United States Court of Appeals for the Federal Circuit

06-1101

ABBOTT LABORATORIES,

Plaintiff-Appellee,

v.

ANDRX PHARMACEUTICALS, INC.,

Defendant-Appellant,

and

ROXANE LABORATORIES, INC. and TEVA PHARMACEUTICALS USA, INC.,

Defendants.

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Appealed from: United States District Court for the Northern District of Illinois

Judge David H. Coar

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Defendants.

DECIDED: January 5, 2007

Before MICHEL, Chief Judge, PROST, Circuit Judge, ELLIS,* District Judge.

PROST, Circuit Judge.

Abbott Laboratories ("Abbott") brought suit against Andrx Pharmaceuticals, Inc. ("Andrx") alleging infringement of its patents relating to extended release formulations of clarithromycin. Abbott moved for a preliminary injunction based on Andrx's alleged infringement of claims 1, 4, and 6 of U.S. Patent No. 6,010,718 ("'718 patent"); claim 2

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* Hon. T.S. Ellis, III, from the United States District Court for the Eastern District of Virginia, sitting by designation.

of U.S. Patent No. 6,551,616 ("'616 patent"); and claims 8 and 16 of U.S. Patent No. 6,872,407 ("'407 patent"). The district court granted the injunction with respect to all the asserted claims. The court concluded that Abbott had shown a likelihood of proving infringement of the '616 and '718 patents under the doctrine of equivalents and infringement of the '407 patent under literal infringement, and that Andrx had not shown a likelihood of proving that any of the patents are invalid. Ranbaxy Labs. Ltd. v. Abbott Labs., Abbott Labs. v. Andrx Pharms. Inc., Nos. 04 C 8078, 05 C 1490 (N.D. Ill. Nov. 10, 2005) ("Ranbaxy-Andrx").[1] Andrx appeals, arguing (1) that Abbott is collaterally estopped from asserting certain claims in the three patents because of findings of invalidity and unenforceability of the patents in proceedings against other defendants; and (2) that the district court erred in finding that Abbott is likely to succeed in proving infringement with respect to any of the asserted claims of the three patents. Because we find that collateral estoppel does not apply and the district court did not abuse its discretion in finding Abbott is likely to succeed on the merits, we affirm.

I. BACKGROUND

Abbott Laboratories accused several manufacturers of infringement of its patents related to its extended release clarithromycin product, Biaxin XL®. Three such cases are relevant to this appeal—Abbott's cases against Teva Pharmaceuticals ("Teva"), Ranbaxy, and Andrx, the defendant in the instant appeal. Each of these defendants

[1] The district court issued a single Memorandum Opinion and Order resolving two separate motions for preliminary injunction filed against Andrx, and Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. (collectively "Ranbaxy"). The motion against Ranbaxy was filed in case number 04 C 8078 and is discussed at pages 5-36 of the Memorandum Opinion, the motion against Andrx was filed in case number 05 C 1490 and is discussed at pages 37-57 of the same Memorandum Opinion.

sought approval to manufacture and market a generic version of Biaxin XL® and accordingly filed abbreviated new drug applications ("ANDAs") with the Food and Drug Administration ("FDA"). Each of the ANDAs was approved. Abbott's claims of infringement against these three defendants are all being heard before a single district judge in the Northern District of Illinois. Abbott filed motions for preliminary injunctions against each of the three generic drug manufacturers seeking to enjoin their production and marketing of extended release clarithromycin. The instant appeal is from the district court's grant of a preliminary injunction against Andrx based on the court's conclusion that Abbott is likely to prove infringement of the '718, '616, and '407 patents, and that Andrx is not likely to succeed in proving its defenses.

The '718 patent describes and claims extended release formulations comprising erythromycin derivatives combined with a pharmaceutically acceptable polymer. The extended release formulations enable patients to take one pill per day rather than twice, as had been required with the immediate release formulation. The '616 is a continuation-in-part of the '718 patent and claims a method of reducing adverse gastrointestinal side effects, relative to immediate release formulations of erythromycin-derived drug formulations, by using extended release formulations. The '407 patent is a continuation patent of the '616 patent and claims erythromycin derivative formulations with certain specified pharmacokinetic properties. The claims at issue in this appeal are solely those on which Abbott based its motion for a preliminary injunction against Andrx: claims 1, 4, and 6 of the '718 patent, claim 2 of the '616 patent, and claims 8 and 16 of the '407 patent.

Certain holdings in Abbott's cases against Ranbaxy and Teva are relevant to our analysis in this appeal. First, in the district court's order resolving Abbott's motion for a preliminary injunction against Ranbaxy, the court held that Ranbaxy had shown that it was likely to succeed in proving that the '616 and '407 patents are unenforceable due to inequitable conduct. Ranbaxy-Andrx, slip op. at 7. Second, the district court held, in an order resolving Abbott's preliminary injunction motion against Teva, that Teva had raised a substantial question that claim 2 of the '616 patent was obvious under 35 U.S.C. § 103, and therefore Teva was likely to succeed in proving invalidity of that claim. Abbott Labs. v. Andrx Pharms., Inc., No. 05 C 1490, slip op. at 22 (N.D. Ill. June 8, 2005) ("Teva I"). Finally, on appeal from Teva I, this court held that Teva had also raised substantial questions as to the validity of claims 2, 4, and 6 of the '718 patent. Abbott Labs. v. Andrx Pharms., Inc., 452 F.3d 1331, 1348 (Fed. Cir. 2006) ("Teva II").

Turning to the history of the instant appeal, Abbott's complaint against Andrx sought, inter alia, declaratory judgment of infringement of the '407, '616, and '718 patents. On May 18, 2005, Abbott moved to preliminarily enjoin Andrx from marketing its generic version of extended release clarithromycin ("the Andrx product"). In opposition to Abbott's motion, Andrx contended that it does not infringe any of the asserted patents, either literally or under the doctrine of equivalents. In addition, Andrx defended against Abbott's motion by arguing that Abbott's patents are invalid for indefiniteness under 35 U.S.C. § 112, ¶ 2 (all three patents), invalid for anticipation under 35 U.S.C. § 102(b) (the '718 and '616 patents), and invalid for obviousness under 35 U.S.C. § 103. Ranbaxy-Andrx, slip op. at 53-58.

