Timing is everything

THE CASE:
Fresenius USA, Inc v Baxter International, Inc
US Court of Appeals for the Federal Circuit
2 July 2013

Bryan J Vogel and **Matthew B McFarlane** explore patent litigation after *Baxter II* and the race to 'final judgment' under AIA-rules

Just last year, the Federal Circuit endorsed the potential for different outcomes in the United States Patent and Trademark Office ("USPTO") and in district court patent litigation.[1] Short on the heels of that decision, the Federal Circuit has now concluded that, in certain circumstances, a later outcome obtained at the USPTO can override and void a district court's adjudication of a lawsuit. In *Fresenius USA, Inc v Baxter International, Inc*,[2] a spilt panel of the Federal Circuit highlights how significantly a patent holder's fortune might change depending on the timing and nature of a decision from a district court or the USPTO or, as in the case of patent-holder Baxter, both forums.

In proceedings in federal court, a patent challenger bears the burden of proving invalidity by clear and convincing evidence. By contrast, before the USPTO in reexamination proceedings, there is no presumption of validity, and invalidity need only be shown by a preponderance of the evidence. What, then, is the result if a federal court and the USPTO are both asked to address the validity of patent claims and the USPTO finds the claims invalid before "final judgment" is entered by the federal court? *Baxter II* illustrates exactly what might happen and offers a forecast of what life might be like under the new USPTO proceedings introduced by the America Invents Act ("AIA").

The *Baxter II* case

Over a decade ago, Fresenius sought declaratory judgment of non-infringement and invalidity of five patents held by Baxter, including US Patent No. 5,247,434 (the "'434 patent"), covering hemodialysis machine components and their methods of use.[3] In 2006, Fresenius stipulated that its hemodialysis machine infringed claims of the '434 patent, but at trial, the jury found those claims obvious in light of the prior art. After trial, the district court granted Baxter's motion for judgment as a matter of law that Fresenius failed to prove the claims were obvious by clear and convincing evidence.

Meanwhile, the Patent Office conducted an *ex parte* reexamination of the '434 patent. Just after the jury's verdict in 2007, the Examiner finally determined the '434 patent claims to be obvious in light of the prior art.

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In 2009, the Federal Circuit affirmed the district court's conclusion that Fresenius presented insufficient evidence to invalidate the '434 patent claims, and remanded the case to the district court to consider Baxter's entitlement to a permanent injunction and post-verdict royalties to remedy Fresenius' infringement.[4] Judges Newman and Dyk concurred, but specifically disagreed as to whether the district court should consider a stay of further proceedings on remand pending the outcome of reexamination in the USPTO.[5]

In 2010, the Board of Patent Appeals and Interferences affirmed the examiner's determination, cancelling claims of the '434 patent.[6] Baxter appealed this decision to the Federal Circuit, which affirmed the Board's conclusion in a 2012 opinion.[7] On its face, this decision contradicted its earlier conclusion in 2009 that the '434 claims were not invalid. But the Federal Circuit noted that, because of different analyses, different factual records, and different standards of proof, the USPTO and district courts could reach a different conclusion as to validity.[8] Yet the Federal Circuit was sensitive to the possibility that a losing party might get a "second bite at the apple" in the USPTO and benefit from a lower burden of proof on reexamination:

> 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 PTO, using the same presentations and arguments, even with a more lenient standard of proof, the PTO ideally should not arrive at a different conclusion.[9]

On remand in 2012, the district court awarded damages and entered final judgment. As a result of the two parallel proceedings, Baxter *won* a judgment in the district court but *lost* the patent claims in the USPTO.

Appealing the district court's damage award, Fresenius asked the Federal Circuit to find that Baxter no longer had a cause of action for infringement because the patent claims were cancelled in reexamination.[10] Baxter responded that the USPTO's conclusion had no bearing on a prior decision of the district court that "conclusively" determined liability for infringement.[11]

The Federal Circuit agreed with Fresenius. Holding that cancelled claims could not sustain a viable cause of action, the Federal Circuit vacated the district court's judgment and remanded the case with instructions to dismiss.[12]

To understand the effect of reexamination, the Federal Circuit reviewed the reexamination

statutes and corresponding legislative history, and concluded that Congress intended for cancellation or amendment of claims to cure invalidity could extinguish a patentee's pending lawsuit in the district court.[13]

Importantly, the Federal Circuit concluded that the district court's judgment finding of infringement and no invalidity was not sufficiently "final" to preclude further activity of the USPTO regarding reexamination. The Federal Circuit reasoned that a judgment could not be final unless a matter was "finally concluded" in that no issue of law or fact remains to be determined.[15] Because issues relating to damages were still pending before the district court at the time the USPTO cancelled the claims, the decision was not "final," and cancellation retroactively applied to terminate the pending lawsuit in the district court.[16]

Judge Pauline Newman offered an extensive dissent that considered whether the Federal Circuit's decision offended the Constitution by elevating the decision of the USPTO, an agency of the executive branch, over the judgment of a district court.[17] While acknowledging that reexamination could affect a pending infringement suit, Judge Newman expressed concern that the majority's decision interfered with the finality of judgments and unfairly invited the relitigation of matters that have been fully litigated in another forum.[18] Whether the Federal Circuit's opinion offends the separation of powers, as Judge Newman suggests it does, is a question that an *en banc* Federal Circuit will likely be asked to review, and may ultimately be heard by the Supreme Court.

