UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 1:16-cv-00308-TWP-MPB
	)	
DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC.,	)	
	)	
Defendants.	)	

ENTRY ON PLAINTIFF'S MOTION TO AMEND FINAL JUDGMENT

This matter is before the Court on Plaintiff Eli Lilly's ("Lilly") Motion to Amend Final Judgment. (Filing No. 244.) Also before the Court is Defendants Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s, (collectively, "Dr. Reddy's") Motion for Leave to File Surreply Brief. (Filing No. 250.) Lilly takes no position on Dr. Reddy's Motion for Leave to File Surreply. (Filing No. 251.) The Court **grants** Dr. Reddy's Motion, and has considered its Surreply.[1] For the reasons stated below, the Court determines that Lilly's Motion to Amend Final Judgment is **granted**.

I. BACKGROUND

On February 5, 2016, Lilly filed a Hatch-Waxman patent infringement action against Dr. Reddy's following Dr. Reddy's submission of a New Drug Application ("NDA") seeking approval to market a pemetrexed ditromethamine product. (Filing No. 1.) Lilly alleged that Dr. Reddy's product infringed upon its U.S. Patent No. 7,772,209 ("209 Patent") on its ALTIMA® cancer

[1] The Court agrees with Dr. Reddy's that new arguments were made in Lilly's Reply Brief, and therefore has considered Dr. Reddy's surreply to address these arguments. A party may seek leave from the court to file a surreply to address new matters argued in the reply brief. *Heckler & Koch, Inc. v. German Sport Guns GmbH*, No. 1:11-CV-1108-SEB-TAB, 2013 WL 2406262, at *3 (S.D. Ind. May 31, 2013).

chemotherapy product, which uses pemetrexed disodium. A bench trial was held beginning on February 1, 2018 and concluding on February 2, 2018.

On June 22, 2018, the Court entered a Final Judgment in favor of Lilly. (Filing No. 242.) The Court found that Dr. Reddy's product infringed Lilly's product under the doctrine of equivalents. The Final Judgment stated that, "Judgment is entered in favor of Plaintiff Eli Lilly & Co. and against Defendant Dr. Reddy's Inc. and this action is TERMINATED." *Id.* On June 27, 2018, Lilly filed the pending Motion to Amend Final Judgment (Filing No. 244) requesting an amendment which would provide particular relief as follows:

> 1. The filing of NDA No. 208297 infringed at least claims 9, 10, 12, 13, 14, 15, 18, 19, 21, and 22 of U.S. Patent No. 7,772,209.
>
> 2. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of any product that is the subject of NDA No. 208297 shall be not earlier than the latest date of expiration of U.S. Patent No. 7,772,209, including any period of pediatric exclusivity.
>
> 3. JUDGMENT IS ENTERED in favor of Lilly and against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

Filing No. 244-1. Dr. Reddy's objects to the Motion.

II. DISCUSSION

Dr. Reddy's asserts three bases for denying Lilly's Motion to Amend Final Judgment: 1) the amendment is unnecessary and would give Lilly an unjustified windfall; 2) the Court is not required to grant the relief sought by Lilly; 3) Lilly's enumeration of the asserted claims is inaccurate and overbroad. In turn, Lilly responds that the Hatch-Waxman Act requires this Court to amend the Final Judgment in accordance with Lilly's proposal. Lilly seeks to amend the Final Judgment to order resetting the effective date of approval of Dr. Reddy's product to a date not earlier than the date of the expiration of the patent which has been infringed (including pediatric exclusivity). (Filing No. 248 at 1.)

The relevant statute reads:

> (4) For an act of infringement described in paragraph (2)—
>
> > (A) the court *shall* order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
> >
> > (B) injunctive relief *may* be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,
> > ….

