



Divided panel lets USPTO reexamination decision trump prior District Court ruling

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Fresenius USA, Inc v Baxter Int'l, Inc, 721 F 3d 1330 (Fed Cir 2013)

Abstract

In *Fresenius*, a divided Federal Circuit panel held that the United States Patent and Trademark Office's cancellation of patent claims during re-examination proceedings is binding on concurrent non-final infringement litigation. This important case addresses the interplay between court and administrative agency proceedings at the USPTO for a given patent.

Legal context

In today's patent litigations, many litigants are involved in simultaneous proceedings in the United States Patent and Trademark Office (USPTO) and the District Courts. For example, District Court cases addressing infringement and invalidity are proceeding while, at the same time, the invalidity of the subject patent is being challenged in re-examination or review proceedings before the USPTO. In *Fresenius USA, Inc v Baxter Int'l, Inc, 721 F 3d 1330 (Fed Cir 2013)* (*'Fresenius II'*), the Federal Circuit held that the USPTO's cancellation of claims in a parallel proceeding trumped the District Court's enforcement of those same claims, even after an affirmation by the Federal Circuit on the merits.

Facts

Baxter is the owner of US Patent No 5,247,434, which relates to haemodialysis machines. In 2003 Fresenius, a manufacturer of haemodialysis machines, filed suit in the United States District Court for the Northern District of California seeking declaratory judgments of invalidity and non-infringement with respect to three of Baxter's patents, including claims 26–31 of the '434 Patent.

Baxter subsequently moved for judgment as a matter of law that there was insufficient evidence to support its invalidity defence. In 2007 the District Court granted Baxter's motion for judgment as a matter of law. Baxter appealed and, in 2009, the Federal Circuit affirmed the District Court's finding that the '434 Patent was not invalid, but vacated the District Court's separate injunction and post-verdict



royalty awards and remitted the case to the District Court on those issues. *Fresenius USA, Inc v Baxter Int'l, Inc*, 582 F 3d 1288 (Fed Cir 2009) ('*Fresenius I*'). On remand in 2012, the District Court awarded Baxter post-verdict damages of approximately US\$25 million and entered a final judgment in Baxter's favour: affirmed by *In re Baxter Int'l, Inc*, 678 F 3d 1357 (Fed Cir 2012).

However in 2005, during the District Court litigation Fresenius requested *ex parte* re-examination of claims 26–31. In the re-examination in 2007, the examiner entered a final rejection of those claims, finding them invalid as obvious in light of the prior art. The Board of Patent Appeals and Interferences affirmed this ruling in 2010.

Thus, the District Court sided with Baxter in finding that the patent was not invalid, while the USPTO reached the opposite conclusion and found that the same patent was invalid. When the District Court entered its final judgment of no invalidity after the USPTO had concluded the opposite, this set up a direct conflict between the court system and the USPTO.

This set the stage for the United States Court of Appeals for the Federal Circuit ('Federal Circuit') to consider the doctrine of separation of powers and ultimately determine which ruling had priority.

Analysis

In the *Fresenius II* decision authored by Judge Dyk, and joined by Judge Prost, the Federal Circuit vacated and remanded the District Court's decision on the validity of the '434 Patent. According to the Federal Circuit, the USPTO's cancellation of the '434 Patent's claims rendered the District Court's judgment moot and ended any viable cause of action for Baxter.

The Federal Circuit focused its discussion on the history of the reissue and re-examination statutes. The court stated that if an original patent claim is cancelled through re-examination, the patentee's cause of action is extinguished and the suit fails.

However, Baxter had argued that the USPTO's cancellation of the asserted claims could not be given effect at this *particular* point in the present litigation, because the validity of the '434 Patent and Fresenius's liability for infringement of that patent were already conclusively decided in 2007, before the USPTO reached its decision on invalidity. Baxter argued that, since the District Court's 2007 judgment was 'final' and 'binding' on the parties, it was *res judicata*.

