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.	)	**Case No. 05 C 1490** Judge Coar Magistrate Judge Brown

ABBOTT LABORATORIES' EMERGENCY MOTION TO MODIFY THIS COURT'S JUNE 26, 2006 ORDER TO COMPEL RECALL OF ALL GENERIC CLARITHROMYCIN EXTENDED RELEASE PRODUCT SOLD BY TEVA PHARMACEUTICALS USA, INC.

Plaintiff Abbott Laboratories ("Abbott") hereby moves on an emergency basis for an order modifying this Court's June 26, 2006 Order ("Order") to compel Teva Pharmaceuticals USA, Inc. ("Teva") to immediately recall all of its generic clarithromycin extended release product which was sold to Teva's customers in violation of Judge Coar's preliminary injunction order. In support of the motion, Abbott states as follows:

I. SUMMARY OF ARGUMENT

1. On July 12, 2006, Judge Coar ruled that his preliminary injunction order against Teva remains valid, binding, and enforceable unless and until the Federal Circuit's mandate issues. *See* Exhibit A at 3 ("I am not touching the injunction until such time as I receive a mandate from the Federal Circuit. … [T]he injunction remains in place."). Contrary to Teva's counsel's representations to Abbott's counsel that Teva had sold "limited" quantities of its

product, Abbott has now learned that Teva already had sold massive quantities of its product to its customers and that retailers and wholesalers continue to sell large quantities of Teva's product

2. Indeed, Teva sold *millions* of its tablets to wholesalers and retailers in violation of the preliminary injunction order and hundreds of thousands of Teva's tablets have been sold and continue to be sold to the public. *See* Declaration of Frank Dzvonik at ¶¶ 2-3. Abbott is suffering, and will continue to suffer, irreparable injury unless and until Teva's tablets are recalled from the market. Accordingly, Abbott seeks an emergency modification of the Court's Order to require Teva to immediately recall all of its generic clarithromycin extended release product from its customers.

II. BACKGROUND

3. Teva has admitted that on June 22, 2006, it began sales of its generic clarithromycin extended release product to at least ten of its customers, including Walgreen's, a major national retailer. *See* Exhibit B at 11, 14, 19. It is beyond dispute that such sales violated the express terms of Judge Coar's June 8, 2005 preliminary injunction order. *See* Exhibit C.

4. On the afternoon of Monday, June 26, 2006, Abbott filed an emergency motion to maintain the *status quo* under which Judge Coar's preliminary injunction against Teva prevents Teva from selling or offering to sell its generic clarithromycin extended release product. This Court conducted an emergency hearing following referral of Abbott's emergency motion to this Court. During the hearing, counsel for Teva confirmed in open court that Teva had commenced selling, distributing, and delivering its generic clarithromycin extended release product to at least ten of Teva's customers. *See* Ex. B at 11, 14, 19.

5. This Court then issued an Order noting that Teva "has stipulated in open court that it will comply with the preliminary injunction until the District Court's decision on the

emergency motion, and will notify its customers of its stipulation to comply with the preliminary injunction… with a copy of the preliminary injunction attached to the notice." *See* Exhibit D. The Court further ordered Teva to provide Abbott's counsel with a list of Teva's customers receiving that notice as well as the content of that notice, which was to be treated as Highly Confidential Information under the terms of the protective order. *Id.*

6. On July 12th, Judge Coar ruled as follows:

> I'm not, I am not touching the injunction until such time as I receive a mandate from the Federal Circuit. They have the perfect right to disagree with my decision, and I am bound to follow a final order of the Federal Circuit. But in the meantime I am not going to take their opinion – the opinion of the panel. It doesn't persuade me one way or the other. If I am bound, I am bound. But if I am not bound, I am not persuaded. So far as I'm concerned, *the injunction remains in effect*.

See Ex. A at 3-4 (emphasis added).

7. On July 13, 2006, Ted Dane, counsel for Abbott, contacted Jim Galbraith, counsel for Teva, to request that Teva immediately recall its generic clarithromycin extended release product from all of Teva's customers that have received such product. *See* Exhibit E. Mr. Dane noted that Abbott would seek emergency judicial relief in the event that Teva did not agree to recall its product immediately. *Id.*

8. Counsel for Teva finally responded to Mr. Dane's email at 11 a.m. EDT on July 14, 2006, but did not agree to recall Teva's product from its customers.

