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FRESENIUS USA, INC. V. BAXTER, INT'L, INC.

721 F.3D 1330 (FED. CIR. 2013)

I. INTRODUCTION

In *Fresenius USA, Inc., v. Baxter Int'l, Inc.*, the United States Court of Appeals for the Federal Circuit considered whether, under the reexamination statute found at 35 U.S.C. § 307, the cancellation of claims by the United States Patent and Trademark Office (“PTO”) was binding in pending district court litigation.¹ Following a declaratory judgment action, the district court found certain patent claims infringed and not invalid.² The federal circuit affirmed the decision, but remanded for the district court to determine the scope of relief.³ The district court awarded the patent holder damages for infringement, but stayed execution of the judgment pending appeal.⁴ In the interim, the federal circuit affirmed the PTO’s reexamination determination that all asserted claims were invalid.⁵ The Federal Circuit held that in light of the cancellation of the underlying claims, the pending litigation was moot.⁶

II. BACKGROUND

A. Litigation

In April, 2003, Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. (collectively, “Fresenius”) brought a declaratory judgment action in district court against Baxter International, Inc. and Baxter Healthcare Corporation (collectively, “Baxter”)⁷

1. *Fresenius USA, Inc. v. Baxter Int'l, Inc.* (Fresenius II), 721 F.3d 1330, 1332 (Fed. Cir. 2013).

2. *Id.* at 1331.

3. *Id.*

4. *Id.* at 1332.

5. *Id.*

6. *Fresenius II*, 721 F.3d at 1347.

7. Baxter’s ‘434 patent, “Method and Apparatus for Kidney Dialysis,” discloses a hemodialysis machine integrated with a touch screen user interface

alleging, *inter alia*, that claims 26-31 of U.S. Patent No. 5,247,434 (“the ‘434 patent’”)⁸, certain claims of U.S. Patent No. 5,744,027 (“the ‘027 patent’”), and certain claims of U.S. Patent No. 6,284,131 (“the ‘131 patent’”) were invalid and not infringed.⁹ Baxter counterclaimed alleging infringement.¹⁰ Fresenius stipulated that its 2008K hemodialysis machine met every claim limitation of the ‘434, ‘027, and ‘131 patents, but it asserted that the patents’ claims were invalid.¹¹ In June, 2006, a jury returned a unanimous verdict in favor of Fresenius, finding the relevant claims of the ‘434 patent, as well as certain claims of the ‘027 and ‘131 patents, invalid as obvious based on prior art.¹² However, in February, 2007, the district court granted Baxter’s motion for judgment as a matter of law (“JMOL”), finding that the jury’s determination of invalidity of the claims was not supported by substantial evidence.¹³ In October, 2007, the district court proceeded to a jury trial on damages, wherein the jury awarded

that allows a user to monitor and control certain parameters. *Fresenius USA, Inc. v. Baxter Int’l, Inc. (Fresenius I)*, 582 F.3d 1288, 1292 (Fed. Cir. 2009). In 1998, Fresenius introduced the alleged infringing device, “the 2008K machine.” *Id.*

8. *Fresenius I*, 582 F.3d at 1294. Independent claim 26 of the ‘434 patent reads:

A hemodialysis machine comprising: (a) a means for controlling a dialysate parameter selected from a group consisting of dialysate temperature and dialysate concentration, and means for delivering the dialysate to a dialysate compartment of a hemodialyzer; and (b) a user/machine interface operably coupled to said dialysate-delivery means, the user/machine interface comprising a touch screen adapted to display an indicium corresponding to a parameter pertinent to operation of the hemodialysis machine for performing hemodialysis and to permit the user, by touching the indicium, to cause a change in the parameter.

Id. at 1293. Further, dependent claim 30 requires “a means for delivering an anticoagulant to a patient wherein the touch screen further provides an indicium soliciting input from the user corresponding to a rate of anticoagulant delivery. *Id.*

9. *Fresenius Med. Care Holdings, Inc. v. Baxter Int’l, Inc.*, No. 03-CV-1431, 2007 WL 518804, at *1 (N.D. Cal. Feb. 13, 2007).

10. *Id.*

11. *Id.* at *2.

12. *Id.*

13. *Id.* at *8-13.