The district court held a hearing on September 21, 2005 on Abbott's preliminary injunction motion against Andrx and issued a single order resolving both Abbott's motion against Andrx and Abbott's motion against Ranbaxy. With respect to Andrx, the court held that Abbott succeeded in proving a likelihood of success on its claims that Andrx infringes claims 1, 4, and 6 of the '718 patent under the doctrine of equivalents; induces and contributes to infringement under the doctrine of equivalents of claim 2 of the '616 patent; and literally infringes claims 8 and 16 of the '407 patent. Ranbaxy-Andrx, slip op. at 39-53. As to Andrx's invalidity defenses, the district court held that Andrx failed to meet its burden of raising a substantial question of invalidity as to any of the three asserted patents. Id., slip op. at 53-58. Accordingly, the court granted Abbott's motion for a preliminary injunction based on the '718, '616, and '407 patents.

Andrx appeals the district court's preliminary injunction order enjoining it from manufacturing and marketing its extended release clarythromycin product. Because this court's opinion in Teva II issued after the filing of briefs in Andrx's appeal, the parties' briefs did not address the estoppel effect, if any, of that opinion on the instant appeal. We therefore granted Abbott's motion, made after oral argument, requesting leave to provide supplemental briefing, requesting the parties to brief the court regarding the extent to which Teva II has a collateral estoppel or other binding effect on the instant appeal. Accordingly, both Abbott and Andrx filed supplemental briefs on this issue.[2]

We have jurisdiction over this appeal pursuant to 28 U.S.C. § 1292(c)(1).

[2] Abbott filed, along with its supplemental brief, a motion to file a supplemental appendix. The motion is denied.

II. DISCUSSION

On appeal, Andrx presents two distinct arguments as to why the district court erred in granting a preliminary injunction. First, Andrx asserts that Abbott is collaterally estopped from seeking a preliminary injunction based on holdings in the preliminary injunction proceedings against Teva and Ranbaxy that all of the asserted claims are invalid or unenforceable. Second, Andrx argues that the district court erred in finding that it could infringe any of the asserted patents. Specifically, Andrx contends that it cannot infringe the '718 and '616 patents under the doctrine of equivalents because it does not contain the "pharmaceutically acceptable polymer" required by all the asserted claims. Andrx also contends that the district court erred in concluding that Abbott showed a likelihood of prevailing in asserting infringement of the '407 patent because the court specifically found that the Andrx product did not satisfy one limitation of the asserted claims.

We address each of Andrx's arguments in turn below, reviewing the district court's decision to grant a motion for preliminary injunction for an abuse of discretion. Novo Nordisk of N. Am., Inc. v. Genentech, Inc., 77 F.3d 1364, 1367 (Fed. Cir. 1996). "To overturn the grant of a preliminary injunction, we must find that the district court made a clear error of judgment in weighing the relevant factors or based its exercise of discretion on an error of law or on clearly erroneous factual findings." Pfizer, Inc. v. Teva Pharms., USA, Inc., 429 F.3d 1364, 1372 (Fed. Cir. 2005).

The four factors relevant to the district court's decision to grant or deny a preliminary injunction are "(1) the likelihood of the patentee's success on the merits; (2) irreparable harm if the injunction is not granted; (3) the balance of hardships

between the parties; and (4) the public interest." Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1338-39 (Fed. Cir. 2003) (citing Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001)). In order to establish the first preliminary injunction factor, Abbott must show that it will likely prove that Andrx infringes at least one valid and enforceable patent claim. Pfizer, 429 F.3d at 1372. Likewise, in order to defeat the injunction based on invalidity or unenforceability defenses, Andrx, as the party bearing the burden of proof on the issue at trial, must establish a substantial question of invalidity or unenforceability, i.e., that it is likely to succeed in proving invalidity or unenforceability of the asserted patents. See Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal, 126 S.Ct. 1211, 1219-20 (2006) ("[T]he burdens at the preliminary injunction stage track the burdens at trial."); Ashcroft v. Am. Civil Liberties Union, 542 U.S. 656, 666 (2004).

A. Collateral Estoppel

Andrx's contentions regarding collateral estoppel involve the district court decisions in preliminary injunction proceedings regarding defendants Ranbaxy and Teva and this court's decision in Teva's appeal from those proceedings.

When Abbott moved for preliminary injunctions against Teva, Ranbaxy, and Andrx, the district court accepted separate arguments and held separate hearings for each defendant. Abbott presented different infringement contentions specific to the accused product of each defendant and each defendant presented its own and different defenses. In particular, Teva argued that claims of the '616 and '718 patents were invalid based on different prior art than that raised by Andrx. The district court did not find Teva's invalidity defenses regarding claims 2, 4, and 6 of the '718 patent

persuasive and granted an injunction against Teva based on those claims. Teva I, slip op. at 9-20. The court found that Teva had raised a substantial question of validity as to claim 2 of the '616 patent and denied a preliminary injunction based on that claim. Id., slip op. at 20-22. In the preliminary injunction proceedings against Andrx, however, the court granted the requested injunction based partly on claim 2 of the '616 patent, finding that Andrx had not raised a substantial question of validity based on its different validity arguments regarding that claim. Ranbaxy-Andrx, slip op. at 53-58, 62. Andrx argues that, having found claim 2 of the '616 patent invalid against Teva, the district court erred in permitting Abbott to enforce the claim against Andrx.

