

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and	)	
AMGEN MANUFACTURING, LIMITED,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 15-839 (RGA)
	)	
HOSPIRA, INC.,	)	
	)	
Defendant.	)	
_____	)	

**MOTION FOR PRELIMINARY INJUNCTION**

Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (together, “Amgen”) move for a preliminary injunction to enjoin Defendant Hospira, Inc. from launching a biosimilar version of Amgen’s EPOGEN<sup>®</sup> (epoetin alfa) product until Hospira has complied with the requirement of 42 U.S.C. § 262(l)(8)(A), which states that “[t]he subsection (k) applicant shall provide notice to [Amgen] not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).”

The grounds for this Motion are fully set forth in Amgen’s opening brief in support of this Motion, the Declaration of John R. Labbé and exhibits thereto, the Declaration of Daniel Billen, and the Declaration of Eric M. Gaier, Ph.D. and exhibits thereto, filed contemporaneously herewith.

As reflected in its opening brief in support of this motion, Amgen has made a reasonable effort to reach agreement with Hospira on the subject matter set forth in this Motion, and the parties have been unable to reach agreement.

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Date: May 26, 2017

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and Amgen Manufacturing, Limited*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on May 26, 2017, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to registered participants, and further certify that I caused copies of the foregoing document to be served upon the following counsel in the manner indicated:

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Plaintiffs,	)	
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	)	
HOSPIRA, INC.,	)	
	)	
Defendant.	)	
_____	)	

**[PROPOSED] ORDER PRELIMINARILY ENJOINING  
HOSPIRA FROM COMMERCIAL MARKETING  
OF ITS PROPOSED BIOSIMILAR EPOETIN PRODUCT**

WHEREAS, the Court having considered Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited’s (together, “Amgen”) Motion for a Preliminary Injunction (the “Motion”) and the parties’ submissions and arguments in support of the Motion and in opposition thereto; and

WHEREAS, good cause having been shown for the relief sought in the Motion;

IT IS HEREBY ORDERED this \_\_\_\_\_ day of \_\_\_\_\_, 2017 that Amgen’s Motion is GRANTED.

IT IS FURTHER ORDERED that:

1. If the U.S. Food and Drug Administration (“FDA”) licenses a biosimilar epoetin product that is the subject of abbreviated Biologics License Application No. 125545 (“the licensed biosimilar epoetin product”), Hospira, Inc. (“Hospira”) must provide Amgen written notice on or after the date that FDA issues the license and at least 180 days before the date of first commercial marketing of the licensed biosimilar epoetin product. 42 U.S.C. § 262(l)(8)(A).

2. Hospira, its officers, agents, servants, employees, and attorneys, and other persons who are in active concert or participation with them including, for example, Pfizer Inc. and Vifor (International) Ltd., are enjoined from any commercial marketing of the licensed epoetin biosimilar product, including offering for sale, selling, or commercial use of the licensed epoetin biosimilar product in the United States, until the date that is no earlier than 180 days after Hospira provides Amgen the post-licensure notice required under 42 U.S.C. § 262(l)(8)(A), as described in paragraph (1).

3. This injunction shall remain in full force and effect unless and until modified by a further order of this Court.

4. Amgen is not required to post a bond.

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THE HONORABLE RICHARD G. ANDREWS  
UNITED STATES DISTRICT JUDGE