\$14.266 million to Baxter for infringement of the three asserted patents.¹⁴ In April 2008, the district court permanently enjoined Fresenius from selling infringing machines, and ordered Fresenius to pay ongoing post-verdict royalties.¹⁵ Both parties appealed to the Federal Circuit.¹⁶

In September, 2009, the Federal Circuit reversed the district court's JMOL decision as to the '027 and '131 patents, but affirmed the JMOL grant as to claims 26-31 of the '434 patent.¹⁷ In light of the foregoing modification, the court vacated both the injunction and the royalty award and remanded for the district court to reconsider.¹⁸ On remand, Baxter moved for a final decision regarding the permanent injunction and ongoing royalty, whereas Fresenius sought a new trial for pre-verdict damages of the '434 patent.¹⁹ In May 2011, the district court denied Fresenius' motion for a new pre-verdict damages trial, and scheduled further proceedings regarding the post-verdict royalties.²⁰

On March 8, 2012, the district court awarded Baxter post-verdict damages at a reduced royalty rate, and entered final judgment on March 16, 2012 for Baxter.²¹ It ordered Fresenius to pay Baxter \$14.266 million plus-interest in pre-judgment damages, \$9.3 million plus interest in post-verdict royalties, and costs.²² Fresenius appealed seeking a new pre-verdict damages trial, while

14. *Fresenius I*, 582 F.3d at 1294.

15. *Id.*

16. *Id.*

17. *Fresenius I*, 582 F.3d at 1297-99. Regarding the '434 patent, "Fresenius failed to present any evidence – let alone substantial evidence – that the structure corresponding to the means for delivering dialysate limitation, or an equivalent thereof, existed in the prior art." *Id.* at 1299. Regarding Claim 30, "substantial evidence does not support the jury's implicit finding that the prior art contained a stepper motor means for delivering an anticoagulant." *Id.* at 1300.

18. *Id.* at 1302-03. Regarding the royalty award, the district court was instructed to "consider whether the previous award [was] proper in light of this court's modification." *Fresenius I*, 582 F.3d. at 1303.

19. *Fresenius II*, 721 F.3d at 1333.

20. *Id.* The permanent injunction issue was moot as the '434 patent expired in April of 2011. *Id.*

21. *Id.* at 1333.

22. *Id.* at 1334.

Baxter cross-appealed the court's reduction of the post-verdict royalty.²³ On May 3, 2012, the district court granted Fresenius' motion to stay execution of the new judgment pending the appeal in *Fresenius II*, the present case.²⁴ In doing so, the court rejected Baxter's argument that it was entitled to enforce and execute on the 2007 judgment.²⁵

B. PTO

In 2005, concurrent with the pending district court litigation, Fresenius filed ex parte reexamination of claims 26-31 of the '434 patent.²⁶ In December 2006, the examiner made an initial determination that claims 26-31 would have been obvious, and in December of 2007, issued a final determination rejecting said claims.²⁷ Regarding claim 26, the examiner concluded, *inter alia*, that the "means for delivering the dialysate to a dialysate compartment of a hemodialyzer" and other requisite elements of the claim were present in the prior art.²⁸ In doing so, the examiner relied upon Lichtenstein, a reference not present before the PTO during initial examination.²⁹ Regarding claim 30, the examiner relied upon a combination of references including Thomson and

23. *Id.*

24. *Id.*

25. *Fresenius II*, 721 F.3d at 1334. The court noted that "[t]he district court explained that 'the March 16, 2012 final judgment appears to supercede [sic] the Nov. 7, 2007[,] final judgment.'" *Id.*

26. *See In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1360 (Fed. Cir. 2012). The PTO agreed that a substantial new question of patentability had been raised considering new prior art references and granted the request. *Id.*

27. *See Ex parte Baxter Int'l, Inc.*, APL No. 2009-006493, 2010 WL 1048980 (Bd. Pat. App. & Interf. Mar. 18, 2010).

28. *Ex parte Baxter*, 2010 WL 1048980, at *5.

29. *Fresenius II*, 721 F.3d at 1334. The examiner concluded that "it would have been prima facie obvious . . . to have modified [a] dialysis machine or the dialysis machine of Lichtenstein, to utilize a touch screen . . . to control the central processing unit microcomputer and machine [] for delivery of treated or treatment fluids to a patient." *Ex parte Baxter*, 2010 WL 104890, at *5.