Defendant Ranbaxy also raised different defenses than Andrx. Ranbaxy defended against a preliminary injunction by arguing, inter alia, that Abbott's patents were unenforceable due to Abbott's inequitable conduct before the United States Patent and Trademark Office ("PTO"). Id., slip op. at 7. Andrx did not expressly raise unenforceability defenses to the district court for purposes of fending off a preliminary injunction.[3] The district court issued a single order deciding the preliminary injunction issues for both Ranbaxy and Andrx. The court found that Ranbaxy showed a likelihood of success in proving that the '616 and '407 patents were unenforceable due to inequitable conduct and therefore denied a preliminary injunction against Ranbaxy based on those patents. Id., slip op. at 18. In the order, the court also granted a

[3] Andrx asserts that it raised unenforceability due to inequitable conduct as a defense, pointing to a single statement made at the district court's preliminary injunction hearing. The district court opinion only noted that Andrx raised invalidity defenses, not any unenforceability defenses. Ranbaxy-Andrx, slip op. at 53. Therefore, we will not consider Andrx as having asserted unenforceability defenses in opposition to Abbott's motion for preliminary injunction.

preliminary injunction against Andrx based on the same two patents. Id., slip op. at 62. Andrx argues that the district court erred by failing to preclude Abbott from enforcing these patents against Andrx after finding them unenforceable against Ranbaxy. The district court's order did not address this estoppel issue.

At the time the district court issued its order resolving the preliminary injunction motions against Ranbaxy and Andrx, the preliminary injunction findings in Teva I were on appeal to this court. When Andrx and Abbott briefed the instant appeal, this court's Teva II decision had not issued. In Teva II, this court affirmed the district court's finding that Teva had shown a substantial question of validity as to claim 2 of the '616 patent. 452 F.3d at 1347. This court also reversed the district court, finding that Teva had also shown a likelihood of proving the invalidity of claims 2, 4, and 6 of the '718 patent. Id. at 1348. In its appeal, Andrx has extended the scope of its collateral estoppel arguments to encompass this court's decision in Teva II, i.e., Andrx argues that Abbott is also precluded from asserting claim 2 of the '616 patent and claims 2, 4, and 6 of the '718 patents because of the finding in Teva II that Teva showed there was a substantial question as to those claims' validity.

On appeal, Andrx argues that the Supreme Court's decision in Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation, 402 U.S. 313 (1971), requires that Abbott cannot assert patents against one party which have been found to be invalid or unenforceable against another party. In Blonder-Tongue, the Supreme Court permitted accused infringers to plead collateral estoppel, also known as issue preclusion, when facing an infringement claim on a patent already declared invalid in a proceeding against another defendant. Id. at 350. Andrx primarily argues on appeal that Blonder-

Tongue renders the district court's decision granting preliminary injunction erroneous as a matter of law—i.e., after decisions in Ranbaxy-Andrx, Teva I, and Teva II finding that those defendants had shown a likelihood of proving invalidity or unenforceability of Abbott's patents, Abbott should not have been permitted to continue to assert the patents in preliminary injunction proceedings against Andrx.

In response, Abbott argues that the courts' findings in the preliminary injunction proceedings against Teva and Ranbaxy should not be accorded preclusive effect and that Blonder-Tongue does not compel the application of findings in the other cases to Abbott's case against Andrx.

Whether collateral estoppel applies to prevent Abbott from attempting to preliminarily enjoin Andrx based on decisions in preliminary injunction proceedings against other defendants is a procedural issue not unique to patent law. We therefore apply the law of the regional circuit, here the Seventh Circuit.[4] Dana v. E.S. Originals, 342 F.3d 1320, 1323 (Fed. Cir. 2003). We first address the parameters for applying collateral estoppel addressed by the Supreme Court in Blonder-Tongue, followed by an

[4] Abbott asserts that the question of whether to extend Blonder-Tongue to the preliminary injunction context is a question unique to patent law and should be governed by the law of this court, citing Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc., 170 F.3d 1373, 1381 n.4 (Fed. Cir. 1999). We disagree. The very footnote cited by Abbott from Pharmacia supports application of Seventh Circuit law in this case:

> Application of Blonder-Tongue, being an issue of patent law, is a matter within our exclusive jurisdiction and is hence subject to this court's law. However, because the application of general collateral estoppel principles, such as finality of judgment, is not a matter within the exclusive jurisdiction of this court, we must apply the law of the circuit in which the district court here sits . . . .

170 F.3d at 1381 n.4 (emphasis added).

analysis of the application of Blonder-Tongue's collateral estoppel principles in the Seventh Circuit.

In Blonder-Tongue, the Supreme Court discussed the importance of a final determination on the merits to application of collateral estoppel. The decision was limited to the issue of "permitting a patent holder to sue on his patent after it has once been held invalid following opportunity for full and fair trial." Blonder-Tongue, 402 U.S. at 330 (emphasis added). The Supreme Court emphasized

> we should keep firmly in mind that we are considering the situation where the patentee was plaintiff in the prior suit and chose to litigate at that time and place. Presumably he was prepared to litigate and to litigate to the finish against the defendant there involved. Patent litigation characteristically proceeds with some deliberation and, with the avenues for discovery available under the present rules of procedure, there is no reason to suppose that plaintiff patentees would face either surprise or unusual difficulties in getting all relevant and probative evidence before the court in the first litigation.

Id. at 332. Blonder-Tongue held that, in such situations, a defendant could plead estoppel if it "identifies the issue in suit as the identical question finally decided against the patentee in previous litigation." Id. at 333. Once this showing has been made, the patentee must be permitted to demonstrate that he did not have a "fair opportunity procedurally, substantively and evidentially to pursue his claim the first time." Id. "Determining whether a patentee has had a full and fair chance to litigate the validity of his patent in an earlier case is of necessity not a simple matter." Id. Relevant factors include which party had the choice of forum; whether the patentee had an incentive to fully litigate in the prior litigation; and whether the patentee was deprived of crucial evidence of witnesses in the first litigation through no fault of its own. Id.

