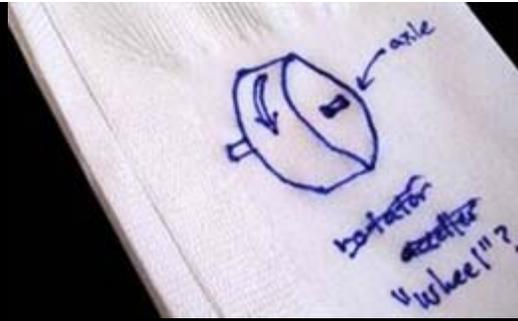


TC's inside IP



Final Really Does Mean Final in the Federal Circuit

By Michael L. Nepple

Defendants in patent infringement lawsuits often request that the United States Patent and Trademark Office ("PTO") reexamine the patent-in-suit. Patent reexamination is a process where the validity of an issued patent is again reviewed by the PTO. Patent infringement litigation, of course, takes place in federal district courts. Often, a patent infringement action brought by the patentee in federal district court and a reexamination proceeding initiated by the accused infringer in the PTO proceed at the same time. In *Fresenius USA v. Baxter International*¹, the Federal Circuit ruled that where a reexamination and a patent infringement lawsuit involving the same patent are concurrently proceeding, the first action to reach true finality may render the other moot². In the litigation, the Federal Circuit had earlier affirmed the trial court's judgment that the patent was infringed and not invalid, but remanded the case back to the trial court to determine damages and entitlement to injunctive relief. Before the issues of damages and entitlement to injunctive relief were finally resolved, the PTO determined in the reexamination proceeding that the patent is invalid and the PTO determination was affirmed by the Federal Circuit. In a subsequent appeal, the Federal Circuit ruled that the reexamination trumped the litigation because the reexamination was finalized before the litigation was finalized.

Two Forums, Three Appeals, and a Complicated Procedural Background

In 2003, Fresenius filed a declaratory judgment action in federal court, seeking a judicial determination that, among other things, certain claims of the Baxter patent were invalid³. In 2006, a jury found the claims of the Baxter patent invalid⁴. However, the district court granted Baxter's post-trial motion for a judgment as a matter of law, finding that Fresenius had not presented sufficient evidence to support a jury verdict of patent invalidity⁵. The district court entered judgment in favor of Baxter. On Fresenius' appeal to the Federal Circuit in 2009, the Federal Circuit affirmed the district court's decision and remanded the case back to the district court to determine the proper amount of damages and whether to enter an injunction against Fresenius (hereinafter *Fresenius I*)⁶. In response to the Federal Circuit's remand, the district court entered a second judgment in favor of Baxter in March of 2012⁷, and Fresenius again appealed to the Federal Circuit (hereinafter *Fresenius II*)⁸.

While the federal court litigation was proceeding, Fresenius was also pursuing a reexamination of the patent in the PTO. In 2005, two years after Fresenius filed its declaratory judgment action in

federal court, Fresenius filed for ex parte reexamination of the Baxter patent⁹. In 2007, a PTO patent examiner issued a final rejection, finding that the claims at issue in the Baxter patent were invalid as obvious¹⁰. The examiner's decision was affirmed by the PTO's Board of Patent Appeals and Interferences ("BPAI") in 2010¹¹. Baxter timely appealed the BPAI's decision to the Federal Circuit, which, in May 2012, held that the PTO's determination of invalidity was correct¹². At that time, Fresenius' appeal of the March 2012 second judgment was pending before the Federal Circuit.

On appeal in *Fresenius II*, Fresenius contended that Baxter no longer possessed a valid claim for patent infringement as a result of the Federal Circuit's decision to affirm the PTO's determination that the Baxter patent was invalid¹³. After all, if the patent was invalid, Baxter had no right to enforce it in a federal court infringement action. Thus, Fresenius asserted that Baxter's infringement action was now moot and the district court's March 2012 final judgment in favor of Baxter should be vacated and Baxter's infringement case dismissed. In contrast, Baxter noted that the issue of patent validity was previously litigated by Fresenius in the district court, and decided in Baxter's favor in the first appeal, *Fresenius I*. Thus, according to Baxter, because Fresenius litigated, and lost, the issue of the invalidity of the Baxter patent in *Fresenius I*, and because the remand to the district court was only to resolve issues unrelated to patent validity (specifically Baxter's damages and its right to an injunction), Fresenius was precluded by *res judicata* from using the PTO's recent determination of patent invalidity to moot Baxter's infringement case¹⁴.

