
- In regard to specific lawsuits, subsequent determinations of invalidity by the USPTO can trump prior Article III determinations of validity and liability, provided that any issue – even if unrelated to either validity of infringement – of the case is on appeal. However, a favourable outcome for the patent owner may hinder validity challenges in subsequent (or co-pending) litigation.

#### Litigation stays

In 2011, the America Invents Act created *inter partes* review to replace the older *inter partes* reexamination.<sup>(4)</sup> One major difference between the two is the relatively short timeframe mandated by statute. Under the America Invents Act, the patent owner has up to three months to oppose a petition for review<sup>(5)</sup> and the USPTO then has up to three months to grant or deny the petition.<sup>(6)</sup> The USPTO must then issue a final decision within one year (with an extension of six months if good cause is shown) of its decision to institute the *inter partes* review.<sup>(7)</sup> Thus, unlike the older *inter partes* reexamination, which could take as long as 80 months from filing to receiving notice of intent to issue the reexamination certificate,<sup>(8)</sup> the America Invents Act statutorily mandates up to an approximately two-year timeline from the first filing of a petition for review to the issuance of a final written decision on the merits for an *inter partes* review.

Upon filing of a petition for *inter partes* review at the USPTO, a motion to stay a parallel litigation may be filed. Federal courts apply a three-factor test to determine whether to grant a stay of litigation pending *inter partes* review:

- whether a stay would simplify issues being litigated;
- whether a stay would cause undue prejudice or provide a clear tactical disadvantage to the non-moving party; and
- the stage of litigation.

While all courts use the three-factor test, courts naturally differ as to how much weight is given to each factor.

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Between September 16 2012 and April 30 2014 a total of 241 motions to stay were filed in district courts pending *inter partes* review in the USPTO.<sup>(9)</sup> Of the 241 motions filed, 151 were filed by one party, of which 147 (97%) were filed by defendants.<sup>(10)</sup> To date, district courts have ruled on 123 motions, with 28 outstanding.<sup>(11)</sup> Of the 123 motions, the district courts:

- granted or recommended granting 68 motions (55.2%);
- denied or recommended denying 39 motions (31.2%); and
- denied in part or granted in part 16 motions (13%).<sup>(12)</sup>

From these statistics, it can be seen that there is a real possibility of staying a patent litigation using the *inter partes* review route, assuming, among other factors, a significant overlap of underlying issues between the litigation and *inter partes* review, and shifting a key aspect of the dispute to an administrative agency, the USPTO.

### Two venues of challenging patents: two standards of proving invalidity

Patent challengers have always had two venues for challenging the validity of patents asserted against them: claims could be challenged at the USPTO or as a defence against infringement in Article III courts. While the statutory grounds for challenging validity are the same in both venues, the burden of proof faced by the challenger is different. This difference is apparent from a series of disputes between Baxter International, Inc and Fresenius USA, Inc in the Board of Patent Appeals at the USPTO, the Northern District of California and the Federal Circuit.

In 2003, Fresenius filed for declaratory judgment against Baxter in the Northern District of California, seeking a declaration that claims of Baxter's patent, US Patent No 5,247,434 ('434 patent'), were invalid.<sup>(13)</sup> After trial, the jury found by clear and convincing evidence that Claims 26 to 31 were invalid under Section 103 of Title 35 of the US Code. Post-trial, Baxter succeeded on its motion for judgment as a matter of law that the claims were not obvious. Fresenius appealed to the Federal Circuit. In the Federal Circuit's first encounter with the '434 patent, the appellate court affirmed the district court's grant of judgment as a matter of law, concluding that "Fresenius failed to present any evidence – let alone substantial evidence – that... Fresenius's proffered prior art" rendered the patent claims obvious.<sup>(14)</sup>

Parallel to its declaratory judgment action in the Northern District of California, Fresenius filed for *ex parte* patent reexamination in the USPTO. In contrast with the district court (the Federal Circuit appeal was then pending), the examiner found that the same references Fresenius provided at trial, either alone or read in combination, rendered the same challenged Claims 26 to 31 obvious.<sup>(15)</sup> Baxter appealed to the board and, while that appeal was pending, the Federal Circuit affirmed the district court's judgment, finding that Fresenius had failed to establish patent invalidity. The board, meanwhile, presented with the same references, arguments and claims, reached the opposite outcome, affirming the examiner's finding that the challenged claims were invalid in light of the references.<sup>(16)</sup>