In sum, Blonder-Tongue permitted the use of defensive collateral estoppel when the accused infringer shows 1) that a patent was found invalid in a prior case that had proceeded through final judgment and in which all procedural opportunities were available to the patentee; 2) that the issues litigated were identical; and 3) that the party against whom estoppel is applied had a full and fair opportunity to litigate. Abbott argues that none of the Blonder-Tongue requirements for the application of collateral estoppel are present in this case. According to Abbott, the Teva I, Teva II, and Ranbaxy-Andrx decisions were not final judgments for purposes of estoppel; the issues litigated in the current and prior proceedings were not identical because in each proceeding the issue was whether the particular defendant had shown a likelihood of succeeding based on its own asserted defenses; and it did not have a full and fair opportunity to litigate the issue of invalidity in those proceedings.

With respect to the final judgment issue, Abbott argues that the Teva I, Teva II, and Ranbaxy-Andrx decisions were not final judgments for purposes of estoppel because they resulted from preliminary injunction proceedings in which either the district court or this court found only that the defendants had shown a likelihood of proving invalidity or unenforceability. Abbott argues these findings were based on a limited record and limited opportunities for collecting or presenting evidence, and were expressly preliminary rather than final findings on these issues. In response, Andrx agrees that Blonder-Tongue addressed the case of a final judgment on the merits and therefore is not directly applicable to a preliminary injunction determination. Andrx argues, however, that Blonder-Tongue should be extended to estop Abbott from seeking a preliminary injunction based on patents that have been found to be

preliminarily unenforceable or invalid against other defendants. Andrx also contends that the preliminary injunction holdings of invalidity and unenforceability in Teva I, Teva II, and Ranbaxy-Andrx are "final" in the limited sense of having resolved the issue of whether substantial questions of invalidity or unenforceability exist.

To determine whether findings made during preliminary injunction proceedings may invoke collateral estoppel under Blonder-Tongue we look to the law of the Seventh Circuit. That circuit has clearly held that in "certain rare instances," a finding need not be part of a final judgment on the merits in order to be preclusive. A.J. Canfield v. Vess Beverages, 859 F.2d 36, 38 (7th Cir. 1988) ("Canfield"); see also Miller Brewing v. Jos. Schlitz Brewing Co., 605 F.2d 990, 996 (7th Cir. 1979). [5]

In Miller, Miller Brewing Company sued a competitor based on the trademark "Lite." In a prior case, the Seventh Circuit had upheld a district court's denial of a preliminary injunction based on the finding that the same asserted trademark was invalid as generic. Miller, 605 F.2d at 991. In the second case, Miller had sued another competitor, Schlitz, based on the same trademark. The district court found that the prior finding of invalidity in the preliminary injunction context collaterally estopped Miller from asserting the mark against Schlitz. On appeal, the Seventh Circuit considered whether the prior determination was a final judgment for purposes of issue preclusion, as required by Blonder-Tongue. Id. at 995-96.

On the question of whether the prior preliminary invalidity finding constituted a final judgment, the court expressly held that a judgment need not be final in the sense of

[5] This court has likewise held that a holding need not be a part of a final judgment in order to be sufficiently final to invoke issue preclusion. Dana, 342 F.3d at 1323-25.

28 U.S.C. § 1291. Id. at 996. Rather, "'[f]inality' in the context here relevant may mean little more than that the litigation of a particular issue has reached such a stage that a court sees no really good reason for permitting it to be litigated again." Id. The decision should be "sufficiently firm to be accorded conclusive effect." Factors to consider in determining whether a decision was adequately deliberated and firm include whether the parties were fully heard, the court supported its decision with a reasoned opinion, and the decision was subject to appeal. Id. But preclusion should be refused, the court held, if the decision was "avowedly tentative." Id. In Miller, the court held that the generic status of the "Lite" mark had been so thoroughly litigated in the first preliminary injunction proceeding that, as to that issue, there was a sufficient final judgment. Id.

Subsequent to Miller, the Seventh Circuit had occasion to clarify when a preliminary injunction is a final judgment for purposes of issue preclusion. In Canfield, the court discussed the preclusive effect of several holdings made in prior proceedings on the issue of whether Canfield's trademark "chocolate fudge" was generic for use with diet sodas. In a first proceeding, a court had granted Canfield a preliminary injunction against defendant Vess after a preliminary finding that the asserted mark was not generic. Canfield, 859 F.2d at 37 (citing A.J. Canfield Co. v. Vess Beverages, Inc., 612 F.Supp. 1081 (N.D. Ill. 1985) ("Vess I")). The Seventh Circuit had affirmed the preliminary injunction. Id. (citing A.J. Canfield Co. v. Vess Beverages, Inc., 796 F.2d 903 (7th Cir. 1986) ("Vess II")).

In another court, Canfield sought a preliminary injunction against defendant Yoo-Hoo based on the same mark. The court in those proceedings found the trademark generic and denied a preliminary injunction. Id. at 38 (citing Yoo-Hoo

Chocolate Beverage Corp. v. A.J. Canfield Co., No. 85-3701, 1986 WL 9720, at *1 (D.N.J. Apr. 1, 1986)). Because the district court considered extensive evidence on the issue during the preliminary injunction proceeding, it determined that Canfield "will not and cannot succeed on the merits based upon the undisputed facts submitted." Yoo-Hoo, 1986 WL 9720 at *18. The court did give Canfield additional time, however, to come forward with additional evidence that it did not present at the preliminary injunction hearing on why its mark for "chocolate fudge" should not be found generic. Canfield, 796 F.2d at 38. When Canfield failed to do so, the court entered a final judgment in favor of Yoo-Hoo. Id.

In a third proceeding, Canfield sued and sought preliminary relief against another defendant, Honickman, for use of the same "chocolate fudge" mark. There, the court held that the term was generic for purposes of granting a preliminary injunction. Id. at 38 (citing A.J. Canfield v. Honickman, 808 F.2d 291 (3d Cir. 1986)).