The court agreed with Baxter that, under well-established principles of *res judicata*, the cancellation of a patent's claims cannot be used to re-open a suit that had concluded, in which a final judgment was reached and damages were awarded. However, the court stated that there was no question of reopening a final judgment here, because no judgment had been entered. While the District Court's 2007 judgment was final for purposes of appeal, and might have been given preclusive effect in another infringement case between these parties, it was not sufficiently final to preclude application of the intervening final judgment because the issue



of post-verdict damages was remanded back to the District Court, and therefore was not yet resolved. The court concluded that where the scope of relief remains to be determined, there is no final judgment binding the parties. As such, the Federal Circuit found that the District Court decision was not final for purposes of preclusion.

Baxter had also argued that allowing a USPTO determination to control the outcome of pending litigation would be unconstitutional, because it violates the doctrine of the separation of powers. It further argued that the Supreme Court made clear that the power to issue a final judgment and thereby conclusively resolve a case resides exclusively in the judicial branch. The Federal Circuit quickly dispatched this argument, again relying on the fact that the present case could not be 're-opened' since the suit was never effectively closed in the first place.

Finally, Baxter argued that giving effect to the cancellation of claims would improperly give the re-examination statute a 'retroactive' effect on the enforceability of the patent. Baxter further argued that, if Congress intended for affirmed determinations of validity to be set aside, it would have drafted the re-examination statute to provide for such a result. In rejecting this argument, the Federal Circuit stated that, contrary to Baxter's viewpoint, Congress did intend for cancelled claims to be void *ab initio* and, in 1980, amended the statutory language so that the provision was applicable to re-examinations.

In conclusion, the Federal Circuit held that the USPTO's cancellation of claims 26–31 effectively ended any viable cause of action for Baxter. As a result, the pending litigation was moot and the Federal Circuit vacated the District Court's judgment and remanded with instructions to dismiss.

Judge Newman's dissent

In a 30-page dissent, Judge Newman argued that the majority ruling was an unconstitutional violation of separation of powers. She opined that all of the issues of patent validity were resolved in *Fresenius I*. In her opinion, the majority opinion improperly authorized the USPTO, an administrative agency, to override and void the final judgment of a federal court. Judge Newman added that the issue of validity of the '434 Patent had been raised, litigated, and decided, with full participation of the accused infringer and it could not be re-litigated.

Practical significance

The majority opinion and Judge Newman's dissent reflects a long-standing split within the Federal Circuit and brings to light the constitutional separation of powers issues that are raised by parallel invalidity proceedings before the USPTO and District Courts.

The majority opinion in *Fresenius II* sets a precedent that a USPTO invalidity determination can override a contrary final judgment of a court on the same invalidity issue. As a consequence of *Fresenius II*, District Courts may have an incentive to grant stays and 'pass the buck' to the USPTO, knowing that concurrent USPTO proceedings could



render all issues moot. In this case, if the litigation had been resolved before the Federal Circuit affirmed the USPTO decision, Fresenius might have been out of luck, and responsible for \$25 million in damages.

Moreover, the fact that a conflicting USPTO decision can trump an unfavourable and not-yet-final court decision may give potential litigants an incentive to prolong court proceedings in the hope that a favourable USPTO decision will be rendered in time to avoid an enormous loss in district court. Of note, the Federal Circuit did state in its opinion that, at various points, the district court declined to stay the litigation pending the USPTO re-examination. Moreover, the very lengthy 10-year review of the '434 Patent played a large part in the unusual circumstances resulting from this case.

Nevertheless, *Fresenius II* holds that the cancellation of patent claims during re-examination is binding on concurrent non-final infringement litigation. This confirms that re-examination practice can be an effective defence strategy to invalidate a patent that is asserted in litigation. Patent holders and attorneys should be mindful of the binding effect given to USPTO decisions during patent infringement litigation, lest they suffer the same fate as Baxter.

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