

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

**WARNER CHILCOTT LABORATORIES IRELAND
LIMITED,
WARNER CHILCOTT COMPANY, LLC, WARNER
CHILCOTT (US), LLC,
AND MAYNE PHARMA INTERNATIONAL PTY.
LTD.,**
Plaintiffs-Appellees,

v.

**MYLAN PHARMACEUTICALS INC. AND MYLAN
INC.,**
Defendants-Appellants.

2011-1611

Appeal from the United States District Court for the District of New Jersey in case no. 09-CV-2073, Judge William J. Martini.

Decided: December 12, 2011

DOMINICK A. CONDE, Fitzpatrick, Cella, Harper & Scinto, of New York, New York argued for plaintiffs-appellees. With him on the brief were DIEGO SCAMBIA;

and BRIAN L. KLOCK, of Washington, DC. Of counsel on the brief was JONATHAN M.H. SHORT, McCarter & English, LLP, of Newark, New Jersey.

LARRY L. SHATZER, Wilson Sonsini Goodrich & Rosati, P.C., of Washington, DC, argued for defendants-appellants. With him on the brief were Shaun R. Snader; and Tung-On Kong, of San Francisco; and Jennifer Koh, of San Diego, California.

Before RADER, *Chief Judge*, DYK and O'MALLEY, *Circuit Judges*.

O'MALLEY, *Circuit Judge*.

This is a Hatch-Waxman Act case in which Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, “Mylan”) appeal the district court’s entry of a preliminary injunction prohibiting Mylan from launching the generic version of 150 mg Doryx, which is the branded name for the doxycycline hyclate delayed-release tablets sold by Plaintiffs-Appellees. Because the district court relied on disputed facts in granting the preliminary injunction without holding an evidentiary hearing, and failed to make any findings as to Mylan’s invalidity defense, we *vacate* the preliminary injunction and *remand* this action for further proceedings.

I. BACKGROUND

Plaintiff-Appellee Mayne Pharma International Pty. Ltd. (“Mayne”) is the holder of New Drug Application No. 50-795 relating to delayed release tablets containing 75 mg base, 100 mg base, and 150 mg base of doxycycline hyclate. Mayne also owns U.S. Patent No. 6,958,161 (“the ‘161 Patent”), entitled “Modified Release Coated Drug Preparation,” which covers the branded drug Doryx.

Mayne licenses the '161 Patent to Plaintiffs-Appellees Warner Chilcott¹ and has partnered with Warner Chilcott to market Doryx in the United States.

On December 5, 2008, Mylan filed an Abbreviated New Drug Application (“ANDA”) to sell a generic version of 150 mg Doryx. Mylan included with its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '161 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Mylan’s proposed generic drug. Following Mylan’s ANDA, on May 1, 2009, Warner Chilcott filed an infringement suit against Mylan in district court, triggering the thirty-month statutory stay of approval of Mylan’s ANDA product by the U.S. Food and Drug Administration (“FDA”). The district court consolidated Warner Chilcott’s suit against Mylan for discovery purposes with several other suits Warner Chilcott filed against other companies that, like Mylan, are seeking to sell generic versions of Doryx.

The only claim at issue for purposes of this appeal is claim 21 of the '161 Patent, which recites:

A tablet for oral administration, the tablet being a modified release preparation having one or more coated core elements, each core element comprising an active ingredient comprising an acid salt of doxycycline and having a modified release coating, wherein a *stabilising coat is provided between each core element and its modified release coating* so that, upon in vitro dissolution testing, the

¹ The following Warner Chilcott entities are named plaintiffs in this lawsuit: Warner Chilcott Laboratories Ireland Limited; Warner Chilcott Company, LLC; and Warner Chilcott (US), LLC. For ease of reference, we refer to all Plaintiffs-Appellees collectively as “Warner Chilcott.”

amount of active ingredient released at any time on a post-storage dissolution profile is within 40 percentage points of the amount of active ingredient released at any time on a pre-storage dissolution profile.

'161 Patent col. 14 ll.20-23 (emphasis added).

