IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES,	)	
	)	
Plaintiff,	)	
	)	**No. 05 C 5373**
v.	)	
	)	**HONORABLE DAVID H. COAR**
SANDOZ, INC.	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

This matter comes before this Court on the motion of plaintiff, Abbott Laboratories ("Abbott"), for a temporary restraining order (a "TRO") against defendant, Sandoz, Inc. ("Sandoz").[1] Abbott seeks to enjoin Sandoz from marketing a generic extended release form of the antibiotic drug, clarithromycin, that allegedly infringes Abbott's U.S. Patent Nos. 6,010,718 (the "'718 patent"), 6,551,616 (the "'616 patent") and 6,827,407 (the "'407 patent") relating to its Biaxin XL product. For purposes of this motion, however, only the '718 patent is at issue. For the reasons stated below, Abbott's motion for a TRO is **DENIED**.

BACKGROUND

Abbott filed a complaint against Sandoz alleging patent infringement. Sandoz manufactures and markets generic versions of branded pharmaceuticals in the United States. Abbott sought a declaratory judgment that Sandoz would infringe the '718, '616, and '407

[1] This Court already denied the Plaintiff's motion with regard to the alternative remedy of enforcing the parties' Rule 26(f) joint report and proposed discovery plan in a separate order.

patents. Each of these patents pertains to Abbott's branded antibiotic product, BIAXIN XL, which is an extended release formulation of clarithromycin, an erythromycin derivative.

Clarithromycin is a macrolide antibiotic used to treat bacterial infections, particularly those of the skin and upper respiratory system. Abbott held a patent on the immediate release version of clarithromycin, marketed as BIAXIN, until the patent expired on May 23, 2005. Abbott began marketing BIAXIN in the United States in approximately 1991. In 2000, Abbott was issued two formulation patents (the '616 and the '718 patents) on an extended release formulation of clarithromycin. Abbott began marketing this extended release formulation under the name BIAXIN XL in 2000. As of May 2005, Abbott estimated that BIAXIN XL accounted for approximately 70% of the sales in the BIAXIN market. Generic competitors entered the market for immediate release clarithromycin on May 24, 2005.

Abbott brought an application for a temporary restraining order against Andrx Pharmaceuticals, Inc. ("Andrx") and Teva Pharmaceuticals USA, Inc. ("Teva") in this Court. Andrx and Abbott entered a stipulated temporary restraining order on May 20, 2005. This Court held a hearing and entered a temporary restraining order against Teva on May 20, 2005. This Court then held a hearing on Abbott's motion for a preliminary injunction against Teva and ultimately issued a preliminary injunction. That preliminary injunction order was vacated by the Federal Circuit Court of Appeals. Teva and Abbott subsequently entered into a settlement agreement.

Now Sandoz seeks to bring to market a generic version of an extended release clarithromycin product that undoubtedly will cause Abbott some loss of market position. Thus,

Abbott seeks to stop Sandoz's intrusion upon the market for extended release clarithromycin products.

STANDARD FOR TEMPORARY RESTRAINING ORDER

A TRO is an emergency remedy issued to maintain the status quo until a hearing can be held on an application for a preliminary injunction. *Coca-Cola Co. v. Alma-Leo U.S.A., Inc.*, 719 F. Supp. 725, 726 (N.D. Ill. 1989). Like a preliminary injunction, a TRO is designed to minimize the hardship to the parties pending the ultimate resolution of the lawsuit. *Faheem-El v. Klincar*, 841 F.2d 712, 717 (7th Cir. 1988). The standards for a TRO and a preliminary injunction are functionally identical in this circuit. *Bernina of America, Inc. v. Fashion Fabrics Int'l*, 2001 WL 128164, at *1 (N.D.Ill. Feb. 9, 2001).

A party seeking injunctive relief, including the entry of a TRO, must make a four-part threshold showing that (1) the movant has some likelihood of success on the merits of the underlying litigation; (2) immediate irreparable harm will result if the relief is not granted; (3) the balance of the hardships weighs in the movant's favor; and (4) the impact on the public interest is in favor of the relief. *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 973 (Fed. Cir. 1996); *see also Duct-O-Wire Co. v. U.S. Crane, Inc.*, 31 F.3d 506, 506 (7th Cir. 1994). The movant's TRO can only be granted if it can establish both of the first two factors, specifically, likelihood of success on the merits and irreparable harm. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001).