Baxter II's forecast

Baxter II's conclusion that a USPTO reexamination may override a previous, but not final, district court decision comes at an interesting time in patent litigation. The USPTO reached its determination of invalidity after reexamination. Before the AIA, the USPTO had procedures for *ex parte* reexamination (EPRex) and *inter partes* reexamination (IPRex).[19]

After the AIA, EPRex remains an anonymous and relatively inexpensive tool for a patent challenger to seek to invalidate issued claims. But the AIA supplanted *inter partes* reexamination (IPRex) with *inter partes* review (IPR) and post-grant review (PGR). Like IPRex, IPR and PGR provide no presumption of validity and uses a preponderance of the evidence standard with the broadest claim construction possible. But, unlike IPRex, IPR and PGR provide for fast-paced trial-like adversarial proceedings, making stays of concomitant district court proceedings more likely. IPR and PGR also have estoppel and preclusive effects that impact later district court challenges to patent validity.

Through the AIA, Congress clearly intended to strengthen procedures in the USPTO for reevaluating patents after issuance. *Baxter II* reveals the tension inherent in different decisions in two different forums, potentially resulting in different outcomes for a patentee's right to exclude use of their invention – and potential retroactive effect.

Notwithstanding Congress' clear intent to offer a quasi-judicial mechanism for the disposition of disputed patents in the USPTO according to the AIA, the separation of powers doctrine delineates the authority any one branch of the federal government may exercise. In other words, Congress may have intended for the Executive Branch, through the USPTO in the Department of Commerce, to have certain adjudicatory power over issued patents. But that grant may not usurp the power of the Judicial Branch to render judgments between litigating parties – vested in the federal courts in Article III of the Constitution – a power that extends "to all cases, in law and equity, arising under ... the laws of the United States".[20] Under its authority to "promote the progress of science and useful arts",[21] Congress established the patent laws and granted the federal courts exclusive jurisdiction over judgments deciding patent infringement cases.[22]

An issued patent is presumed valid,[23] and only valid patent claims can be infringed.[24] A common defense to patent infringement is that an asserted claim is invalid for failing to satisfy one or more of the requirements of patentability.[25] Yet the patent laws allow parties to challenge a patent's validity through EPRex, IPR and PGR.[26] If any of those procedures reveals a claim to be invalid in light of the prior art, the USPTO cancels challenged claims and deprives the patentee of the right to exclude others from practicing the invention covered by those claims.

EPRex and IPR have proven to be popular

weapons in an accused infringer's arsenal for several reasons. Most importantly, these USPTO procedures carry a lower evidentiary standard than proving prior art invalidity[27] by clear and convincing evidence in a district court litigation.[28] During EPRex and IPR, the patent examiner applies the broadest reasonable interpretation of the claims, potentially increasing the pool of relevant prior art beyond that available after a *Markman* hearing in the district court.[29] Finally, a district court may stay a pending litigation until resolution of proceedings in the USPTO, but is not required to do so.[30]

Baxter II illustrates that parallel proceedings raise the possibility of inconsistent outcomes and create a race to judgment that, in a second forum, may destroy patent rights confirmed in a first forum. Parties to patent infringement lawsuits should understand the potential impact of this decision, if upheld:

- In general, according to the majority in *Baxter II*, the first 'final judgment' will prevail. According to the majority in *Baxter II*, a 'final judgment' means a final non-appealable decision in the federal courts or a non-appealable termination of proceedings in the USPTO.
- According to the majority in *Baxter II*, if the USPTO cancels patent claims, a pending *non-final* litigation ends because the patentee no longer has a patent right. As a result, prior decisions of the district court in that litigation are moot.
- USPTO proceedings provide a parallel and independent pathway to invalidate patent claims, and offer mechanisms that can be pursued at the same time as a patent litigation in the district court.
- EPRex, IPR and PGR may be particularly valuable to an accused infringer, because the USPTO uses the broadest reasonable interpretation of the claims and applies a lower standard of review than a district court.
- Under the majority's view in *Baxter II*, EPRex and IPR may offer a potential 'second bite at the invalidity apple', because a later decision from the USPTO cancelling claims may trump a district court decision to the contrary, as long as the district court's judgment is not 'final'.