In this case, Warner Chilcott's infringement argument turns on whether Mylan's ANDA product has the claimed "stabilizing coat." On July 20, 2011, following the parties' submissions and a hearing pursuant to *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (en banc), the district court construed the emphasized language above, which includes "stabilizing coat," to mean "a layer of material(s) between each core element and its modified release coating, which keeps the migration of core materials to a minimum such that the interaction of core materials with coating materials is reduced or prevented." *Warner Chilcott Labs. Ireland v. Impax Labs., Inc.*, 2011 WL 2971155, at *7 (D.N.J. Jul. 20, 2011).

On August 24, 2011, just over one month before the end of the FDA's thirty-month stay on September 27, 2011, Warner Chilcott filed a motion for a temporary restraining order and preliminary injunction against Mylan, seeking to prohibit Mylan from launching its generic 150 mg product once it received final approval from the FDA.² The parties briefed Warner Chilcott's motions and submitted witness declarations, including

² Mylan received tentative approval of its ANDA on June 10, 2011 and expected final approval on or before September 30, 2011. As of the date of this opinion, however, Mylan has not yet received final approval. At oral argument before this court, Mylan asserted its belief that the FDA was withholding final approval because of the district court's preliminary injunction, but Mylan did not offer any support in the record for that assertion.

declarations from their respective experts. The district court heard arguments from counsel regarding both motions on September 21, 2011. The court did not conduct an evidentiary hearing and did not hear live testimony from any of the witnesses. The hearing lasted just over an hour.

The majority of the hearing focused on the parties' respective experts and various tests those experts had performed to show the existence or non-existence of a "stabilizing coat" in Mylan's ANDA product. In other words, the court's primary focus was on the question of whether Warner Chilcott was likely to succeed on the merits of its infringement claim, a question which turned on a battle of experts. Warner Chilcott's expert relied on one test to conclude that Mylan's product met the "stabilizing coat" limitation, while Mylan's expert relied on five different tests to reach the opposite conclusion. The district court recognized that determining which tests to credit was "one of the threshold inquiries," and that there existed "some serious factual disputes between the experts" on this issue. Joint Appendix ("J.A.") A25; *see also* J.A. 57 ("[T]here's clearly factual disputes between the two of you."). The court also acknowledged that "this would all be the subject of further testimony and examination and credibility," J.A. 51, which the court would consider at the full trial on the merits.

After the court expressed its views on this issue, Mylan's counsel requested a one- or two-day evidentiary hearing with live witness testimony, where the court could hear from the battling experts. The court declined to conduct a hearing, however, and indicated that it would reserve these issues for a full trial. The court noted, moreover, that it would not have time to conduct such a trial until January 2012 because of an upcoming lengthy criminal trial that would occupy the court's schedule

during the fall of 2011. *See* J.A. 54-55 (“I have a six- to eight-week trial starting October 11th, a murder trial, and that has to get priority So I have no time the rest of this fall, certainly no time to do a preliminary injunction hearing, which I don’t think limited testimony is going to be so helpful. I’d rather have the full trial.”).

Ultimately, the district court ruled that Warner Chilcott had demonstrated that: (1) it was likely to succeed in proving that Mylan’s product infringed the ’161 Patent; (2) it would suffer irreparable harm absent an injunction; and (3) that the balance of hardships favored Warner Chilcott. On this basis, the court entered a preliminary injunction pending resolution of the trial on the merits. Notably, the district court did not address Mylan’s arguments that the ’161 Patent is invalid because of anticipation or obviousness, though it did acknowledge that those claims had been asserted.

The day after the hearing, the district court issued a two-page order granting Warner Chilcott’s motion and preliminarily enjoining Mylan from selling generic 150 mg Doryx “during the pendency of this injunction and until the Court has resolved all issues of validity and infringement relating to the patents-in-suit.” Order Granting Preliminary Injunction Against Defendants Mylan Pharmaceuticals Inc. and Mylan Inc., *Warner Chilcott Labs. Ireland Ltd. v. Mylan Pharms., Inc.*, Case No. 09-cv-2073 (Sept. 22, 2011), ECF No. 53. The court also ordered Warner Chilcott to post a bond in the amount of \$36 million.