Vess, the defendant against whom a preliminary injunction had been entered in Vess I returned to court for vacatur of the injunction against it based on the holdings in Honickman and Yoo-Hoo that the asserted mark was generic. Canfield, 859 F.2d at 37. Canfield countered by arguing that the earlier findings in Vess I and Vess II that the mark was not generic precluded application of the later-decided Honickman and Yoo-Hoo holdings that the mark was generic. The Canfield court discussed when it is appropriate to give preclusive effect to holdings made during preliminary injunction proceedings.

> In general, rulings in connection with grants or denials of preliminary relief will not be given preclusive effect. Such rulings are often made on an incomplete record and are inherently tentative in nature. Usually, the

> grant or denial of relief is based not on a conclusive determination, but on an estimate of the likelihood of success.

Canfield, 859 F.2d at 38 (citations omitted). In "certain rare circumstances," however, the court held that decisions granting or denying preliminary injunctions may be sufficiently final to be given preclusive effect. Id. The exception to the general rule permits decisions regarding preliminary relief to accord preclusive effect if the decisions are necessarily based upon a determination that constitutes an "insuperable obstacle" to the plaintiff's success on the merits. Id. (citing Miller, 605 F.2d at 995). Such an insuperable obstacle exists when a prior decision made in connection with a preliminary injunction proceeding "clearly intended to firmly and finally resolve the issue," rather than "estimate the likelihood of success" of proving that issue. Id.; see also Teamsters Local 705 v. Apex Auto. Warehouse, Inc., No. 90 C 6768, 1991 U.S. Dist. LEXIS 9471 (N.D. Ill. July 8, 1991) (citing Canfield, 859 F.2d at 38) ("When the prior injunction was based upon the same issue the party seeks to foreclose, and the court in the earlier decision conclusively determined that issue, then that situation falls within the insuperable obstacle test.")

The Canfield court thus had to determine whether each prior case resolved the issue of whether "chocolate fudge" is generic in a way that intended to firmly and finally resolve the issue. The court found that in both the Yoo-Hoo case and the Honickman case, the district court opinions did reach final resolutions on that issue. The Yoo-Hoo court had given Canfield the opportunity to present further evidence after its preliminary finding that the mark was generic, and when Canfield did not, entered a final judgment in Yoo-Hoo's favor. Such a resolution was "clearly a decision on the merits for purposes of collateral estoppel." Id. at 38. The Honickman court had found the term

generic only for purposes of a preliminary injunction. The opinion, however, showed that the deciding judge "clearly intended to firmly and finally resolve the issue." Id. Therefore, it too was afforded preclusive effect.

The district court's holding in Vess I, on the other hand, was not considered sufficiently firm to be accorded preclusive effect. The district court judge in Vess I had made no explicit finding as to whether the asserted mark was generic. Id. at 38-39. Also, while the judge had raised the issue, he had not finally resolved it. Id. at 39. The Canfield court held, therefore, that "any discussion of genericness in Vess I was in terms of probabilities, not certainties, and the brief mention of the issue was not full litigation and decision on the merits for purposes of issue preclusion." Id. at 39.

Applying the principles of Canfield and Miller to the instant appeal, we conclude that the determinations made in proceedings against defendants Teva and Ranbaxy were not "full litigation and decision on the merits for purposes of issue preclusion." Andrx argues that there has been a final resolution of the limited issue of whether there is a substantial question of invalidity of Abbott's patents, but Seventh Circuit law does not support this view. A determination that there is merely a likelihood of proving invalidity is a determination made solely in terms of "probabilities, not certainties" and is therefore not "full litigation and decision on the merits for purposes of issue preclusion." Id.

In both the Teva and Ranbaxy cases, the district court judge did not intend to "firmly and finally resolve the issue" for which preclusion is asserted, the validity or enforceability of the Abbott patents, in its preliminary injunction proceedings. As with the opinion in Vess I, the Ranbaxy-Andrx opinion makes conclusions regarding the

issue solely in terms of "probabilities, not certainties." For example, the court's unenforceability finding with respect to Ranbaxy explicitly "preliminarily finds both the '616 and the '407 patents" unenforceable due to inequitable conduct. Ranbaxy-Andrx, slip op. at 18-19 (emphasis added). Similarly, the invalidity findings with respect to defendant Teva by both the district court and this court were solely that Teva showed a "likelihood" of success in proving invalidity and were not conclusive findings. Teva II, 452 F.3d at 1348; Teva I, slip op. at 4. Contrary to the requirement of Miller, the Teva II panel's decision on invalidity was "avowedly tentative." Teva II, 452 F.3d at 1337 ("[O]ur decision today in no way resolves the ultimate question of invalidity." (emphasis added)). Under Seventh Circuit precedent, we do not find this case, therefore, to present the rare circumstance in which a determination made during a preliminary injunction is sufficiently final to be accorded preclusive effect. Andrx's arguments seeking to collaterally estop Abbott from preliminarily enforcing its patents against Andrx are accordingly rejected.

In light of this conclusion with respect to final judgments, we do not reach the parties' arguments regarding whether the issues litigated in the prior and present proceedings are identical, or whether Abbott had a full and fair opportunity to litigate in the prior proceedings. The collateral estoppel effect of Teva I, Teva II, and Ranbaxy-Andrx was the only appealed basis for reversing the district court's finding that the three Abbott patents are preliminarily valid and enforceable as to Andrx. Accordingly, we affirm the district court's judgment in that regard.

B. Infringement

Andrx also challenges the district court's finding that Abbott showed a likelihood

of proving infringement of its asserted claims by Andrx. Irrespective of the conclusion above regarding whether Abbott is estopped from relitigating the validity and unenforceability of certain claims in its patents, we must still reach Andrx's infringement arguments as to claim 1 of the '718 patent because it was not at issue in the proceedings against the other defendants. Cf. Bourns, Inc. v. United States, 537 F.2d 486 (Ct. Cl. 1976) (holding that if the obviousness inquiry as to unadjudicated claims present identical issues to those already adjudicated in a prior suit in which other claims were found invalid, the patentee may be estopped from asserting the unadjudicated claims). However, because of the holding that collateral estoppel does not apply here, the arguments regarding claims 4 and 6 of the '718 patent, claim 2 of the '616 patent, and claims 8 and 16 of the '407 patent still require our review.

