

# United States Court of Appeals for the Federal Circuit

03-1067

FOREST LABORATORIES, INC. and ONY INC.,

Plaintiffs-Appellees,

v.

ABBOTT LABORATORIES,

Defendant-Appellant,

and

TOKYO TANABE COMPANY, LTD.,

Defendant.

Kenneth B. Herman, Fish & Neave, of New York, New York, argued for plaintiffs-appellees. With him on the brief were Herbert F. Schwartz, Richard M. Barnes, Christopher J. Harnett, A. Joy Arnold, and Robert B. Wilson.

Thomas M. Durkin, Mayer, Brown, Roe & Maw, of Chicago, Illinois, argued for defendant-appellant. With him on the brief was Maggie J. Schneider. Of counsel was Linda T. Coberly.

Appealed from: United States District Court for the Western District of New York

Chief Judge Richard J. Arcara

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DECIDED: August 7, 2003

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Before LOURIE, RADER, and DYK, Circuit Judges.

LOURIE, Circuit Judge.

Abbott Laboratories appeals from the decision of the United States District Court for the Western District of New York awarding attorney fees and expenses to ONY, Inc. and Forest Laboratories, Inc. based on Abbott's conduct that led to a holding of equitable estoppel. Forest Labs., Inc. v. Abbott Labs., No. 96-CV-159A (W.D.N.Y. Sept. 4, 2001) ("Forest IV"). Because we conclude that the court erred in finding this case to be "exceptional" under 35 U.S.C. § 285, we reverse.

## BACKGROUND

Tokyo Tanabe Company, Ltd. owns U.S. Patents 4,338,301 and 4,397,839, which are directed to a lung surfactant composition for treating respiratory distress syndrome in premature babies. Pursuant to an exclusive license of the '301 and '839 patents, Abbott developed a commercial product known as Survanta<sup>®</sup> in the 1980s. At about the same time, ONY developed its own product for treating neonatal respiratory distress syndrome called Calf Lung Surfactant Extract ("CLSE"). In June 1991, ONY entered into an agreement with Forest for Forest to further develop and market CLSE under the trade name Infasurf<sup>®</sup>.

From 1983 until 1991, Abbott and ONY maintained contact regarding the development of CLSE. Abbott met with ONY in November 1983 to discuss the development, composition, and testing of CLSE, and later informed ONY that it had opted to develop the Tanabe product instead of CLSE because the Tanabe product had patent protection. In April 1984, at Abbott's request, ONY submitted a memorandum of invention to Abbott disclosing "everything known about CLSE" for Abbott to conduct a patentability search. Upon completion of the search, Abbott informed ONY that CLSE was likely not patentable in light of two "pertinent references," but did not mention the '301 and '839 patents; nonetheless, Abbott encouraged ONY that it "look[ed] forward to working with [ONY] in the future." In April 1986, Abbott again met with ONY to discuss the possibility of joint development of CLSE and suggested that "some future collaboration" might still be possible. Abbott continued to monitor the development of CLSE until 1991, while internally expressing concern that ONY might receive FDA approval for CLSE before Abbott could do so for Survanta<sup>®</sup>.

In July 1991, Abbott received both FDA approval and orphan drug status (providing seven years' market exclusivity) for Survanta<sup>®</sup>, which it then proceeded to market. Several years later, Abbott informed ONY and Forest that it had reason to believe that Infasurf<sup>®</sup> would infringe the '301 and '839 patents if it were to be marketed. Nonetheless, in March 1995, ONY filed a new drug application for approval to market Infasurf<sup>®</sup>. The FDA then notified ONY that Infasurf<sup>®</sup> was the "same drug" as Survanta<sup>®</sup> under the Orphan Drug Act, 21 U.S.C. §§ 360aa-360dd (1994), and that it therefore could not be approved for sale until Abbott's period of exclusivity expired in July 1998.