After unsuccessfully requesting that the district court stay its injunction pending appeal, Mylan filed a motion to stay the preliminary injunction in this court and requested expedited briefing on the merits of Mylan’s challenge to the district court’s preliminary injunction. This

court ordered expedited briefing, scheduled oral argument on the merits of Mylan’s appeal, and ultimately denied Mylan’s motion to stay. The court heard argument on the merits appeal on November 22, 2011.

II. STANDARD OF REVIEW

This court applies regional circuit law, here that of the Third Circuit, when reviewing a district court’s decision to grant a preliminary injunction. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1367 (Fed. Cir. 2008) (citing *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891, 894 (Fed. Cir. 1998)). We review the district court’s decision for “an abuse of discretion, an error of law, or a clear mistake in the consideration of proof.” *Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004) (quotation and citation omitted). “Thus, we exercise plenary review over the district court’s conclusions of law and its application of law to the facts, but review its findings of fact for clear error, which occurs when we are left with a definite and firm conviction that a mistake has been committed.” *Id.* (quotation and citation omitted).

III. DISCUSSION

A plaintiff seeking a preliminary injunction must establish that: (1) “he is likely to succeed on the merits”; (2) “he is likely to suffer irreparable harm in the absence of preliminary relief”; (3) “the balance of equities tips in his favor”; and (4) “an injunction is in the public interest.” *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008) (citations omitted). Such an injunction is “an extraordinary remedy never awarded as of right.” *Id.* (citation omitted). Where, as here, an accused infringer has challenged the validity of a patent in response to a motion for a preliminary injunction, this court has addressed the procedures district courts are to use to analyze the question of validity. *See, e.g., Titan Tires Corp. v.*

Case New Holland, Inc., 566 F.3d 1372, 1378-79 (Fed. Cir. 2009). As it relates to the present appeal, we have explained that “the trial court first must weigh the evidence both for and against validity that is available at this preliminary stage in the proceedings.” *Id.* at 1379.

In this case, the district court abused its discretion in two ways. The court: (1) failed to hold an evidentiary hearing despite acknowledging that the decision turned on disputed factual issues; and (2) did not weigh the evidence or make any findings as to Mylan’s invalidity challenge.³ As discussed below, these errors warrant vacating the preliminary injunction.

A. Failure to Hold Evidentiary Hearing

In the Third Circuit, as in other circuits, “a district court cannot issue a preliminary injunction that depends upon the resolution of disputed issues of fact unless the court first holds an evidentiary hearing.” *Elliott v. Kiese-wetter*, 98 F.3d 47, 53 (3d Cir. 1996) (citing *Profl Plan Examiners of New Jersey, Inc. v. Lefante*, 750 F.2d 282, 288 (3d Cir. 1984)); *see also Ty, Inc. v. GMA Accessories, Inc.*, 132 F.3d 1167, 1171 (7th Cir. 1997) (“If genuine issues of material fact are created by the response to a motion for a preliminary injunction, an evidentiary hear-

³ While the trial court also did not address the public interest, neither party presses that point on appeal or argues that there are public interest factors that would materially alter the analysis of the propriety of temporary injunctive relief in this case. Thus, while it is generally error to fail to address *any* of the four preliminary injunction factors, we do not rely on that error in resolving this appeal. *See McAulay v. U.S. Banknote Corp.*, 13 U.S.P.Q.2d 1990, 1991 (Fed. Cir. 1989) (unpublished) (citing *Pretty Punch Shoppettes, Inc. v. Hawk*, 844 F.2d 782, 784-85 (Fed. Cir. 1988)); *Texas Instruments, Inc. v. Tessera, Inc.*, 231 F.3d 1325, 1329 (Fed. Cir. 2000).

ing is indeed required.”). In such cases, “[t]he chief question . . . is whether, in ordering the preliminary injunction, the district court relied upon any facts that were properly disputed.” *Williams v. Curtiss-Wright Corp.*, 681 F.2d 161, 163 (3d Cir. 1982).