Andrx makes two arguments as to why it cannot infringe Abbott's asserted claims in any of the three patents. First, Andrx argues that it cannot infringe the '718 and '616 patents because its product does not satisfy the "pharmaceutically acceptable polymer" limitation in the patents either literally or under the doctrine of equivalents. Second, Andrx argues that the district court erred in finding that Abbott showed a likelihood of proving infringement of the '407 patent because the district court explicitly found that Andrx's product did not meet one of the pharmacokinetic property requirements recited in the claims.

Turning to the first of these arguments, Andrx asserts that the district court erred in granting a preliminary injunction based on the '718 and '616 patents because Abbott did not show that it is likely to succeed in proving infringement of the "pharmaceutically acceptable polymer" claim limitation. Andrx asserts that it cannot infringe literally or

under the doctrine of equivalents because its product does not include a "pharmaceutically acceptable polymer" as required by the claims. All of the asserted claims of the '718 patent—claims 1, 4, and 6—and claim 2 of the '616 patent contain this limitation.

The "pharmaceutically acceptable polymer" in the '718 and '616 patent serves as the release controlling agent for the claimed extended release clarithromycin compositions. '718 patent, col. 1. l. 67 – col. 2 l. 2. Both sides concede that Andrx's product does not contain a polymer, but instead uses glyceryl monostearate ("GMS") as its release controlling ingredient. Abbott therefore does not assert that Andrx infringes the claims of the '718 and '616 patents literally, but solely under the doctrine of equivalents. The parties dispute whether GMS is properly referred to as a wax or a fat and whether it can be found to be an equivalent of the claimed polymer.

1. Claim Construction

When determining whether the Andrx product is likely to infringe the "pharmaceutically acceptable polymer" claim limitation as an equivalent, we start with construction of that claim term. The district court construed the term "pharmaceutically acceptable polymer" in its preliminary injunction order for defendant Teva.

> The '718 patent description of the "pharmaceutically acceptable polymer" uses a closed term. Claim drafters often use the term "group of" to signal a Markush group, which lists specified alternatives in a patent claim . . . . By its nature, a Markush group is closed. The '718 patent describes the "pharmaceutically acceptable polymer" as "a water-soluble hydrophilic polymer selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acids copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof." . . . The term excludes other forms of polymers, such as hydrophobic or water insoluble substances (e.g., wax).

Teva I, slip op. at 11. The court subsequently adopted that construction for purposes of the preliminary injunction proceedings against Andrx despite Abbott's protest that the district court's construction in Teva I was overly narrow.

> Abbott urges this Court to modify its construction of the phrase "pharmaceutically acceptable polymer" from its previous opinion in the related Teva matter. . . . When a term is undefined, the first place a court is to look for a definition is the specification. This Court followed that procedure, looked in the specification, and read the Markush group containing definition there. It is not persuaded by the case law Abbott cites that it erred in so doing and declines to alter its construction.

Ranbaxy-Andrx, slip op. at 40-41 (citation omitted).

Abbott argues, as it did to the district court, that the district court erred in its claim construction because it relied on "Markush group" language in the specification, i.e., language indicating that the claimed pharmaceutically acceptable polymer is "selected from the group consisting of" the polymers expressly identified in the specification. Given that the specification used the "selected from the group of" language, the district court limited the pharmaceutically acceptable polymers to those listed. Abbott argues that this was erroneous because limiting claim scope based on Markush language only applies when the phrase is used in the claims, not in the written description.

Abbott also disagrees with Andrx's contention that the written description provides an explicit definition of "pharmaceutically acceptable polymer" that should overcome the canon that the term should be given its ordinary meaning to one of skill in the art in the context of the patent. Further, Abbott argues that the patent does not include any intentional disclaimer or disavowal of claim scope of the polymer limitation. It urges that the specification merely identifies exemplary polymers that are suitable for

use in the invention and does not provide a definition. It notes that when defining other terms in the patent, the '718 patent explicitly states what the term "means."

The district court's claim construction, Abbott argues, would also violate the doctrine of claim differentiation because claims 2 and 3, which depend from claim 1 expressly claim the more specific types of polymers to which the court limited the term. Accordingly, Abbott asserts that the correct construction of "pharmaceutically acceptable polymer" is according to the plain and ordinary meaning that one of skill would understand it to have in the context of the patent—"any polymer, suitable for use in pharmaceutical compositions to be administered in humans that, alone or together with other polymers, is capable of forming a matrix to control and extend drug-dissolution release into the bloodstream."

Andrx responds that Abbott wrongly relies on these principles of claim construction to argue that the district court's construction was impermissibly narrow. First, Andrx argues that Markush language is just as limiting when used in the written description as when it is used in a claim. Second, Andrx argues that Abbott misapplies the doctrine of claim differentiation. Finally, Andrx asserts that Abbott's construction ignores an express definition of the term "pharmaceutically acceptable polymer" given in the specification and instead imports limitations from preferred embodiments.

This court reviews the district court's claim construction de novo on appeal. Cybor Corp. v. FAS Techs, Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998). "[T]he words of a claim 'are generally given their ordinary and customary meaning.'" Philips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Further, "the ordinary and

customary meaning of claim term is the meaning that the term would have to a person of ordinary skill in the art in question." Id. at 1313. The court looks to sources such as the words of the claims themselves, the written description of the patent, and extrinsic evidence to ascertain the meaning of the term "pharmaceutically acceptable polymer." Id. at 1314.

First, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." Id. at 1314. Claim 1 of the '718 patent requires a composition that includes only a "pharmaceutically acceptable polymer." '718 patent, col. 11 ll. 31-32. Claim 2, not asserted here, depends from claim 1 and further requires that the pharmaceutically acceptable polymer "is a hydrophilic water-soluble polymer." Id., col. 11 ll. 39-40. Claim 3, also not asserted in this case, depends from claim 2 and more specifically requires that

> the polymer is selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl ceullulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof.

Id., col. 11 ll. 42-47. Therefore, the language of the claims and claim differentiation imply that the "pharmaceutically acceptable polymer" term in claim 1 is likely broader than the "hydrophilic water-soluble polymer" described in claim 2 and encompasses more compounds than those listed in claim 3.

Next, the claims "'must be read in view of the specification, of which they are a part.' . . . [I]t is the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (citations omitted). Here, the specification describes:

> The pharmaceutically acceptable polymer is a water-soluble hydrophilic polymer selected from the group consisting of polyvinylpyrrolidine,

> hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof. Preferably, the polymer is selected from hydroxypropyl cellulose, hydroxypropylmethyl cellulose, and methyl cellulose. More preferably, the polymer is hydroxypropylmethylcellulose. Most preferably, the polymer is a low viscosity hydroxypropylmethyl cellulose with viscosity ranging from about 50 cps to about 200 cops. The most preferred low viscosity polymer is a hydroxypropylmethyl cellulose with a viscosity of about 100 cps, commercially available under the Tradename Methocel™ K 100 LV from The Dow Chemical Company.

'718 patent, col. 3 l. 65 – col. 4 l. 14.

The district court focused on the "selected from the group consisting of" phrase in the specification to hold that there was a Markush group and therefore Abbott was limited to the listed polymers. A Markush group is a form of drafting a claim term that is approved by the PTO to serve a particular purpose when used in a claim—to limit the claim to a list of specified alternatives. Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1372 (Fed. Cir. 2005); Manual of Patent Examining Procedure § 803.2 (8th ed. 2001). The term "Markush group" does not have any meaning within the context of a written description of a patent and therefore to the extent the district court relied on the Markush group language to limit its construction to the compounds listed in the written description, it erred.

The district court also appears to have grounded its claim construction on the theory that the "pharmaceutically acceptable polymer" is explicitly defined in the written description when it states, "The pharmaceutically acceptable polymer is a water-soluble hydrophilic polymer . . . ." '718 patent, col. 1 ll. 65-66 (emphasis added). Although a term may have an ordinary meaning to one of ordinary skill in the art, the patentee may "expressly define terms used in the claims." Phillips 415 F.3d at 1321 (quoting

Vitronics, 90 F.3d at 1582. The patentee here states in the written description that "a pharmaceutically acceptable polymer is" a specific subset of polymers. The word "is" may signify that a patentee is serving as its own lexicographer. However, there is significant evidence at this stage of the litigation to believe that the patentee here was not providing a definition of the "pharmaceutically acceptable polymer" claim term in the written description. First, the '718 patent unambiguously provides definitions of other claim terms, that may be different from the ordinary understanding of a person of skill in the art, by stating that the term has a particular meaning within the patent. See, e.g., '718 patent, col. 3 ll. 34-35 ("'Erythromycin derivative' as used herein, means . . . ." (emphasis added)); col. 3, ll. 40-41 ("'Pharmaceutically acceptable' as used herein, means . . . ." (emphasis added)). In contrast, the written description states that the "pharmaceutically acceptable polymer is . . . ," which does not as unambiguously signify that the description provided is definitional. Further, neither party's expert declared that the language in the written description is purely definitional from the point of view of one of skill in the art. Indeed, the two experts offer differing constructions as to how the term "pharmaceutically acceptable polymer" would be understood by one of ordinary skill in the art, neither construction limiting the polymer to hydrophilic, water-soluble substances. Decl. of Arthur H. Kibbe Ph.D. in Opp'n to Abbott Labs. Mot. for a Prelim. Inj. Against Andrx Pharms. at 21-22, ¶ 46, 48 ("Kibbe Declaration"); Decl. of Gilbert Stephen Banker, Ph.D, D.Sc., in Supp. of Abbott Labs.' Application for a TRO and Mot. for a Prelim. Inj. Against Andrx Pharms., Inc. at 12. Also, it appears that if the "pharmaceutically acceptable polymer" is defined to be "a water-soluble hydrophilic polymer," that definition would not cover some of the very polymers listed because they

are not water-soluble. See Kibbe Declaration at 22, ¶ 49. Finally, as noted above, the claims of the '718 patent do not support a conclusion that the "pharmaceutically acceptable polymer" in claim 1 is limited by the "hydrophilic" or "water-soluble" limitations in claim 2, or to the specific compounds listed in claim 3. We therefore conclude that the district court erred at this preliminary stage in limiting the "pharmaceutically acceptable polymer" term to hydrophilic, water-soluble compounds selected from a list given in the written description of the '718 and '616 patents.

2. Infringement

Turning to infringement, Andrx argues that, under the district court's claim construction, the Andrx product cannot infringe the "pharmaceutically acceptable polymer" claim limitation. The parties conceded below that there is no literal infringement of the limitation by the GMS ingredient in the Andrx product. Ranbaxy-Andrx, slip op. at 37. The district court found, however, that Abbott did show a likelihood of success of proving that the Andrx product infringes under the doctrine of equivalents. On appeal, Andrx argues that GMS cannot be an equivalent of the "pharmaceutically acceptable polymer" term for two reasons: first, because it would violate the specific exclusion principle; and second, because a finding of equivalence would vitiate the claim limitation. We address each of these arguments in turn.