Confronted with the opposite determination from the Federal Circuit, the board explained that "although claims 26-31 were not proven invalid in court, a lower standard of proof [...applies] at the USPTO and therefore the agency is not bound by the court's determination".<sup>(17)</sup> Specifically, the board noted that in district court litigation, issued patents are given a presumption of validity, and challengers have a statutory burden to prove invalidity by clear and convincing evidence. In contrast, the board explained that there is no presumption of validity at the USPTO for issued patents; the fact that challengers need only prove invalidity by preponderance of evidence and that the USPTO allows the "broadest reasonable interpretation" in claim construction both contribute to a lower standard of proof for challengers to meet at the USPTO.<sup>(18)</sup>

Baxter appealed the board's rejection to the Federal Circuit. In the second encounter with the '434 patent, the Federal Circuit panel, in a split decision, affirmed the board's decision that the challenged claims were obvious in light of the references presented.<sup>(19)</sup> Importantly, the Federal Circuit apparently agreed with the board's conclusion that due to a lower standard of proof, reexaminations at the USPTO are not bound by prior district court rulings on invalidity, and that "fundamentally, the USPTO in reexamination proceedings and the court system in patent infringement actions take different approaches in determining validity and on the same evidence could quite correctly come to different conclusions".<sup>(20)</sup> However, the court did note that:

*"when a party who has lost in a court proceeding challenging a patent, from which no additional appeal is possible, provokes a reexamination in the USPTO, using the same presentations and arguments, even with a more lenient standard of proof, the USPTO ideally should not arrive at a different conclusion."*<sup>(21)</sup>

Yet this observation, even if it were intended to have legal effect, did not carry the day under the facts at hand.

Regardless of the lower standard of proof at the USPTO, after the USPTO renders a final decision in an *inter partes* review, unsuccessful patent challengers are estopped in subsequent USPTO proceedings and subsequent district court or International Trade Commission actions from challenging the reviewed claims on any ground that was raised or "reasonably could have been" raised during the *inter partes* review.<sup>(22)</sup> This is a change from *ex parte* reexamination, which did not create legal estoppel.

Furthermore, aside from estoppel, favourable outcomes for the patentee during *inter partes* review have the potential to hinder invalidity challenges in pending district court litigations. In *Procter & Gamble Co v Team Techs, Inc* the Southern District of Ohio found no invalidity on summary judgment, citing in part the defendant's failure to meet the USPTO's lower standard of proving invalidity during *inter partes* review.<sup>(23)</sup> In determining that the patent was valid, the court pointed out that "PTAB rejected [defendant's invalidity arguments], under a lower standard of proof, not once, but twice".<sup>(24)</sup>

## Finality

The Federal Circuit denied Baxter's petition for rehearing *en banc* while affirming that the cancellation of claims by the USPTO was binding in the pending district court infringement litigation.<sup>(25)</sup> The Federal Circuit held that the cancellation of claims by the USPTO may reverse previous determinations of validity (as well as infringement) so long as any aspect of a case remains subject to appeal – even an appeal in which liability and validity is already settled.<sup>(26)</sup>

The *Baxter-Fresenius* disputes leave patentees and challengers in an interesting situation:

- A challenger which failed at the district court may nonetheless prevail in a subsequent reexamination using the same arguments. In other words, while determinations of Article III courts have full collateral estoppel effect in subsequent litigations, they are not necessarily binding on subsequent administrative agency decisions.<sup>(27)</sup>
- On the other hand, cancellation of claims by the USPTO is binding in pending district court litigation.<sup>(28)</sup>

From *In re Baxter International* (678 F 3d 1357 (Fed Cir 2012)) and *Fresenius USA Inc v Baxter International, Inc* (721 F 3d 1339 (Fed Cir 2013)), the Federal Circuit has effectively decided that while an Article III court's ruling on patent validity is sufficiently final to have collateral estoppel effect on subsequent litigation brought in an Article III court, the Article III court finding that challengers failed to prove invalidity of patents is not binding in subsequent proceedings in the USPTO.

In the majority opinion affirming the board rejection of the claims, Judge O'Malley noted that the procedural posture in which the *Baxter* opinions leave patent owners and challengers is "an unremarkable one".<sup>(29)</sup> The decision affirms the *res judicata* principle, saying that "if a federal court awards relief to a patent holder against an infringer, a subsequent reexamination decision that the patent is invalid does not disturb the judgment of the court or alter its binding effect on the parties".<sup>(30)</sup> However, the majority found the case not final because, although issues of validity, infringement and past damages were established, the issue of post-verdict relief was still on appeal.<sup>(31)</sup>