9. This Court's June 26, 2006 Order further noted that "[u]nless ordered otherwise by the District Judge either party [may] return to the Magistrate Judge for modification of this order for good cause."[1] Ex. D. In light of Judge Coar's ruling that the preliminary injunction remains valid and enforceable, the continued retail sales of Teva's product to the public, and

[1] Judge Coar also directed that "[a]ny emergency motions should go to the magistrate judge." Ex. A at 4.

Teva's refusal to recall its product, Abbott seeks modification of the Court's order to require Teva to immediately recall all of its generic clarithromycin extended release product that Teva sold in violation of the preliminary injunction order to restore the *status quo* and to prevent further irreparable harm to Abbott.

II. TEVA SHOULD BE ORDERED TO IMMEDIATELY RECALL ITS PRODUCT TO RETURN THIS CASE TO THE *STATUS QUO* AS IT EXISTED PRIOR TO TEVA'S VIOLATION OF THE PRELIMINARY INJUNCTION ORDER

10. In order to return the case to the *status quo* as it existed prior to Teva's violation of the preliminary injunction whereby there were to be no sales of Teva's generic clarithromycin extended release product and no Teva tablets on the market, this Court's Order should be modified to require Teva to immediately recall its generic clarithromycin extended release product from all of Teva's customers that purchased and received shipments of Teva's product. Absent such a modification of this Court's order, Abbott will continue to suffer irreparable harm.

11. At the July 12th hearing, Judge Coar rejected Teva's arguments regarding the impact of the mandate. *See* Ex. A at 4 ("You briefed it and I read it. I disagree with you."). Judge Coar ruled in open court that his preliminary injunction order against Teva remains in place unless and until the Federal Circuit's mandate issues.[2] *See id.* at 3-4. Because Abbott timely filed a petition for rehearing in the Federal Circuit on July 6, 2006, the mandate will not issue until the petition is resolved, or the Federal Circuit otherwise directs. *See* Fed. R. App. P. 41(b), (d). As a result, it is indisputable that Teva violated Judge Coar's preliminary injunction order.

[2] The July 12th hearing on Abbott's Emergency Motion to Enforce the Preliminary Injunction was attended by, among others, Teva counsel Jim Galbraith and Deanna Keysor. Although a written order has not yet been made available to the parties, a copy of the transcript has been attached as Exhibit A.

12. Despite this Court's June 26 Order, pursuant to which Teva's customers that had purchased and received Teva's product prior to the entry of the Order were provided with a copy of the preliminary injunction order and were notified of Teva's intent to comply with the preliminary injunction, Abbott has learned that some wholesalers and retailers have continued to sell Teva's product. *See* Dzvonik Decl. at ¶¶ 2-3. Indeed, Abbott has learned that millions of Teva's tablets were sold by Teva to retailers and wholesalers in violation of the preliminary injunction order and that hundreds of thousands of Teva's tablets have been sold and continue to be sold to the public. *Id.* Moreover, Abbott has learned that multiple retailers that previously had represented that they were not selling Teva's product are now selling Teva's product because other retailers or wholesalers are selling the product, which likely will cause sales of Teva's product to increase despite the preliminary injunction. *Id.* at ¶ 5. In addition, Abbott has been approached by more than one managed care company that has expressed an intent to lower Abbott's Biaxin® XL product from Tier 2 to Tier 3 on its formulary. *Id.* at ¶ 7.

13. Now that Judge Coar has ruled that his preliminary injunction order remains valid and enforceable, Ex. A at 3-4, Teva should be ordered to return matters to the *status quo* as it existed prior to Teva's violation of the preliminary injunction order. Under that *status quo*, Teva was prohibited from selling its generic clarithromycin extended release product, and thus there were no Teva tablets on the market. *See* Ex. C.