The Majority Opinion – *Fresenius I* is Not a Final Judgment Because Other Issues Remained

As an initial matter, it is worth noting how the federal court and the PTO could reach opposite conclusions regarding the validity of the same patent. When an issued patent is challenged in federal court, the challenger, in this case Fresenius, must prove that the patent is invalid by clear and convincing evidence¹⁵. Federal courts do not actually determine whether a patent is *valid* –because there is already a statutory presumption of validity¹⁶ – but rather determine whether the challenger has met its burden of proving that the patent is invalid.

In contrast, in reexamination proceedings, the PTO determines invalidity (or unpatentability) by a "preponderance of the evidence" standard, a standard significantly easier to meet than the clear and convincing standard applied by federal courts¹⁷. In addition, the claim scope in a PTO reexamination may be broader than the scope determined by a federal court, because the PTO is directed by statute to give claim terms the "broadest reasonable interpretation."¹⁸ Thus, given the different burdens of proof and potential variations in claim scope, it is not surprising that in some circumstances a federal court and the PTO will come to different conclusions regarding the validity of the same patent.

Against that background, in *Fresenius II*, the Federal Circuit majority (Judges Dyk and Prost), framed the question presented as whether, under the patent reexam statute, the cancellation of claims by the PTO in the reexamination is binding in pending district court litigation. Whether the issue of validity was still pending in the district court turned on the issue of whether the first appeal in *Fresenius* ("*Fresenius I*"), was sufficiently "final", even though issues regarding the proper amount of damages and Baxter's right to an injunction remained pending, to preclude Fresenius from asserting the PTO's decision that the patent was invalid. The majority began its analysis by reviewing the patent reissue and reexamination statutes, and drawing out the general rule that when a claim is cancelled by the PTO in reexamination, the patent holder loses its cause of action for infringement of such claim.¹⁹ The majority also noted that there are several concepts of finality, and that the judgment in *Fresenius I* may be "final" for purposes of appeal, or application of *res judicata* in another infringement case between the same parties, but this type of finality was not dispositive of the issue presented.²⁰

In looking at the issue of finality, the majority applied a strict standard, finding that a judgment is

not sufficiently “final” to preclude an intervening PTO invalidity determination from being applied unless the earlier judgment “leaves nothing for the court to do but execute the judgment.”²¹ The majority rejected Baxter’s argument that the *Fresenius I* appeal was sufficiently final to prevent the PTO reexamination final judgment from being applied. According to the majority, “it could hardly be clearer that Congress meant for cancellation to terminate pending suits.”²² Thus, because the *Fresenius* litigation in federal court was still pending, the judgment in *Fresenius I* (and remand solely for issues unrelated to the question of patent validity) was not “sufficiently final” to preclude *Fresenius* from asserting the PTO’s determination of patent invalidity in the federal litigation. According to the court, “[t]he intervening decision invalidating the patents unquestionably applied in the present litigation, because the judgment in this litigation was not final.”²³ Because Baxter’s patent was determined to be invalid, Baxter no longer possessed a viable claim against *Fresenius*, the infringement case was moot and the Federal Circuit remanded to the trial court with instructions to dismiss Baxter’s infringement claim.²⁴

The Dissenting Opinion – So What, *Fresenius I* Was a Final Decision on the Issue of Validity

Judge Newman wrote a lengthy and strongly-worded dissent. In her view, the PTO, as a non-Article III tribunal, does not have the power to overturn a final decision of the judicial branch.²⁵ Judge Newman believes that the question of patent validity, which was decided in favor of Baxter and against *Fresenius* at the district court level, and then affirmed by the Federal Circuit in *Fresenius I*, was sufficiently “final” to preclude *Fresenius* from relying upon the PTO’s subsequent determination of patent invalidity in the *ex parte* reexamination to terminate Baxter’s infringement lawsuit. She noted that “*Fresenius* contested liability and lost, by declaratory judgment action brought in the district court, and on appeal to Federal Circuit ... The judgment of validity of the ‘434 patent was not subject to redetermination, and was final in all respects.”²⁶ Thus, because the issue of invalidity had been decided in *Fresenius I*, Judge Newman believes that the judgment is also binding upon the PTO, which can “neither invalidate, nor revive, a patent whose validity the court has adjudicated.”²⁷