The majority's view of finality is not without controversy. In both the Federal Circuit's ruling that the cancellation of claims by the USPTO was binding in the pending district court litigation and its denial of rehearing *en banc*, Judge Newman, in dissent, criticised the majority's rulings permitting an administrative agency to reverse a prior Article III court determination.<sup>(32)</sup> The judge found unpersuasive the majority's view of finality, noting that the decision "destabilizes issued patents, by ignoring the rules of finality".<sup>(33)</sup>

Baxter International then petitioned for certiorari to the Supreme Court, arguing that the Federal Circuit's view of finality of judicial decisions contravened the case law from other circuits. Baxter asked the Supreme Court to decide two issues:

- whether an Article III court's final judgment may be reversed based on the decision of an administrative agency; and
- whether a final determination of liability that has been affirmed on appeal may be reversed based on the decision of an administrative agency, even if an appeal regarding the post-verdict remedy is pending.

The Supreme Court denied certiorari on May 19 2014, leaving the Federal Circuit's controversial view of finality, as well as the implications that the *Baxter* decisions have on the interaction of Article III courts and administrative agencies, and thus the broader issues of constitutional separation of powers, for another day.

## Comment

Given the real possibility of staying litigation, the lower burden of proof at the USPTO for proving invalidity and cancelling patent claims asserted, coupled with the new legal estoppel of final determinations in subsequent civil action and the Federal Circuit's decision allowing reversal of prior Article III determinations of validity and thus liability, provided that any issue of the case is on appeal, the new *inter partes* review proceedings ensure an increasingly significant role for the USPTO in asserting patents and add a complex dimension to the fight over patent rights.

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## Endnotes

- (1) See [www.uspto.gov/ip/boards/bpai/stats/aia\\_statistics\\_05\\_22\\_2014.pdf](http://www.uspto.gov/ip/boards/bpai/stats/aia_statistics_05_22_2014.pdf).
- (2) Data obtained from the searchable database DocketNavigator on May 25 2014.
- (3) *International Flavors & Fragrances, Inc v United States*, IPR2013-00124 (PTAB May 2014).
- (4) Leahy-Smith America Invents Act, Pub L No 112029, 125 Stat 284 (2011).
- (5) 35 USC § 313, 37 CFR § 42.107.
- (6) 35 USC § 314.
- (7) 35 USC § 316.
- (8) USPTO statistics, accessed on June 30 2014, [www.uspto.gov/dashboards/patents/main.dashxml](http://www.uspto.gov/dashboards/patents/main.dashxml).
- (9) Data obtained from the searchable database DocketNavigator on May 14 2014.
- (10) *Id.*
- (11) *Id.*
- (12) *Id.*
- (13) *Fresenius Medical Care Holdings, Inc v Baxter Int'l Inc*, No C 03-1431 SBA, 2007 WL 518804 (ND Ca).
- (14) *Fresenius USA, Inc v Baxter International*, 582 F 3d 1288 (Fed Cir 2009).
- (15) *Ex Parte Baxter Int'l, Inc*, Appeal 2009-006493, 2010 WL 1048980 (Board of Patent Appeals and Interferences, 2010).
- (16) *Id* at \*12.
- (17) *Id.*
- (18) *Id.*
- (19) *In re Baxter*, 678 F 3d 1357 (Fed Cir 2012).
- (20) *Id* at \*1377 citing *In re Swanson*, 540 F 3d 1368 (Fed Cir 2008).
- (21) *Id.*
- (22) 35 USC § 315(e).
- (23) *The Procter & Gamble Co v Team Techs., Inc*, No 1:12-cv-552 (SD Ohio July 3 2014).
- (24) *Id* at 24.
- (25) *Fresenius USA, Inc v Baxter International, Inc*, 721 F 3d 1330 (Fed Cir July 2 2013), rehearing *en banc* denied, *Fresenius USA, Inc v Baxter International, Inc*, 733 F 3d 1369 (Fed Cir November 5 2013).
- (26) *Fresenius USA, Inc v Baxter International, Inc*, 733 F 3d 1369 (Fed Cir November 5 2013).
- (27) *In re Baxter*, 678 F 3d 1357.
- (28) *Fresenius USA, Inc v Baxter International, Inc*, 721 F 3d 1330.
- (29) *Fresenius USA, Inc v Baxter International, Inc*, 733 F 3d 1369.
- (30) *Id.*
- (31) *Id.*
- (32) *Fresenius USA, Inc v Baxter International, Inc*, 721 F 3d 1330, *Fresenius USA, Inc v Baxter International, Inc*, 733 F 3d 1369.
- (33) *Fresenius USA, Inc v Baxter International, Inc*, 733 F 3d 1369, 1382.

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