Andrx first contends that permitting its product to infringe would violate the specific exclusion principle. This principle limits what can be claimed under the doctrine of equivalents by mandating that "the concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims." Athletic Alternatives, Inc. v. Prince Mfg. Inc., 73 F.3d 1573, 1582 (Fed. Cir. 1996). According to

Andrx, the district court's claim construction consistently held that the pharmaceutically acceptable polymer excludes other forms of polymers such as hydrophobic or water insoluble substances such as waxes. Therefore, any equivalence that encompasses hydrophobic or water insoluble substances, Andrx argues, would violate the specific exclusion principle. As discussed above, we hold that the district court erred by limiting the scope of pharmaceutically acceptable polymers covered by the claims to hydrophilic or water-soluble substances. Therefore, we need not consider Andrx's argument that specific exclusion bars the application of the doctrine of equivalents because GMS is a hydrophobic, water-insoluble substance.

Andrx also argues that permitting its product to infringe the "pharmaceutically acceptable polymer" term under the doctrine of equivalents would vitiate that claim limitation. A finding of equivalence of the Andrx product is erroneous as a matter of law, Andrx contends, because the Andrx product "employs a material[, GMS] that is the exact opposite of the material recited in the claims of the '718 patent (polymer vs. nonpolymer (or even further, hydrophilic water soluble polymer vs. hydrophobic water insoluble nonpolymer))." Andrx argues that, regardless of whether GMS meets the test for factual equivalence by performing substantially the same function in substantially the same way to achieve substantially the same result, a finding of equivalence by something that is the opposite of the claimed limitation would essentially read the limitation out of the claim. Andrx also argues that GMS was well known in the prior art, but not claimed by Abbott in its claims. Therefore, Andrx contends, allowing GMS to infringe as an equivalent would seriously undermine the public notice function required by patent claims.

Abbott responds that under either its asserted claim construction or that adopted by the district court, the equivalence of GMS to the claimed "pharmaceutically acceptable polymer" would not vitiate the claim limitation because the district court found that GMS was an equivalent of the polymer limitation under the function-way-result test. Andrx did not appeal the factual equivalence, so Abbott argues that Andrx has no basis for arguing that the claim term is vitiated by a finding of equivalence. Andrx replies that Abbott's arguments regarding factual equivalence are immaterial to the issue on appeal, whether a water insoluble hydrophobic non-polymeric substance, can be considered insubstantially different from its antithesis, the claimed water soluble hydrophilic polymer.

On the issue of vitiation, the district court held

> Andrx argues that a finding of equivalency vitiates the claim by reading the pharmaceutically acceptable polymer limitation out of it. That is incorrect. A finding of equivalency under the doctrine of equivalents is a fact-specific inquiry. It does not require a revision of the claim language or limitation.

Ranbaxy-Andrx, slip op. at 44 n.17.

A claim element is not vitiated merely because it does not literally exist in the accused product—"such an interpretation of the 'all elements' rule would swallow the doctrine of equivalents entirely." Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1018 (Fed. Cir. 2006). Rather,

> [a] holding that the doctrine of equivalents cannot be applied to an accused device because it 'vitiates' a claim limitation is nothing more than [(1)] a conclusion that the evidence is such that no reasonable jury could conclude that an element of an accused device is equivalent to an element called for in the claim, or [(2)] that the theory of equivalence to support the conclusion of infringement otherwise lacks legal sufficiency.

Id. at 1018-19.

Here, Andrx appears to argue the second type of vitiation described by Depuy Spine—that Abbott's theory as to the "polymer" claim element is legally insufficient to prove equivalence. Specifically, Andrx argues that GMS, a hydrophobic, non-polymeric substance, is the antithesis of the required polymer. See Planet Bingo v. Gametech Int'l, No. 05-1476, slip op. at 13 (Fed. Cir. Dec. 12, 2006) (explaining that a theory of equivalence may be legally insufficient when the accused product contains the antithesis of the claim limitation). Therefore, Abbott's assertion that it can avoid a finding of vitiation because it showed factual equivalence does not address Andrx's argument that Abbott's theory of equivalence is legally insufficient. It also appears that the district court did not consider this aspect of vitiation. Rather, the court addressed only whether GMS could factually be an equivalent of the polymer limitation.

Nevertheless, as discussed above, we hold that the district court erred in construing the "pharmaceutically acceptable polymer" claim term as only covering hydrophilic, water-soluble substances. Because this erroneous construction forms the basis for Andrx's vitiation arguments that GMS cannot be an equivalent of the required polymer, we reject those arguments.

We are left with the district court finding that GMS could be factually equivalent to the required polymer under its erroneous claim construction—that GMS performs the same function, in the same way, to achieve the same result as the "pharmaceutically acceptable polymer" in the claims. Ranbaxy-Andrx, slip op. at 44. Andrx does not argue in this appeal that the district court erred in this finding of factual equivalence. Although the district court's equivalence analysis applied an erroneous claim construction, its conclusion regarding equivalence would clearly also apply under a

claim construction that was not erroneously narrowed as explained above. Therefore, we affirm the district court's finding, based on the preliminary record, that Abbott showed a likelihood of success in proving infringement of claims 1, 4, and 6 of the '718 patent and claim 2 of the '616 patent under the doctrine of equivalents.

3. Infringement of the '407 Patent

Because we hold that the district court did not err in granting a preliminary injunction based on the '718 and '616 patents, we need not reach whether the court erred in also basing its preliminary injunction on the '407 patent.

C. Other Preliminary Injunction Factors

Other than likelihood of success on the merits, the other factors relevant to the district court's decision to grant or deny a preliminary injunction are (1) irreparable harm if the injunction is not granted; (2) the balance of hardships between the parties; and (3) the public interest. As Andrx does not challenge the district court's findings on these factors on appeal, we do not disturb the district court's conclusion that these factors weigh in Abbott's favor.

CONCLUSION

Because Abbott has shown a likelihood of success in proving infringement of at least one claim and the district court found that Andrx did not show it was likely to prevail in its defense, which was a finding unchallenged on appeal, we affirm.[6]

AFFIRMED

[6] Nothing in this opinion precludes either Abbott or Andrx from seeking in district court either vacation of the injunction currently appealed or a new injunction based on matters not previously presented to the district court.