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

ABBOTT LABORATORIES,

Plaintiff,

v.

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

Defendants.

Civil Action No. 05 C 1490

Judge Coar

Magistrate Judge Mason

ANDRX PHARMACEUTICALS, INC.'S MOTION TO VACATE PRELIMINARY INJUNCTION

Defendant, Andrx Pharmaceuticals, Inc. ("Andrx"), hereby moves the Court to vacate the preliminary injunction entered against it on November 10, 2005 due to a significant change in circumstances that has occurred subsequent to the entry of the injunction. Specifically, on June 22, 2006, the United States Court of Appeals for the Federal Circuit vacated the preliminary injunction previously entered herein against Teva Pharmaceuticals USA, Inc. ("Teva"). In view of the Federal Circuit's decision and for the reasons that follow, Andrx submits that the preliminary injunction entered against Andrx should be vacated immediately.

1. On June 3, 2005, this Court entered a preliminary injunction against Teva, holding that, while Teva had raised a substantial question as to the validity of claim 2 of U.S. Patent No. 6,551,616 ("'616 patent") pursuant to 35 U.S.C. § 103, it had not established that claims 2, 4 and 6 of U.S. Patent No. 6,010,718 ("'718 patent") are invalid for obviousness. Abbott Laboratories' U.S. Patent No. 6,872,407 ("'407 patent") was not asserted against Teva in its preliminary injunction motion.

2. On November 10, 2005, in a consolidated order, this Court entered a preliminary injunction against Andrx and Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy"). As to Ranbaxy, this court held that both the '616 and '407 patents are unenforceable based on Abbott's inequitable conduct, that claims 1 and 4 of the '718 are valid and not infringed but that claim 6 is valid and infringed. In a separate section of the preliminary injunction order, this Court held as to Andrx that all three patents are valid, enforceable and infringed.

3. Teva, Ranbaxy and Andrx appealed from the preliminary injunction orders to the United States Court of Appeals for the Federal Circuit. The Teva appeal proceeded on its own and the Ranbaxy and Andrx appeals were consolidated for hearing purposes only.

4. On June 22, 2006, the Federal Circuit rendered an opinion vacating the preliminary injunction as to Teva. A copy of the Federal Circuit opinion is attached hereto as Exhibit "A." The Ranbaxy and Andrx appeals are now fully briefed and remain pending before the Federal Circuit.

5. In its opinion, the Federal Circuit determined that Teva had raised substantial issues as to the validity of each of the claims relied upon (in both the '616 and '718 patents) for the preliminary injunction. In so holding, the Federal Circuit expressly determined "for purposes of the preliminary injunction Abbott as the moving party has not established a likelihood of success on the merits." Opinion at pg. 28. Andrx expressly adopted Teva's invalidity assertions in its briefing of the preliminary injunction motion and at oral argument on the motion.

6. Based on this Court's prior rulings in the Ranbaxy and Andrx preliminary injunction order and the Federal Circuit's decision in the Teva case, all three patents in suit now have been judicially determined to be invalid and/or unenforceable for obviousness or inequitable conduct.

7. As expected, immediately following the Federal Circuit's release of its decision, Teva announced the "introduction and availability" of its generic version of Biaxin® XL. Attached as composite Exhibit "B" are copies of Teva's "New Product Announcement," "Product Facts" sheet and product insert.

8. Previously, Abbott made clear in these proceedings that it plans to come to market with its own generic version of Biaxin® XL (i.e., an "authorized generic") "if another party has launched a generic version of Biaxin® XL already." Abbott's Reply in Support of its Motion for Preliminary Injunction at pg. 23. *See also* Deposition of Sean McKercher at pg. 46. Excerpts of the Reply and McKercher deposition are attached as Exhibits "C" and "D," respectively.

9. The Federal Circuit, having found that Abbott has not established a likelihood of success on the merits, determined "Abbott no longer is entitled to a presumption of irreparable harm. See Reebok Int'l Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1556 (Fed. Cir. 1994). Opinion at pg. 29. As to Abbott's economic arguments, the Federal Circuit stated: "[W]e do not doubt that generic competition will impact Abbott's sales of Biaxin XL, but that alone does not establish that Abbott's harm will be irreparable. As we stated in Illinois Tool Works, Inc. v. Grip-Pack, Inc., if this court were to accept a patentee's "argu[ments] that, 'apart from the presumption,' its 'potential lost sales' alone demonstrate 'manifest irreparable harm,' acceptance of that position would require a finding of irreparable harm to every manufacturer/patentee, regardless of circumstances." 906 F.2d 679 (Fed. Cir. 1990)." Opinion at pg. 29.

10. Based on the foregoing analysis, the Federal Circuit concluded "absent the presumption of irreparable harm and in light of the arguable sufficiency of monetary damages, Abbott has not established that irreparable harm supports the grant of the injunction." Opinion at pg. 31.

11. With generic competition entering the market, including Abbott's own authorized generic, any notion of irreparable harm has evaporated. Circumstances now have significantly changed from the time the Andrx injunction was entered and that injunction no longer should remain pending. The vacation of the Andrx injunction order would moot the pending appeal and the parties would proceed to trial. If Andrx prevails at trial, its damages would be lessened by the vacation of the injunction order. If Abbott prevails, which seems unlikely given both this Court's and the Federal Circuit's rulings to date, Andrx could be responsible for damages but those damages would be limited based on the open and vigorous generic market that will now exist as a result of the Federal Circuit's decision in the Teva case.

12. Importantly, as to the '407 patent, the only patent not yet addressed by the Federal Circuit (but which, as noted above, this Court already has determined preliminarily is unenforceable based on inequitable conduct), this Court determined that the Andrx product does not meet at least one of the limitations (the immediate release formulation-related limitation) of claim 8 of that patent. Preliminary Injunction Order at pp. 50-51. Such finding required a determination of non-infringement as a matter of law. *See Freedman Seating Co. v. American Seating Co.*, 420 F.3d 1350, 1358 (Fed. Cir. 2005) and *Kustom Signals, Inc .v. Applied Concepts, Inc.*, 264 F.3d 1326, 1333 (Fed. Cir. 2001). Thus, as to the '407 patent, Abbott's likelihood of success as to Andrx is even more remote because this court already has determined, factually, that the Andrx product does not infringe even if that patent ultimately is held to be valid when considered by the Federal Circuit. It also bears note that the Federal Circuit agreed with this Court's preliminary claim constructions and that Andrx is relying on those constructions in the appellate court and in these proceedings, while Abbott is taking issue with those constructions. Once properly applied to the facts, those constructions will result in a finding of non-

infringement in favor of Andrx as to all three patents. While unnecessary to the instant motion, Andrx makes this observation in further support of its motion to vacate.

WHEREFORE, based on a significant change in circumstances and applicable law, Andrx respectfully submits that the injunction entered against it on November 10, 2005 should be vacated immediately.

Dated: June 26, 2006

ANDRX PHARMACEUTICALS, INC.

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