

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

MERCK SHARP & DOHME LLC,	X	:	
	:	:	
Plaintiff,	:	:	
	:	:	C.A. No. 1:19-cv-00101-IMK
v.	:	:	
	:	:	
MYLAN PHARMACEUTICALS INC.,	:	:	
	:	:	
Defendant.	:	:	

**STIPULATED MODIFIED AMENDED FINAL JUDGMENT**

**THIS MATTER** having come before the Court upon the Complaint of Plaintiff Merck Sharp & Dohme LLC (“Merck”) alleging that Defendant Mylan Pharmaceuticals Inc. (“Mylan”) infringed United States Patent No. 7,326,708 (“the ’708 Patent”) and United States Patent No. 8,414,921 (“the ’921 Patent”), and with Counterclaims filed by Mylan seeking a judgment of invalidity and noninfringement;

**WHEREAS** following a bench trial before this Court, the Court, on September 21, 2022, entered a Final Judgment (ECF No. 194) and amended on September 29, 2022 (ECF No. 197), in favor of Merck;

**WHEREAS** subsequent to the entry of the Final Judgment, the parties have entered into a settlement agreement dated March 14, 2023 (the “Settlement Agreement”);

**WHEREAS** the parties have jointly moved the Court to amend its Final Judgment pursuant to Federal Rule Civil Procedure 60(b), and for good cause shown by the parties, the Order is amended as follows:

**IT IS ORDERED** that the *Amended Final Judgment* (ECF No. 197) is vacated;

**ORDERED AND ADJUDGED** that Final Judgment shall be entered in favor of Plaintiff and against Defendant; and it is further

**ORDERED AND ADJUDGED** that, pursuant to the provisions of 35 U.S.C. § 271(e)(4)(B), Mylan, its officers, agents, servants, employees and attorneys, and those persons acting in privity or in active concert with Mylan, are enjoined, unless otherwise permitted pursuant to the terms of the Settlement Agreement, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States (to the extent such activities are not protected by 35 U.S.C. § 271(e)(1)), of the drug products that are the subject of Mylan's ANDA No. 202473 until the expiration of the '708 Patent; and it is further

**ORDERED AND ADJUDGED** that, pursuant to the provisions of 35 U.S.C. § 271(e)(4)(B), Mylan, its officers, agents, servants, employees and attorneys, and those persons acting in privity or in active concert with Mylan, are enjoined, unless otherwise permitted pursuant to the terms of the Settlement Agreement, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States (to the extent such activities are not protected by 35 U.S.C. § 271(e)(1)), of the drug products that are the subject of Mylan's ANDA No. 202478 until the expiration of the '708 Patent and the '921 Patent; and it is further

**ORDERED** that the stay of approval under 21 U.S.C. § 355(j)(5)(B)(iii) is terminated. Nothing herein prevents the U.S. Food and Drug Administration from granting final approval to ANDA Nos. 202473 and 202478 at any time.

**ORDERED AND ADJUDGED** that the Clerk be and is hereby directed to enter forthwith this Amendment to the Order upon the Civil Docket.

Dated: May 2, 2023

  
UNITED STATES DISTRICT COURT JUDGE

We hereby consent to the form and entry of this Order:

/s/ Michael W. Carey  
*Attorneys for Plaintiff*  
*Merck Sharp & Dohme LLC*

/s/ Gordon H. Copland  
*Attorneys for Defendant*  
*Mylan Pharmaceuticals Inc.*