VENABLE

Articles July 9, 2012

AUTHORS

Michael E. Nelson, Ph.D.

RELATED PRACTICES

Intellectual Property Patent Litigation Patent Prosecution and Counseling

ARCHIVES

2012	2008	2004
2011	2007	2003
2010	2006	2002
2009	2005	

Blessing or Curse: *In re Baxter International* Makes Reexamination More Appealing to Patent Challengers

IP Buzz

Can the USPTO invalidate a patent during reexamination that had been upheld during litigation? Yes, according to the Court of Appeals for the Federal Circuit in *In re Baxter International*, where the Federal Circuit addressed the potential conflict predicted since Congress established *ex parte* reexamination procedures at the United States Patent & Trademark Office (USPTO). At least in some circumstances, the USPTO can find a patent invalid, even after a court has upheld its validity.

Baxter International, Inc. owns U.S. Patent No. 5,247,434, directed to hemodialysis machines. In 2003, Fresenius Medical Care Holdings filed for declaratory judgment of noninfringement and invalidity. In 2005, two years after the declaratory judgment suit was filed, Fresenius requested reexamination of the '434. In 2007, the district court granted judgment of validity and infringement, affirmed by the Federal Circuit in 2009. Between 2006 and 2010, the USPTO reexamined the patent. The Board of Appeals at the USPTO, even after consideration of the Federal Circuit decision, found the claims obvious. The Federal Circuit upheld the Board of Appeals in *In re Baxter*.

The Federal Circuit denied that the USPTO could directly overrule a judicial decision, but left a substantial hole. The court noted that if a losing litigant provoked reexamination "using the same presentations and arguments," then "the PTO ideally should not arrive at a different conclusion." During litigation, Fresenius failed to identify structural features in the prior art corresponding to means-plus-function elements of the patent claims, and therefore failed to meet the burden of proof in the district court. Relying on substantially the same references argued by Fresenius at the district court, the USPTO Examiner provided the information Fresenius failed to provide. This was sufficiently different, the Federal Circuit held, to justify the alternative outcome.

Burden of proof doesn't explain the outcome, however. Only factual determinations by the USPTO Board of Appeals are entitled to deference at the Federal Circuit, not the ultimate conclusion of obviousness. The USPTO determines obviousness by a "preponderance of the evidence," while a litigant must prove obviousness by "clear and convincing evidence" because a patent has no presumption of validity before the USPTO. The Federal Circuit in *In re Baxter* upheld the Board's factual findings that structural features corresponding to means-plus-function elements of the patent claims were present in the prior art. However, the Federal Circuit did not discuss (or Baxter did not contest) why structural features from different prior art references rendered the claims obvious. Considering the outcome at the Federal Circuit, if Fresenius had pointed to the same structural features during litigation that the USPTO identified during reexaminaton, the claims would have been found obvious in the district court as well. In this case, reexamination at the USPTO corrected an apparent misstep made during the proceedings at the district court.

Following *In re Baxter*, reexamination after successful litigation may become more common and may become an even more powerful tool available to patent challengers. involved *ex parte* reexamination, where a USPTO Examiner reviews the claims without input from a third party. But *In re Baxter* may also influence *inter partes* reexamination, where a third party – even a losing litigant – may be involved. If, for example, the USPTO adopts arguments provided by a third party during *inter partes* reexamination to find claims unpatentable, *In re Baxter* may provide a second chance for losing litigants to invalidate patents upheld in court. As such, *In re Baxter* may encourage patent challengers to pursue reexamination and new arguments for unpatentability, even when patents have been upheld in court.

Patent holders may find themselves rearguing references presented during litigation, and face reexamination proceedings even after successful litigation. Because of the differences between USPTO and federal court procedure, arguments and tactics that succeed in court may not succeed before the USPTO. Counsel with experience before the USPTO is crucial. Patent holders may want to coordinate

efforts between litigation counsel and patent counsel to harmonize arguments or prepare for reexamination during litigation.