It is hard to imagine the circumstances under which an accused infringer would turn down a second chance to avoid liability for infringement. That appears to be exactly what concurrent proceedings in the USPTO appear to offer. *Baxter II* confirms that a USPTO 'final' decision has the power to not only cancel patent claims but also annul prior judgments based on those patent claims. By clearing a potential second path for patent invalidity, the Federal Circuit may have indeed increased the litigation burden on parties to a patent infringement dispute.[31]

Conclusion

Only time will tell whether *Baxter II*'s majority interpretation of 'final judgment' will hold up on appeal. In the meantime, *Baxter II*'s majority tells parties that validity determinations of the USPTO may provide a way for accused infringers to override an existing district court decision. By actually concluding that the USPTO's decision reaching a different validity decision can override the decision made by the court itself, *Baxter II* perhaps (further) established the USPTO as the forum of choice for patent challengers and district court proceedings as the patentees' better, more advantageous choice. If determined to be constitutional, the shared responsibility of the USPTO and the district courts to resolve patent disputes will force practitioners and their clients into a race to pursue (or avoid) 'final judgment' in either forum to fully comprehend their rights and obligations respecting an asserted patent.

Footnotes

1. *In re Baxter Int'l, Inc*, 678 F.3d 1357 (Fed. Cir. 2012) ("*Baxter I*").
2. Nos. 2012-1334, 2012-1335, 2013 US App. LEXIS 13484 (Fed. Cir. Jul. 2, 2013) ("*Baxter II*").
3. *Fresenius Med Care Holdings, Inc v Baxter Int'l, Inc*, No. 03-cv-1431, 2007 US Dist. LEXIS 14528, at *6 (N.D. Cal. Feb. 13, 2007).
4. *Fresenius USA, Inc v Baxter Int'l, Inc*, 582 F.3d 1288, 1304 (Fed. Cir. 2009) ("Fresenius"). However, the Federal Circuit reversed the district court's grant of judgment as a matter of law as to the two other patents-in-suit. Issues on remand were limited to the district court's revising or reconsideration of the permanent injunction and royalty award given that only the '434 patent was valid and infringed. Id. at 1303, 1304.
5. *Fresenius,* 582 F.3d at 1304-05 (stating that a reexamination decision from the Patent Office would have no effect on the judicial decision reached after trial and appeal); id. at 1305 (observing the likelihood that the Patent Office would find the '434 patent claims obvious even though Fresenius presented insufficient evidence of invalidity at trial).
6. 2010 Pat. App. LEXIS 14245 (BPAI Mar 18, 2010).
7. *Baxter I*, 678 F.3d at 1358.
8. *Baxter I*, 678 F.3d at 1364 (noting that this case "illustrates the distinction between a reexamination and a district court proceeding").
9. *Baxter I*, 678 F.3d at 1365.
10. *Baxter II,* 2013 US App LEXIS 13484, at *2.
11. *Baxter II*, 2013 US App LEXIS 13484 at *26.
12. *Baxter II,* 2013 US App LEXIS 13484 at *46.
13. *Baxter II*, 2013 US App LEXIS 13484 at *23-*25.
14. *Baxter II*, 2013 US App LEXIS 13484 at *28.
15. *Baxter II,* 2013 US App LEXIS 13484 at *29 (stating that finality required that "the litigation must be entirely concluded so that [the] cause of action [against the infringer] was merged into a final judgment ... one that ends the litigation on the merits and leaves nothing for the court to do but execute the judgment") (quotations and citations omitted).
16. *Baxter II,* 2013 US App LEXIS 13484 at *43.
17. *Baxter II,* 2013 US App LEXIS 13484 at *46 (Newman, J, dissenting).
18. *Baxter II,* 2013 US App LEXIS 13484 at *82-*83 (Newman, J, dissenting).
19. The main difference between the two pre-AIA reexamination mechanisms, EPRex and IPRex, is the ability of a challenger to actively participate in the proceedings. Under EPRex, a challenger or the patent owner could only instigate reexamination by raising a substantial new question of patentability as to one or more claims in an issued patent. Once the USPTO granted reexamination, however, that challenger would not be involved in the proceedings. Under IPRex, a third party challenger retained the right to participate before the USPTO, but would be estopped from later asserting that the patent is invalid on grounds that could have been raised during reexamination.
20. US Const. art. III, § 2.
21. US Const. art. I, § 8, cl. 8.
22. 28 USC § 1338; 35 USC § 281 ("A patentee shall have remedy by civil action for infringement of patent.").
23. 35 USC § 282(a).
24. *Pandrol USA, LP v Airboss Ry Prods,* 320 F.3d 1354, 1365 (Fed. Cir. 2003).
25. 35 USC § 282(b).
26. 35 USC §§ 301-307.
27. 35 USC §§ 102, 103.
28. *Microsoft Corp v i4i Ltd P'ship,* 131 S. Ct. 2238, 2242 (2011).
29. *In re Morris*, 127 F.3d 1048, 1054-55 (Fed. Cir. 1997).
30. *Slip Track Systems, Inc v Metal Lite, Inc,* 159 F.3d 1337, 1341 (Fed. Cir. 1998).
31. See *Baxter II,* 2013 US App. LEXIS 13484 at *52 (Newman, J, dissenting).

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