Here, it is clear that the district court relied on disputed factual issues in granting Warner Chilcott’s motion for a preliminary injunction. Indeed, the court expressly identified those disputed issues when it explained that there were “some serious factual disputes between the experts” and “there’s clearly factual dispute between the two of you.” J.A. 25, 57. Rather than resolving those disputes through an evidentiary hearing, followed by adequate factual findings, as Mylan requested, the court put them aside for a later day. That runs afoul of the Third Circuit case law cited above.

This is also not a case like *Elliott*, where the Third Circuit excused the district court’s failure to hold an evidentiary hearing because the district court “impliedly resolved” any factual issues in favor of the plaintiff. 98 F.3d at 54. In this case, the court expressly identified that the dispute between the parties’ experts would necessitate further testimony and cross examination, but nonetheless granted a preliminary injunction on an unsettled record. *Sims v. Greene*, 161 F.2d 87, 88 (3d Cir. 1947) (“The allegations of the pleadings and affidavits filed in the cause are conflicting. Such conflicts must be resolved by oral testimony since only by hearing the witnesses and observing their demeanor on the stand can the trier of fact determine the veracity of the allegations . . . made by the respective parties.”). Although we recognize and are not unsympathetic to the district court’s scheduling demands and the difficulty in balancing a busy criminal docket with pressing civil matters, the district court’s chosen course is contrary to Third Circuit law, and

its decision must be vacated.

B. Lack of Findings as to Validity

The district court also failed to make any findings as to Mylan's invalidity challenge, thus preventing this court from engaging in any meaningful review of that issue. A court "must find the facts specially and state its conclusions of law separately." Fed. R. Civ. P. 52(a)(1). "It is of the highest importance to a proper review of the action of a court in granting or refusing a preliminary injunction that there should be fair compliance with Rule 52(a) of the Rules of Civil Procedure." *Mayo v. Lakeland Highlands Canning Co.*, 309 U.S. 310, 316 (1940); *Kos Pharms.*, 369 F.3d at 712 n.10 (quoting *Mayo* and explaining that a district court's failure to explain each of the likelihood of confusion factors in a trademark infringement analysis "runs afoul of Rule 52(a)"); *see also Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991) ("Sufficient factual findings on the material issues are necessary to allow this court to have a basis for meaningful review."). Absent appropriate findings, the normal course is to vacate the district court's decision and remand the matter for a proper analysis. *See Sabinsa Corp. v. Creative Compounds, LLC*, 609 F.3d 175, 183 (3d Cir. 2010) ("Typically, when a district court fails to adequately support its findings, we merely remand for a re-weighing of the applicable factors."); *Pretty Punch Shoppettes, Inc. v. Hawk*, 844 F.2d 782, 785 (Fed. Cir. 1988) (same).

The district court in this case made no more than passing reference to Mylan's invalidity challenge, and did not make any express findings as to validity of the '161 Patent. Although there is no precise formula district courts must use rendering their findings under Rule 52(a), an utter failure to make any findings contravenes that rule. In addition to violating Rule 52(a), these omis-

sions are also contrary to our case law, which requires district courts to consider both the accused infringer's validity defense and the patentee's arguments in support of its patent. *See Titan Tire*, 566 F.3d at 1379 (“[T]he trial court first must weigh the evidence both for and against validity that is available at this preliminary stage in the proceedings.”). Accordingly, we remand the matter for the district court to make appropriate findings consistent with these authorities.⁴

IV. CONCLUSION

Although the district court's entry of the preliminary injunction in this case is contrary to controlling authority, we are mindful of the court's demanding schedule and desire to avoid duplicating its efforts with a soon-to-be-scheduled bench trial in this case. If doing so serves judicial efficiency, the district court may consider entering a temporary restraining order after this court's mandate issues, then consolidating the preliminary injunction hearing with the bench trial on the merits, assuming that can occur within the timeframes mandated by the Federal Rules of Civil Procedure. *See Salinger v. Colting*, 607 F.3d 68, 84 (2d Cir. 2010). With that in mind, we remand this matter for proceedings consistent with this order.

VACATED AND REMANDED

⁴ While Mylan does so, we take no issue with the adequacy of the trial court's findings on irreparable harm and the balance of hardships, and do not order the court to revisit those questions, unless it chooses to do so.