DISCUSSION

A. Likelihood of Success on the Merits

In order to demonstrate a likelihood of success on the merits, the plaintiff (Abbott) must show, in light of the presumptions and burdens that will be present at any eventual trial on the merits, that it is likely to prove the defendant (Sandoz) infringed its patent, and that any of the defendant's challenges to the validity and enforcement of its asserted patents lack substantial merit. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350-51 (Fed. Cir. 2001). The '718 patent has already been analyzed by both this Court and the Federal Circuit Court of Appeals in another case (the "Teva case"). *See Abbott Laboratories v. Andrx Pharmaceuticals, Inc.*, 452 F.3d 1331 (*vacating Abbott Laboratories v. Andrx Pharmaceuticals, Inc., et. al.*, 2005 WL 1323435 (N.D.Ill. June 3, 2005)).

In the Teva Case, Abbott secured a preliminary injunction against another generic drugmaker, Teva, that was trying to come to market with its own extended release clarithromycin product. 452 F.3d at 1332. Teva conceded that its generic extended release clarithromycin product infringed upon the '718 patent. *Id.* at 1333. However, Teva raised the defense that Abbott's '718 patent claims 2, 4 and 6 were invalid for obviousness under 35 U.S.C. § 103. *Id*. This Court found that Teva had failed to raise a substantial question as to the validity of Abbott's claims 2, 4 and 6. *Id*. On appeal, the Federal Circuit vacated the Order of this Court. *Id*. It held that this Court erred in assessing the content of prior art, which in the Federal Circuit's view, supported Teva's arguments and it held further that Teva had indeed demonstrated a substantial question regarding the validity of the '718 patent's claims 2,4 and 6. *Id*. at 1348.

Sandoz argues here that the holding of the Federal Circuit in the Teva case precludes Abbott's assertion that there are no substantial questions of validity concerning claims 1,2,4 and 6 of the '718 patent. Sandoz is incorrect. The general rule is that "rulings in connection with grants or denials of preliminary relief will not be given preclusive effect." *A.J. Canfield Co. v. Vess Beverages, Inc.*, 859 F.2d 36, 38 (7th Cir. 1988). That is so because preliminary relief hearings "are often made on an incomplete record and are inherently tentative in nature..." and "the grant or denial of relief is based not on a conclusive determination, but on an estimate of the likelihood of success." *Id*. That is exactly the situation here. The Court of Appeals in the Teva case expressly noted that its decision "in no way resolve[d] the ultimate question of invalidity." 452 F.3d at 1347. In *A.J. Canfield Co.*, the court ruling on the preliminary relief made a conclusive determination as to the generality of the word at issue. 859 F.2d at 38. Here, in direct contrast, the Court of Appeals in Teva case did not make a conclusive determination as to the obviousness or invalidity of the '718 claim. Thus, because the Court of Appeals did not make a conclusive determination of invalidity, this Court is not bound to afford the Teva case preclusive effect as to the invalidity issue.

However, even though the Federal Circuit's holding on the issue of whether there was a substantial question as to the obviousness/invalidity of the '718 patent, the practical effect of that Court's holding still militates towards the denial of the TRO in the instant case. Abbott is seeking a TRO based upon the alleged infringement of Sandoz upon the '718 patent. Abbott must show a likelihood that it will succeed at a trial on the merits. In doing so, it must also demonstrate that the allegedly infringed patent claims will likely survive any validity challenges asserted by the alleged infringer. *Amazon.com, Inc.*, 239 F.3d at 1351. Given the holding of the

Federal Circuit Court of Appeals and the deference owed thereto, this Court will not reach a result inconsistent with that holding absent a substantial showing that on a more complete record, the Federal Circuit would have reached a different result.

While Abbott has put forth argument and suggests some evidence that the Teva Case's analysis may have been flawed, on the limited record in the TRO hearing, this Court is not persuaded that the Federal Circuit's reasoning is not controlling in this (Sandoz) case as to the likelihood of prevailing on the invalidity claims.[2]

On the present record and the rationale of the Federal Circuit in the Teva case, Sandoz raises a substantial question as to the validity of the '718 patent. Therefore, for purposes of this TRO motion, there is no need to consider at this point whether Abbott can show a likelihood that Sandoz's generic extended release clarithromycin product actually infringes upon its BIAXIN XL product.

B. Irreparable Harm, Balance of Hardships and Impact on Public Interest

A TRO will only be granted if the movant can establish both a likelihood of success on the merits and irreparable harm. *Amazon.com, Inc.*, 239 F.3d at 1350. Because this Court concludes that Abbott cannot establish a reasonable likelihood of success on the merits, it is unnecessary to determine whether it will be irreparably harmed, to balance the hardships to the parties or the impact on the public interest.

[2] Claim 1 of the '718 patent is an independent claim from which claim 2 depends. While the invalidity defense analysis dealt with claim 2, its dependency upon claim 1 necessarily imputes the same invalidity defense can be mounted against claim 1.

CONCLUSION

For the foregoing reasons, this Court **DENIES** Plaintiff's motion for a temporary restraining order.

Enter:

/s/ David H. Coar

David H. Coar
United States District Judge

Dated: **December 15, 2006**