14. Because some retailers and wholesalers continue to sell Teva's product to consumers, an immediate recall of Teva's improperly sold product is both warranted and necessary as the most expedient manner in which to (a) fully restore the *status quo* as it existed prior to Teva's violation; and (b) prevent further irreparable harm to Abbott.

15. A recall order is firmly within this Court's jurisdiction as an appropriate remedy for violation of Abbott's intellectual property rights and for violation of Judge Coar's preliminary injunction order. *See Perfect Fit Indus., Inc. v. Acme Quilting Co.*, 646 F.2d 800, 805, 806 (2d Cir. 1981) (recognizing the broad power of federal courts to fashion appropriate relief; finding recall appropriate where infringing trade dress was likely to divert customers from plaintiff's products to defendant's); *The Tisket-A-Tasket Group, Inc. v. H.S. Craft Mfg. Co.*, 1999 U.S. Dist LEXIS 21090, at *2, 8 (S.D. Ind. Dec. 1, 1999) (ordering defendant to recall all infringing product from distributors and retail stores and noting that "[u]nfortunately, the preliminary injunction has not preserved the status quo" because defendant violated the injunction); *Cybermedia, Inc. v. Symantec Corp.*, 19 F. Supp. 2d 1070, 1078-79 (N.D. Cal. 1998) (requiring recall of infringing products already in the hands of distributors); *Gund v. Golden Bear Co., Ltd.*, 1992 U.S. Dist. LEXIS 18712, at *13-15 (S.D.N.Y. Dec. 10, 1992) (finding that recall was the only effective remedy where toys which infringed plaintiff's copyright were in the possession of K-Mart, a non-party to the action); *Cullman Ventures, Inc. v. Columbian Art Works, Inc.*, 1989 U.S. Dist. LEXIS 9432, at *7-13 (S.D.N.Y. July 28, 1989) (noting district court's jurisdiction to supervise the enforcement of its injunction and to preserve the status quo pending appeal; ordering defendant to send notice of recall to its customers); *Rohm & Haas Co. v. Cumberland Chem. Corp.*, 1983 U.S. Dist. LEXIS 19879, at *13-16 (S.D. Tex. Jan. 21, 1983) (ordering defendant to recall product preliminarily found to infringe plaintiff's patent).

16. Absent such a modification of the Court's order, Abbott will continue to be irreparably harmed. As noted above, hundreds of thousands of Teva's generic clarithromycin extended release tablets have been sold to the public despite the continuing validity and enforceability of the preliminary injunction order. Such sales are continuing and causing, and

will continue to cause, Abbott irreparable harm. *See* Dzvonik Decl. at ¶ 6. In addition, were one or more managed care companies to lower Abbott's Tier on their formulary, it would cause immediate and irreparable injury to Abbott. *Id.* at ¶¶ 7, 9. Indeed, the mere fact that at least one managed care company has threatened to take such action demonstrates that Abbott already is being irreparably harmed by the continued presence of generic Teva tablets in the marketplace. *Id.* at ¶ 9.

17. Moreover, Teva cannot be heard to complain of any hardship or difficulty in recalling its product, as this situation has been created solely by Teva's misconduct. Teva made the unilateral decision to disregard Judge Coar's injunction and to sell its product to its customers before the Federal Circuit's mandate issued. Indeed, Teva made the situation worse by purposefully refusing to respond to Abbott's repeated requests for confirmation of whether Teva had commenced sales of its product. *See* Abbott Laboratories' Emergency Motion For Enforcement of This Court's Preliminary Injunction Order Against Teva Pharmaceuticals USA, Inc. and For An Order to Show Cause at ¶¶ 9-13; Ex. B at 9-11, 14-15. Thus, because Teva violated the preliminary injunction order and exacerbated the situation by withholding information until massive quantities of Teva's product had been shipped to and received by Teva's customers, it is Teva's responsibility to immediately correct the wrong which it has caused and to return this case to the *status quo* that existed before Teva violated the preliminary injunction order.

18. Accordingly, Abbott submits that good cause has been shown for modification of the Court's Order to require Teva to immediately recall all of its generic clarithromycin extended release product sold to Teva's customers in violation of the preliminary injunction order.