Lichtenstein in his obviousness determination.³⁰ In the *Fresenius II* decision, the court noted that “as we stated in *In re Baxter*, ‘in this case, the patent examiner relied on new prior art that had not been raised [in the initial examination] or in the prior district court proceeding.’”³¹

In March 2010, the Board of Patent Appeals and Inferences affirmed the examiner’s determination.³² The Board noted that Baxter never argued during reexamination that Lichtenstein failed to teach a “means for delivering the dialysate” nor that Thomson failed to teach a “means for delivering an anticoagulant,” despite those elements being the two deficiencies that Baxter had successfully shown from the prior art in the district court litigation.³³ Baxter appealed to the Federal Circuit, and on May 17, 2012, the court affirmed the PTO’s rejection of claims 26-31 of the ‘434 patent.³⁴ The Federal Circuit explained that its holding was not inconsistent with its prior holding in the infringement litigation because, unlike the district court, the examiner sufficiently identified structures in the prior art that would have rendered the claims obvious.³⁵ The PTO terminated the reexamination and issued a certificate cancelling claims 26-31.³⁶

III. DISCUSSION

The issue before the Federal Circuit on appeal was whether, under the reexamination statute, the PTO’s cancellation of the ‘434 patent’s claims was binding in the pending district court

30. *Id.* “Thomson disclose[d] the administration of a secondary fluid such as anticoagulant in administration systems operating under the control of electronic instrumentation.” *Id.* at *6.

31. *Fresenius II*, 721 F.3d at 1334. The court dispelled a notion of inconsistency and further stated that the examiner “based [the] rejections on prior art references that were not squarely at issue during the trial on the invalidity issues, such as Lichtenstein and Thomson.” *Id.* at 1335.

32. *Id.*

33. *Id.*

34. *See In re Baxter*, 678 F.3d at 1366.

35. *Fresenius II*, 721 F.3d at 1335.

36. *Id.*

litigation.³⁷ First, the Federal Circuit gave an overview of the statutory grant of reexamination authority to the PTO, and indicated that the “reexamination statute restricts a patentee’s ability to enforce the patent’s original claims to those that survive reexamination in ‘identical’ form.”³⁸ Also, the court noted that the language and legislative history of the reexamination statute indicate that Congress intended reexamination to proceed concurrently with litigation, noting that claim cancellation would be binding on the concurrent litigation.³⁹

Baxter argued that the 2007 district court judgment conclusively decided the validity of the ‘434 patent and Fresenius’ infringement, thus the cancellation of the claims, after such a final judgment, could be given no effect in the present litigation.⁴⁰ The Federal Circuit focused its analysis upon the concept of “finality,” and concerned itself with whether the judgment in the infringement case was sufficiently final so as to not be impinged by the PTO proceedings and the later affirmation in its *In re Baxter* decision.⁴¹ The court noted that while the judgment was final for purposes of appeal, it was not “sufficiently final” so as to preclude the final judgment in *In re Baxter*, and furthermore, it noted that it had set aside the district court’s judgment in the first infringement case in *Fresenius I*.⁴² Further, the court noted that its remand decision in *Fresenius I* was not “sufficiently final to prevent the application of *In re Baxter* in the pending suit.”⁴³ The court stated that its remand to the district court in *Fresenius I* did not end the controversy between the parties or “leave nothing for the court to do but execute the judgment;” instead, the court noted several unresolved aspects of the district court’s judgment, *i.e.*

37. *Id.* at 1336.

38. *Id.* at 1339.

39. *Id.*

40. *Id.* at 1340.

41. *Fresenius II*, 721 F.3d at 1340-41.

42. *Id.* at 1341.

43. *Id.* “To rise to that level, 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.’” *Id.* (quoting *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1580 (Fed. Cir. 1994)).

