

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

CUMBERLAND PHARMACEUTICALS	)	
INC.,	)	
	)	
Plaintiff,	)	NO. 1:12-CV-03846
	)	
v.	)	JUDGE REBECCA PALLMEYER
	)	
MYLAN INSTITUTIONAL LLC, and	)	MAGISTRATE JUDGE MARIA
	)	VALDEZ
MYLAN INC.,	)	
	)	
Defendants.	)	
_____	)	

**JOINT STIPULATION OF INFRINGEMENT**

Plaintiff Cumberland Pharmaceuticals Inc. (“Cumberland”) and defendants Mylan Institutional LLC and Mylan Inc. (collectively “Mylan”), appearing through counsel, hereby state that:

WHEREAS Mylan filed Abbreviated New Drug Application No. 203624 with the Food and Drug Administration (“FDA”) under 21 U.S.C. § 355(j), to obtain approval for the commercial manufacture, use and sale of Acetylcysteine, Injectable; Intravenous, 200mg/ml (“Mylan Acetylcysteine Intravenous”);

WHEREAS Cumberland has asserted that the filing of Mylan’s ANDA No. 203624 infringes Cumberland’s U.S. Patent No. 8,148,356 (“’356 patent”) and U.S. Patent No. 8,399,445 (“’445 patent”) under 35 U.S.C. § 271(e)(2)(A), and that the commercial manufacture, use and sale of the Mylan Acetylcysteine Intravenous product will infringe the ’356 patent and the ’445 patent under 35 U.S.C. § 271(a), (b);

WHEREAS the Court has construed certain claims of the '356 patent and the '445 patent in its claim construction opinion and order (D.I. 187);

WHEREAS Mylan objects to the Court's claim construction opinion and order (D.I. 187);

WHEREAS in the interest of streamlining this litigation and the issues for trial, the parties desire to forgo litigating the issue of whether or not the commercial manufacture, use, offer to sell, sale, or importation of the product described in Mylan's ANDA No. 203624 would infringe claims 2 and 14 of the '356 patent or claims 1-14 of the '445 patent under 35 U.S.C. §§ 271(a) and/or (b) under the Court's claim construction opinion (D.I. 187) dated February 26, 2014;

IT IS HEREBY STIPULATED by the parties, subject to the approval of the Court, that the following facts and issues are undisputed and admitted for purposes of this action:

1. Without prejudice to any other claim or defense Mylan has in this action, Mylan stipulates and agrees as follows:
  - a. Mylan will not assert before this Court or on appeal that the commercial manufacture, use, sale, offer for sale, or importation of the product described in Mylan's ANDA No. 203624 does not or would not infringe claims 2 and 14 of the '356 patent or claims 1-14 of the '445 patent under 35 U.S.C. §§ 271(a) and/or (b) under the Court's claim construction opinion (D.I. 187) dated February 26, 2014. Mylan retains the right to assert in this Court or on appeal that it is not liable for infringing any such claim if any such claim is found to be

unenforceable or invalid under the Patent Laws of the United States,  
35 U.S.C. § 100 *et seq*;

b. Mylan consents to the entry of a judgment in this action that Mylan's submission of ANDA No. 203624 to the FDA constitutes infringement of the '356 and '445 patents under 35 U.S.C. § 271(e)(2)(A) to the extent that any one of the claims 2 and 14 of the '356 patent or any one of the claims 1-14 of the '445 is not found to be unenforceable or invalid under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*; and

c. Mylan consents to the entry of a judgment in this action that the commercial manufacture, use, sale, offer for sale or importation of the product described in Mylan's ANDA No. 203624, or inducement of or contribution to any such conduct, does and would infringe claims 2 and 14 of the '356 patent and claims 1-14 of the '445 patent under 35 U.S.C. §§ 271(a), (b) under the Court's claim construction opinion (D.I. 187) dated February 26, 2014, to the extent that any such claim is not found to be unenforceable or invalid under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

2. Mylan makes this stipulation without prejudice or waiver of its rights to appeal the Court's February 26, 2014, Claim Construction Order (D.I. 187).



**CERTIFICATE OF SERVICE**

The undersigned certifies that on August 4, 2014, a true and correct copy of **JOINT STIPULATION OF INFRINGEMENT** was filed with the Clerk of the Court using the Electronic Case Filing (ECF) system, which will send notification of such filing via electronic mail to the following counsel of record:

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