19. In order to implement the recall and ensure Teva's immediate compliance, Abbott respectfully requests that the following procedures be followed: (1) Teva should be directed to immediately send recall notices to each of its customers that received its product, by fax or email, substantially in the form attached hereto as Exhibit F, and, in any event, by no later than midnight CDT, Friday, July 14, 2006; (2) Teva should be directed to certify in writing that it has sent the recall notices by filing and serving on Abbott an affidavit to that effect and by providing counsel for Abbott with a copies of each of the recall notices (with the customer-specific in said notices to be treated as Highly Confidential under the protective order) by 10 a.m. CDT on Saturday, July 15, 2006; and (3) Teva should be directed to file and serve upon Abbott, by no later than the close of business on Tuesday, July 18, 2006, a list or chart (to be treated as Highly Confidential under the protective order) containing the names of its customers that returned Teva's product, the date the return was received by Teva, the amount sold to each customer, and the amount returned to Teva by each customer. This list or chart should be updated periodically to reflect any additional returns of product.

III. CONCLUSION

For the reasons set forth above, Abbott respectfully requests that the Court grant its motion and enter an order modifying the Court's June 26, 2006 Order to require Teva to immediately recall all of its generic clarithromycin extended release product from all of Teva's customers that have purchased and received delivery of such product by following the procedures set forth in paragraph 19 above, including by issuing a recall notice substantially in the form set forth in Exhibit F. In addition, Abbott respectfully requests that the Court grant Abbott any other relief that it deems just and equitable.

Dated: July 14, 2006

Respectfully Submitted,

s/ Michael A. Flomenhoft
R. Mark McCareins
Todd J. Ehlman
Michael A. Flomenhoft
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
(312) 558-5600

Of Counsel
Jeffrey I. Weinberger
Ted G. Dane
Andrea Weiss Jeffries
MUNGER, TOLLES & OLSON LLP
355 South Grand Avenue
Los Angeles, California 90071
(213) 683-9100

Jennifer L. Polse
Jason A. Rantanen
MUNGER, TOLLES & OLSON LLP
560 Mission Street, 27th Floor
San Francisco, California 94105
(415) 512-4000

Lara M. Levitan
ABBOTT LABORATORIES – LEGAL DIVISION
100 Abbott Park Road
Abbott Park, IL 60064
(847) 935-2342

Attorneys for Abbott Laboratories

CERTIFICATE OF SERVICE

The undersigned, an attorney, hereby certifies under penalty of perjury that a copy of the foregoing **Abbott Laboratories' Emergency Motion To Modify This Court's June 26, 2006 Order To Compel Recall Of All Generic Clarithromycin Extended Release Product Sold By Teva Pharmaceuticals USA, Inc.**, was served on the following on July 14, 2006:

By Electronic Means and Email:	**By Federal Express and Email:**
Erik F. Dyhrkopp Deanna L. Keysor BELL, BOYD & LLOYD LLC Three First National Plaza 70 West Madison Street Suite 2900 Chicago, IL 60602-4207 (312) 372-1121 dkeysor@bellboyd.com *Attorneys for Teva Pharmaceuticals USA, Inc.*	James Galbraith Robert V. Cerwinski Cynthia Lambert Hardman KENYON & KENYON One Broadway New York, NY 10004 (212) 425-7200 *Attorneys for Teva Pharmaceuticals USA, Inc.*
Steven H. Sklar David M. Airan LEYDIG, VOIT & MAYER, LTD. Two Prudential Plaza 180 North Stetson Street Suite 4900 Chicago, IL 60601 (312) 616-5600 ssklar@leydig.com *Attorneys for Andrx Pharmaceuticals, Inc.*	Eric D. Isicoff ISICOFF, RAGATZ & KOENIGSBERG 1101 Brickell Avenue Suite 800, South Tower Miami, FL 33131 *Attorney for Andrx Pharmaceuticals, Inc.*
	Alan B. Clement Hedman & Costigan, P.C. 1185 Avenue of the Americas New York, NY 10036 (212) 302-8989 *Attorney for Andrx Pharmaceuticals, Inc.*

Dated: July 14, 2006 s/ Michael A. Flomenhoft