In light of Abbott's June 1994 letter claiming infringement and the FDA's notification that Infasurf<sup>®</sup> and Survanta<sup>®</sup> were the "same drug," ONY and Forest sued Abbott and Tanabe in the U.S. District Court for the Western District of New York, seeking a declaratory judgment of noninfringement and invalidity of the '301 and '839 patents. Abbott and Tanabe counterclaimed for infringement. A jury found both patents infringed and not invalid and, in an advisory verdict, rejected ONY and Forest's defense of equitable estoppel. The district court, however, granted ONY and Forest a judgment of noninfringement as a matter of law ("JMOL") on the ground that Abbott and Tanabe had failed to present any evidence at trial to show that CLSE met the water content limitations of the patents in suit either literally or under the doctrine of equivalents. Forest Labs., Inc. v. Abbott Labs., No. 96-CV-159A, 1999 U.S. Dist. LEXIS 23217, at \*20-21 (W.D.N.Y. June 23, 1999) ("Forest I"). In a separate opinion, the court also ruled that Abbott, and Tanabe by imputation, was equitably estopped from asserting infringement of the '301 and '839 patents against ONY and Forest because: (1) Abbott, in bad faith, misled ONY and Forest to believe that it would not assert infringement by encouraging their development of Infasurf<sup>®</sup> and by neglecting its duty to inform them of any possible infringement; (2) ONY and Forest reasonably relied on Abbott's misleading conduct; and (3) ONY and Forest would suffer economic and evidentiary prejudice if Abbott were permitted to proceed with its infringement counterclaim. Forest Labs., Inc. v. Abbott Labs., No. 96-CV-159A, 1999 U.S. Dist. LEXIS 23215, at \*25-26 (W.D.N.Y. June 23, 1999) ("Forest II"). On appeal, we affirmed the JMOL of noninfringement and, having done so, declined to consider the equitable estoppel issue. Forest Labs., Inc. v. Abbott Labs., 239 F.3d 1305, 1314 (Fed. Cir. 2001) ("Forest III").

The district court subsequently granted ONY and Forest's motion for attorney fees and expenses against Abbott, but not Tanabe. The court found the case to be "exceptional" under 35 U.S.C. § 285 because Abbott, in bad faith, encouraged ONY to develop CLSE, disregarded its duty to advise ONY and Forest of possible infringement, and pursued its infringement counterclaim with a "reckless disregard for the facts in an attempt to prevent Infasurf from reaching the market." Forest IV, slip op. at 12. In so finding, the court rejected Abbott's argument that fees could not be awarded for bad-faith conduct that occurred prior to litigation and held that, in any event, Abbott had acted in bad faith during litigation by bringing suit with knowledge of its prior bad-faith conduct toward ONY and Forest. Id. at 11. Having found the case to be exceptional, the court then chose to exercise its discretion and award attorney fees in order to avoid a "gross injustice" and to deter patentees from similar bad-faith conduct in the future. Id. at 15. Upon the parties' stipulation as to the amount of any fee award, the court entered an award against Abbott of \$6.5 million in attorney fees and expenses. Forest Labs., Inc. v. Abbott Labs., No. 96-CV-159A (W.D.N.Y. Sept. 30, 2002).

Abbott timely appealed the fee award to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

## DISCUSSION

A determination whether to award attorney fees under 35 U.S.C. § 285 involves a two-step process. First, a district court must determine whether the prevailing party has proved by clear and convincing evidence, Ruiz v. A.B. Chance Co., 234 F.3d 654, 669 (Fed. Cir. 2000), that the case is "exceptional." 35 U.S.C. § 285 (2000); Cybor Corp. v. FAS Techs., 138 F.3d 1448, 1460 (Fed. Cir. 1998) (en banc). We review de novo whether the court applied the proper legal standard under § 285, and we review the court's factual findings, including whether the case is exceptional, for clear error. Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1378 (Fed. Cir. 2001). A finding is clearly erroneous when, despite some supporting evidence, "the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." United States v. U.S. Gypsum Co., 333 U.S. 364, 395 (1948). Second, if the district court finds the case to be exceptional, it must then determine whether an award of attorney fees is appropriate. Cybor Corp., 138 F.3d at 1460. We review that determination for an abuse of discretion. Id. A district court abuses its discretion when "its decision is based on clearly erroneous findings of fact, is based on erroneous interpretations of the law, or is clearly unreasonable, arbitrary or fanciful." Id. (citation omitted).

On appeal, Abbott first argues that the district court improperly found this case to be exceptional. Abbott contends that the court's underlying determination of equitable estoppel was clear error and, in any event, was based on only a preponderance of the evidence, whereas a finding that a case is exceptional under § 285 requires clear and convincing evidence. Abbott also argues that its private pre-litigation conduct was an inappropriate ground on which to base a finding of exceptionality and that it did not engage in bad-faith conduct during litigation because its legal position was neither frivolous nor baseless. Abbott further maintains that the district court's decision to award attorney fees was an abuse of discretion in light of the court's erroneous, or at least debatable, holding of equitable estoppel; the absence of any allegation of litigation misconduct; and the jury's advisory rejection of ONY and Forest's equitable estoppel defense. Finally, Abbott argues that the fee award serves neither of the intended purposes of § 285 in that it does not deter unwarranted infringement claims or prevent injustice to those falsely accused of infringement.