“royalties on infringing machines, royalties on related disposables, and injunctive relief.”⁴⁴ The court stated that “where the scope of relief remains to be determined, there is no final judgment binding the parties (or the court).”⁴⁵

The Federal Circuit next discussed its decision in *Mendenhall*, wherein it held that a decision finding a patent not invalid but remanding for further damages proceedings was not a final judgment.⁴⁶ In *Mendenhall*, the patent owner asserted its patents against two alleged infringers in two concurrent suits.⁴⁷ In one suit, the federal circuit affirmed the district court’s ruling that the patents were not invalid, but remanded “for determination of damages and other issues.”⁴⁸ While the first case was pending on remand, the district court in the other suit ruled the patents invalid, and the federal circuit “finally adjudged invalid” all asserted claims.⁴⁹ In light of the invalidation, the court in the pending case gave effect to the intervening determination and reversed the liability judgments and awards of damages.⁵⁰

Baxter argued that *Mendenhall*’s holding should only apply where a patent has been invalidated by a district court; noting that different standards apply in a PTO reexamination and a validity proceeding in district court, Baxter argued that the patent’s invalidation in the reexamination should not have a collateral estoppel effect.⁵¹ The Federal Circuit dispelled the notion of distinguishing between the “effects of a final, affirmed court decision determining invalidity and a final, affirmed PTO decision

44. *Id.*

45. *Fresenius II*, 721 F.3d at 1341. The court noted that, *[f]inality will be lacking if an issue of law or fact essential to the adjudication of the claim has been reserved for future determination, or if the court has decided that the plaintiff should have relief against the defendant of the claim but the amount of damages, or the form or scope of other relief, remains to be determined.*

Id. (emphasis in original) (quoting RESTATEMENT (SECOND) OF JUDGMENTS § 13(b) (1982)).

46. *Fresenius II*, 721 F.3d at 1343.

47. *Id.*

48. *Id.*

49. *Id.*

50. *Fresenius II*, 721 F.3d at 1343.

51. *Id.* at 1344.

determining invalidity on a pending litigation.”⁵² The court noted that the latter was binding because Congress had expressly delegated reexamination authority to the PTO, not because of collateral estoppel.⁵³ The court expressed that cancellation of claims extinguishes the underlying basis of a suit based on the patent; further, it stated that “Baxter’s problem is that it no longer has a viable cause of action in the pending case.”⁵⁴

Baxter next argued that allowing the PTO determination to control the outcome of the pending litigation was an unconstitutional violation of the separation of powers doctrine.⁵⁵ The court noted that Baxter’s reliance upon *Plaut* was misplaced because the suit was not over and there had been no final judgment.⁵⁶ The court stated that the controlling principle was that an appellate court must apply the law in effect at the time it renders a decision.⁵⁷ The court indicated that the general rule, as recognized in *Plaut*, controls regardless of whether “a plaintiff’s cause of action is ‘extinguished’ by the repeal of a statute or by the PTO’s cancellation of a claim pursuant to reexamination.”⁵⁸ Lastly, the court remarked that it had not reached the stage at which *Plaut* precludes reopening a case.⁵⁹

In closing, the Federal Circuit held that the cancellation of 26-31 of the ‘434 patent belied Baxter’s viable cause of action against Fresenius, and that the pending litigation was moot.⁶⁰ The court

52. *Id.*

53. *Id.*

54. *Id.* at 1344-45.

55. *Id.* at 1345.

56. *Fresenius II*, 721 F.3d at 1345. The court noted that, “[i]n *Plaut*, the Supreme Court made clear that the power to issue a final judgment and thereby conclusively resolve a case resides in the judicial branch; coordinate branches cannot retroactively compel a case to be reopened.” *Id.*; see generally *Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211 (1995).

57. *Id.* at 1345.

58. *Id.* A cancelled patent “can no more be the foundation for the assertion of a right after the surrender, than could an act of Congress which has been repealed . . . [U]nless it exists, and is in force at the time of trial and judgment, the suits fail.” *Id.* at 1136-37 (quoting *Moffit v. Garr*, 66 U.S. 273, 283 (1861)).

59. *Id.* at 1345-46.

60. *Fresenius II*, 721 F.3d at 1347.

vacated the district court's judgment and remanded with instructions to dismiss.⁶¹

IV. FUTURE IMPLICATIONS

The *Fresenius II* decision further incentivizes accused infringers to seek recourse in the PTO. Correspondingly, the decision poses a risk to patent holders insofar as it provides that an adverse determination by the PTO can override previous favorable determinations made during concurrent litigation. The court's notion of "finality" may prove to be a contentious point, and it potentially undermines district courts' efficacy in handling patent disputes.⁶² By rendering non-"sufficiently final" judgments susceptible to later PTO decisions, the *Fresenius II* decision puts an acute emphasis on timing in patent litigation suits.