Denial of Petition for Rehearing and Rehearing En Banc

Baxter subsequently petitioned the Federal Circuit for rehearing and rehearing *en banc*.²⁸ The petition was denied, with several judges authoring opinions concurring or dissenting in the denial.²⁹ Writing in support of the original panel decision (and the denial of the rehearing petition), Judges Dyk and Prost noted that under Supreme Court and Federal Circuit precedent, there are multiple concepts of “finality” of judgments.³⁰ They further suggested that while there may have been sufficient “finality” in *Fresenius I* for application of *res judicata* to another infringement action, this type of “finality” does not support the collateral estoppel of the PTO’s reexamination proceedings.³¹

In contrast, Judges O’Malley, Rader, Wallach and Newman dissented from the denial.³² In their view, the original panel decision was grounded on an “inapplicable and antiquated view of finality” because “none of the critical questions regarding *Fresenius*’ liability for its past infringement of Baxter’s patents remained undecided or open to debate when the PTO cancelled the ‘434 patent.”³³ “While Baxter lost its right to bring an infringement action against anyone else once the PTO acted[,] ... its right to enforce its judgment in *Fresenius I* was inviolate.”³⁴

Judge Newman also dissented separately from the denial, noting that an administrative agency, such as the PTO, does not have the power to override the judgment of an Article III court.³⁵ She expressed her concern that the original panel decision “destabilizes issued patents, by ignoring the rules of finality” which may impact the value of issued patents and, thus, inventors’ financial incentives to invest in ongoing research and development activities.³⁶

Conclusion

In light of the Federal Circuit's decision, and the fractured denial of the rehearing *en banc* petition, counsel representing both patent holders and alleged infringers alike will need to weigh certain considerations, which may include venue issues (based, for example, upon the estimated length to trial in the venue), whether to seek *inter partes* review, and, if so, the nature and scope of the prior art selected for the *inter partes* review due to estoppel concerns. And if Baxter files for a writ of *certiorari* in the Supreme Court, we will certainly update you in our next *Inside IP* column.

¹*Fresenius USA, Inc. v. Baxter International, Inc.*, Nos. 2012-1334, 1335, 2013 WL 3305736 (Fed. Cir., July 2, 2013). For ease of use, the parties will be referred to simply as "Fresenius" and "Baxter".

²*Id.* at *15.

³*Id.* at *1.

⁴*Id.*

⁵*Id.* at *2.

⁶*Id.*

⁷*Id.* at *3.

⁸*Id.*

⁹*Id.*

¹⁰*Id.*

¹¹*Id.* at *4.

¹²*Id.*

¹³*Id.*

¹⁴*Id.* at *9.

¹⁵*See, e.g., Eli Lilly and Co. v. Teva Pharmaceuticals USA, Inc.*, 619 F.3d 1329, 1336 (Fed. Cir. 2010).

¹⁶35 U.S.C. § 282.

¹⁷MPEP § 706.1.

¹⁸*See, e.g., In re NTP, Inc.*, 654 F.3d 1268, 1274 (Fed. Cir. 2011).

¹⁹*Id.* at *5-8.

²⁰*Id.* at 9.

²¹*Id.* at 10 (internal citations omitted).

²²*Id.* at 14.

²³*Id.* at 12.

²⁴*Id.* at 15.

²⁵*Id.* at *16-17.

²⁶*Id.* at 27.

²⁷*Id.* at 17.

²⁸*Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 733 F.3d 1369, 1370 (Fed. Cir. 2013).

²⁹*Id.*

³⁰*Id.* at 1371.

³¹*Id.*

³²*Id.* at 1372.

³³*Id.* at 1381.

³⁴*Id.*

³⁵*Id.* at 1382.

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