ONY and Forest respond that the district court properly found that Abbott's bad-faith conduct, viz., its failure to raise the issue of infringement with ONY and Forest between 1983 and 1994, while

encouraging the development of Infasurf<sup>®</sup> as an alternative until it received FDA approval for Survanta<sup>®</sup>, makes this case exceptional. They point out that the court did not need to find by clear and convincing evidence that the elements of an equitable estoppel defense were proved, but only that this case was exceptional. ONY and Forest also maintain that a finding of exceptionality was appropriate because Abbott should have recognized that its pre-litigation conduct precluded it from bringing suit. They further argue that Abbott's bad-faith conduct continued during litigation because Abbott persisted with its counterclaim of infringement in complete disregard of its history of dealings with ONY and Forest. In addition, ONY and Forest contend that Abbott's failure to offer any evidence of infringement with respect to the water content limitations of the asserted patents renders this case exceptional. Finally, ONY and Forest argue that the district court did not abuse its discretion in awarding fees in this case because, as the court explained, the holding of equitable estoppel alone did not make ONY and Forest whole, and not awarding fees could encourage other patentees that have engaged in similar bad-faith conduct to bring unwarranted infringement claims.

We agree with Abbott that the district court erred in awarding attorney fees to ONY and Forest. Section 285 provides that a "court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285 (2000). We have repeatedly identified as "exceptional" those cases involving "inequitable conduct before the [Patent Office]; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement." Brasseler, 267 F.3d at 1380 (citation omitted); e.g., Hoffmann-La Roche Inc. v. Invamed Inc., 213 F.3d 1359, 1365 (Fed. Cir. 2000). None of those circumstances is present here, yet the district court found that this case was exceptional due to Abbott's bad-faith conduct which led to a holding of equitable estoppel. Forest IV, slip op. at 9-11. We disagree with the court's expansive reading of § 285.

In interpreting § 285, we have been mindful of the limited circumstances in which an award of attorney fees is appropriate. See Mach. Corp. of Am. v. Gullfiber AB, 774 F.2d 467, 472 (Fed. Cir. 1985). The Senate Report accompanying § 285's predecessor statute, which is applicable to the present statute as well, states that "[i]t is not contemplated that the recovery of attorney's fees will become an ordinary thing in patent suits." Rohm & Haas Co. v. Crystal Chem. Co., 736 F.2d 688, 690-91 (Fed. Cir. 1984) (quoting S. Rep. No. 79-1503 (1946)). Indeed, we have recognized that § 285 is an exception to the American Rule and a change to the pre-1946 practice of not awarding attorney fees based upon equitable considerations in patent cases. Id. at 690. In the context of fee awards to prevailing accused infringers, we have observed that § 285 is limited to circumstances in which it is necessary to prevent "a gross injustice" to the accused infringer, see Mach. Corp., 774 F.2d at 472 (quoting S. Rep. No. 79-1503 (1946)), and have upheld findings of exceptionality to prevent such an injustice only when the patentee has procured its patent in bad faith (i.e., committed inequitable conduct before the Patent Office) or has litigated its claim of infringement in bad faith. See Cambridge Prods., Ltd. v. Penn Nutrients, Inc., 962 F.2d 1048, 1050-51 (Fed. Cir. 1992); Mach. Corp., 774 F.2d at 472.

We have not, however, upheld a finding of exceptionality based on a patentee's bad-faith business conduct toward an accused infringer prior to litigation, and we decline to expand the scope of the statutory term "exceptional" in that manner. Cf. Yarway Corp. v. Eur-Control USA, Inc., 775 F.2d 268, 277-78 (Fed. Cir. 1985) (reversing a finding of exceptionality premised on an accused infringer's bad-faith conduct of attempting to design around a patent in order to circumvent a license agreement). Equitable estoppel may be imposed in a patent case when a patentee induces another party to believe that it will not sue that party for infringement. A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020, 1042 (Fed. Cir. 1992) (en banc). Reliance by the other party as well as prejudice are required in order to estop the patentee from later suing. Id. at 1042-43. The consequence of estoppel is loss of the cause of action, id. at 1028, and we have not extended the consequences to include attorney fees under the rubric of exceptional case. Such business conduct, even though sufficiently relied upon and

prejudicial to lead to estoppel, does not make any subsequent lawsuit exceptional. Accordingly, we conclude that Abbott's "equitable estoppel" conduct was not an appropriate basis for awarding attorney fees under § 285 and that the district court's reliance on that ground was legal error.