35 U.S.C. § 271(e)(4) (emphasis added). Relying on *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011 (N.D. Ill. 2003), Dr. Reddy's contends that 35 U.S.C. § 271(e)(4) "*permits* the Court to order delay of approval sought by Lilly but does not *require* the Court to do so." (Filing No. 247 at 2) (emphasis in original). Moreover, Dr. Reddy's asserts that because it has already agreed not to launch its product commercially until the expiration of the '209 Patent or a successful appeal, the Court need not grant Lilly any further relief. Lilly responds that the statutory language including the word "shall" requires that the Court reset the effective date of any approval, which is sufficient to resolve this case. The Court agrees. Although by the terms of the statute, injunctive relief is a discretionary remedy, resetting the effective date of approval is mandatory. The Federal Circuit has addressed this issue. "Accordingly, upon a finding of patent infringement under § 271(e)(2), the district court must order remedies in accordance with § 271(e)(4)." *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1138 (Fed. Cir. 2018). Lilly notes that the policy justification for this procedure is due to the fact that the Food and Drug Administration (the "FDA") is not a party to Hatch-Waxman patent litigation. Congress vested district courts with the role of ordering the FDA, as a non-party, to take action in compliance with the order when a proposed product is found to infringe. (Filing No. 248 at 6.) Because resetting

the effective date for approval is not a discretionary decision, the Court need not address Dr. Reddy's argument that the amendment is unnecessary and gives Lilly a windfall based on bureaucratic delay at the FDA.

Next, Dr. Reddy's argues that Lilly's enumeration of the asserted claims is inaccurate and overbroad because it includes additional claims that were not asserted against Dr. Reddy's by reciting the words "at least" before the enumerated claims. (Filing No. 247 at 3.) Lilly does not object to striking the words "at least" before the enumerated claims, but notes that dependent claims necessarily would also be found to have been infringed based on the interconnected relationships of the claims, regardless if the claims were not asserted at trial. The Court declines to strike the words "at least" from the amendment in an effort for consistency to parallel other judgments this Court has entered. Case No. 1:12-cv-00086-TWP-MPB, ECF 87 (Accord), ECF 98 (Apotex); Case No. 1:16-cv-00469-TWP-MPB, ECF 28 (Biocon); Case No. 1:14-cv-00104-TWP-MPB, ECF 45 (Glenmark); Case No. 1:16-cv-03460-TWP-MPB, ECF 94 (Hospira); Case No. 1:13-cv-01469-TWP-DKL, ECF 57 (Sun).

III. CONCLUSION

For the reasons stated above, the Court **GRANTS** Lilly's Motion to Amend Final Judgment (Filing No. 244) and **accepts** Lilly's proposed order (Filing No. 244-1). An amended entry of final judgment will follow in a separate order. The Court **grants** Dr. Reddy's Motion (Filing No. 250), and has considered its Surreply.

SO ORDERED.

Date: 7/27/2018

Tanya Walton Pratt

TANYA WALTON PRATT, JUDGE
United States District Court
Southern District of Indiana

DISTRIBUTION:

Anne N. DePrez
BARNES & THORNBURG LLP
(Indianapolis)
adeprez@btlaw.com

Jan M. Carroll
BARNES & THORNBURG, LLP
(Indianapolis)
jan.carroll@btlaw.com

Rory O'Bryan
HARRISON & MOBERLY (Indianapolis)
robryan@harrisonmoberly.com

Stephen E. Arthur
HARRISON & MOBERLY (Indianapolis)
sarthur@harrisonmoberly.com

Charles A. Weiss
HOLLAND & KNIGHT LLP
charles.weiss@hklaw.com

Jeffery B. Arnold
HOLLAND & KNIGHT LLP
jeffery.arnold@hklaw.com

Merri C Moken
HOLLAND & KNIGHT LLP
merri.moken@hklaw.com

Eric H. Yecies
HOLLANDS & KNIGHT LLP
eric.yecies@hklaw.com

Adam L. Perlman
WILLIAMS & CONNOLLY LLP
aperlman@wc.com

Alec T. Swafford
WILLIAMS & CONNOLLY LLP
aswafford@wc.com

Bruce Roger Genderson
WILLIAMS & CONNOLLY LLP
bgenderson@wc.com

Christopher T Berg
WILLIAMS & CONNOLLY LLP
cberg@wc.com

Galina I. Fomenkova
WILLIAMS & CONNOLLY LLP
gfomenkova@wc.com

David M. Krinsky
WILLIAMS & CONNOLLY, LLP
dkrinsky@wc.com

Dov P. Grossman
WILLIAMS & CONNOLLY, LLP
dgrossman@wc.com

Andrew Lemens
WILLIAMS & CONNOLLY LLP
alemens@wc.com

James P. Leeds
ELI LILLY AND COMPANY
jleeds@lilly.com

Charles E. Oswald, IV
HARRISON & MOBERLY
coswald@harrisonmoberly.com