

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION**

ELI LILLY AND COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No.: 1:10-CV-00346-SEB-DML
	)	
HOSPIRA, INC.	)	
	)	
Defendant.	)	

**STIPULATION AND ORDER**

Plaintiff Eli Lilly & Co. (Lilly), by and through its undersigned counsel of record, and Defendant Hospira, Inc. (Hospira), by and through its undersigned counsel of record, hereby stipulate, subject to Court approval, to entry of the following order:

1. This action was filed by Lilly on March 23, 2010, alleging that Hospira's solution product described in New Drug Application No. 200-795, seeking marketing approval from the Food and Drug Administration pursuant to 21 U.S.C. § 355(b), would infringe U.S. Patent Nos. 4,808,614 (“the ‘614 patent”) and 5,464,826 (“the ‘826 patent”). Based on Lilly's timely filing of the action, an automatic 30-month stay of FDA approval of Hospira's solution product is presently in effect pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).
  
2. On November 15, 2010, the '614 patent expired.
  
3. On November 12, 2010, the Federal Circuit issued its mandate in *Sun Pharmaceuticals Industries, Ltd. v. Eli Lilly & Co.*, Appeal No. 2010-1105, affirming the district court’s summary judgment of invalidity of the '826 patent. Lilly intends to file a petition for writ of certiorari to the United States Supreme Court seeking review of the Federal Circuit's decision.

4. Lilly is entering this stipulation to avoid any potentially unnecessary interference with the marketing of otherwise approvable gemcitabine products, without acquiescing in the propriety of the *Sun* judgment or its applicability as collateral estoppel, and without effect on any matters that remain pending in or controlled by *Eli Lilly & Co. v. Sicor Pharmaceuticals, Inc.*, No. 06-cv-238 (S.D. Ind.).

5. Upon the Court's signature below, the 30-month stay on Hospira's solution product is hereby terminated. The FDA may thus grant final approval to Hospira's solution product when it would otherwise, due to the existence of the stay, only tentatively approve such product.

6. Nothing in this stipulation or order shall prevent Lilly from seeking to have the stay reinstated should its petition for certiorari be granted before the FDA approves Hospira's solution product.

7. Nothing in this stipulation or order, or Lilly's acquiescence in its entry, shall constitute a waiver of any claim for damages or preliminary or permanent injunctive relief to which Lilly may otherwise be entitled, and may not be used by Hospira to argue that any such relief should be reduced or is inappropriate.

SO STIPULATED.

December 3, 2010

Respectfully submitted,

s/ Sally Franklin Zweig  
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*Counsel to Defendant Hospira, Inc.*

December 3, 2010

Respectfully submitted,

s/ Jan M. Carroll

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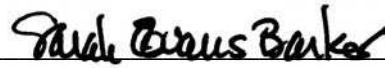
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*Counsel to Plaintiff Eli Lilly and Company*

**IT IS SO ORDERED.**

Date: 12/03/2010



SARAH EVANS BARKER, JUDGE  
United States District Court  
Southern District of Indiana

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