We also agree with Abbott that the district court clearly erred in finding that Abbott engaged in bad-faith litigation. Although a lawsuit pursued in bad faith is a sufficient basis for imposing attorney fees under § 285, such bad faith requires not misleading pre-litigation conduct, but vexatious, unjustified, or frivolous litigation. *See, e.g., Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1375 (Fed. Cir. 2001) (affirming an award of attorney fees under § 285 for the "extreme litigation misconduct" of falsifying evidence); *Eltech Sys. Corp. v. PPG Indus., Inc.*, 903 F.2d 805, 810-11 (Fed. Cir. 1990) (affirming an award of attorney fees under § 285 for pursuing a baseless claim of infringement). There is no suggestion that Abbott engaged in vexatious litigation tactics; the pertinent inquiry is thus whether Abbott knew or should have known that it would be estopped from asserting the '301 and '839 patents against ONY and Forest, but pursued its infringement counterclaim anyway. *See Haynes Int'l Inc. v. Jessop Steel Co.*, 8 F.3d 1573, 1579 (Fed. Cir. 1993) ("A frivolous infringement suit is one which the patentee knew or, on reasonable investigation, should have known, was baseless."), *reh'g granted on other grounds*, 15 F.3d 1076 (1994). The district court answered that question in the affirmative, observing that Abbott "obviously knew of its own bad faith conduct prior to the commencement of the lawsuit," *Forest IV*, slip op. at 11, and nevertheless pursued its infringement counterclaim with a "reckless disregard" for the facts of the case and the validity of ONY and Forest's equitable estoppel defense, *id.* at 12.

The record, however, does not support the district court's finding that Abbott maintained its infringement counterclaim in bad faith. Even if Abbott had knowledge of the events that would ultimately lead to a holding of equitable estoppel, its litigation position was not frivolous or baseless. Indeed, based on the facts of this case, it was far from a foregone conclusion that ONY and Forest would be able to establish their equitable estoppel defense successfully. Abbott never expressly communicated to Forest or ONY that it did not intend to enforce its patents; instead, the district court had to infer a misleading statement from Abbott's conduct and did so only after finding that Abbott had a duty to advise ONY and Forest of any possible infringement when it provided ONY with a patentability opinion. *See ABB Robotics, Inc. v. GMFanuc Robotics Corp.*, 52 F.3d 1062, 1063 (Fed. Cir. 1995); *see also A.C. Aukerman Co.*, 960 F.2d at 1041 ("[E]quitable estoppel is not limited to a particular factual situation nor subject to resolution by simple or hard and fast rules."). Although the equitable estoppel issue is not before us, we note that it was never finally resolved, for we declined to consider Abbott's appeal of that issue when we affirmed the JMOL of noninfringement. *Forest III*, 239 F.3d at 1314. Once it had been concluded that ONY and Forest were not infringing the Abbott-Tanabe patents, whether Abbott would be estopped from enforcing those patents against ONY and Forest became moot. In any event, we cannot even say with confidence that the equitable estoppel determination would have been affirmed had we reached the issue on appeal. Moreover, the district court's denial of ONY and Forest's motion for JMOL at the close of the evidence and the jury's advisory verdict of no equitable estoppel suggest that Abbott's position was not baseless. In light of these considerations, we conclude that Abbott's litigation position with respect to the equitable estoppel issue cannot be characterized as clearly and convincingly vexatious, unjustified, or frivolous. Accordingly, the district court's finding that Abbott engaged in bad-faith litigation was clearly erroneous.

Finally, we reject ONY and Forest's argument that an award of attorney fees is appropriate because Abbott failed to offer any evidence of infringement regarding the water content limitations of the asserted patents. Although Abbott ultimately lost its infringement counterclaim on that ground, *id.*, we cannot say that such a lack of proof is clear and convincing evidence that Abbott, acting in bad faith, asserted a baseless or frivolous counterclaim of infringement. Indeed, the jury's finding of infringement suggests otherwise. Moreover, the district court expressly disclaimed reliance on Abbott's failure to

prove infringement as a basis for imposing attorney fees, noting that Abbott presented “plausible yet untenable arguments regarding claim construction and the doctrine of equivalents.” Forest IV, slip op. at 16-17. Thus, even if Abbott’s lack of evidence of infringement could support a finding of exceptionality under § 285, the district court did not abuse its discretion in choosing not to award fees on that ground.

## **CONCLUSION**

For the foregoing reasons, we conclude that the district court erred in finding this case to be “exceptional” under 35 U.S.C. § 285 based on Abbott’s pre-litigation conduct toward ONY and Forest. Accordingly, the decision of the district court is

REVERSED.