In *Mendenhall*, the court rejected the patent owner's contention that the "proceedings [were] too far advanced for redetermination of liability."⁶³ The timing of the intervening judgment in the *Fresenius II* decision evokes a similar sentiment considering that the PTO decision was given effect despite previous district court and federal circuit judgments in Baxter's favor. Judge Newman argued in her dissent that "[t]he issue of validity of Baxter's '434 patent was raised, litigated, and decided, with full participation of [Fresenius]; it cannot be relitigated."⁶⁴ Judge Newman disagreed with the majority's notion of finality and argued that preclusion should apply to an issue that has been "finally decided in full and fair litigation."⁶⁵ Further, Judge Newman highlighted the fact that the "remand had no relation to any issue in reexamination; validity

61. *Id.*

62. *See* *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 733 F.3d 1369, 1372 (Fed. Cir. 2013). Judges O'Malley, Rader, and Wallach, dissenting from the denial of the petition for rehearing en banc, indicated that "the panel majority's decision in this case goes a long way toward rendering district courts meaningless in the resolution of patent infringement disputes . . . by creating a new regime wherein a district court's final adjudication can be undone by later decisions of the [PTO]." *Id.*

63. *Fresenius II*, 721 F.3d at 1353.

64. *Id.* at 1354.

65. *Id.* at 1355.

had been finally resolved in the courts.”⁶⁶ Following the Supreme Court’s denial of Fresenius’ petition for certiorari after *Fresenius I*, “Fresenius’ liability for infringement, its failure to prove invalidity, and its responsibility for past damages were firmly established and beyond challenge [in court].”⁶⁷ The only live issue concerned the scope of post-verdict relief.⁶⁸ Going forward, further elucidation regarding “finality” for purposes of issue preclusion in patent litigation suits may prove beneficial.⁶⁹

From a tactical standpoint, the *Fresenius II* decision may provide litigants with the impetus to quickly seek favorable decisions in either PTO or federal court proceedings. Patent holders may “race” to obtain a final judgment and damages in district court whereas accused infringers will be incentivized to move quickly through the PTO. Moreover, litigants may employ dilatory tactics and appeal to the federal circuit to prevent an adverse final decision in the interim. In an effort to limit costs, litigants may prefer that judicial proceedings be stayed pending concurrent PTO reexamination. Nearly 76% of reexaminations filed since 1999 were in concurrent litigation.⁷⁰ With *Inter Partes* Review proceedings slated to be completed within one year after institution under the America Invents Act (“AIA”), conflicting determinations in the PTO and concurrent litigation may become more prevalent.⁷¹

66. *Id.* at 1355 (noting that “all of the issues on appeal were finally adjudicated by the Federal Circuit; the remand authorized the district court to determine only post judgment royalties”).

67. *Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 733 F.3d 1369, 1375 (Fed. Cir. 2013); *See Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 559 U.S. 1070, 130 S.Ct. 2120, 176 L.Ed.2d 726 (2010).

68. *Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 733 F.3d 1369, 1375 (Fed. Cir. 2013)

69. *See* Brief for The Biotechnology Industry Organization as Amici Curiae Supporting Rehearing of the Panel Decision, *Fresenius USA, Inc. v. Baxter, Int’l, Inc.*, 721 F.3d 1330 (Fed. Cir. 2013) (Nos. 2012-1334, 2013-1355), 2013 WL 4713612.

70. *See Inter Partes* Reexamination Filing Data, U.S.P.T.O., available at http://www.uspto.gov/patents/stats/inter_parte_historical_stats_roll_up_EOY2013.pdf (last visited Dec. 2, 2013).

71. 35 U.S.C. § 316(a)(11) (West). The Director may extend the one year limitation to 18 months under a showing of good cause. *Id.*

V. CONCLUSION

Fresenius II held that the PTO's cancellation of Baxter's '434 patent claims belied Baxter's viable cause of action against Fresenius.⁷² The federal circuit's remand decision in *Fresenius I* was not "sufficiently final" so as to prevent the application of the intervening *In re Baxter* decision in the concurrent litigation.⁷³ Deeming the pending litigation moot, the Federal Circuit vacated the district court's judgment and remanded with instructions to dismiss.⁷⁴ This holding will further incentivize accused infringers to seek recourse in the PTO.

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72. *Fresenius II*, 721 F.3d at 1347.

73. *Id.* at 1341.

74. *Id.* at 1347.

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