



April 14, 2017

**VIA CM/ECF & HAND DELIVERY**

The Honorable Gregory M. Sleet  
United States District Judge  
District of Delaware  
844 N. King Street, Unit 19  
Wilmington, DE 19801

**Re: Genentech, Inc. v. Amgen Inc., D. Del., C.A. No. 17-165-GMS**

Dear Judge Sleet:

On behalf of Genentech, Inc., we write with respect to the Court's March 1, 2017 Order (D.I. 16) granting without prejudice Amgen Inc.'s oral motion to dismiss the Complaint for lack of subject matter jurisdiction in light of *Amgen Inc. v. Sandoz, Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), *cert. granted*, 2017 WL 125661 (2017), and granting Genentech forty-five days leave to amend.

We write to advise the Court that Genentech will not be filing an amended Complaint. We believe it is more efficient for the Court and the parties to address both the patent merits and Amgen's continued noncompliance with its statutory production obligations, see 42 U.S.C. § 262(l)(2), after the Supreme Court's expected decision in June in *Amgen v. Sandoz*. Amgen, the innovator company in that case, has argued that a wide range of equitable remedies is available to enforce compliance with § 262(l)(2), including among other things an injunction on commercial marketing of an applicant's biosimilar product until the parties complete the "patent dance" in the manner the BPCIA directs. The consequences of, and remedies available for, Amgen's noncompliance with § 262(l)(2) should be more clear after the Court's decision.

The Supreme Court also will be ruling on when a biosimilar applicant may provide the 180-day notice of its intent to launch its biosimilar product required by 42 U.S.C. § 262(l)(8)(A). The Federal Circuit held that Sandoz, the biosimilar maker, could only provide such notice following FDA approval. *Sandoz*, 794 F.3d at 1358. Whether the Supreme Court affirms that ruling will determine when Amgen may provide its 180-day notice in this matter. The timing of that notice also may significantly impact the timing and scope of patent litigation between the parties.

For these reasons, Genentech respectfully requests that the Court enter the attached Proposed Judgment dismissing the present Complaint without prejudice.

We thank the Court for its continued attention to this matter.

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Respectfully submitted,

*/s/ Michael P. Kelly*

Michael P. Kelly (ID #2295)

MPK/tmp

cc: Daniel M. Silver, Esq. (via email)  
Paul B. Gaffney, Esq. (via email)  
Melanie K. Sharp, Esq. (via email)  
Siegmond Y. Gutman, Esq. (via email)

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

GENENTECH, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
AMGEN INC.	)	C.A. No. 17-165-GMS
	)	
Defendant.	)	
	)	

**[PROPOSED] JUDGMENT**

IT IS this \_\_\_\_ day of \_\_\_\_\_ 2017,

ORDERED, ADJUDGED AND DECREED as follows:

The complaint (D.I. 1 in C.A. No. 17-165-GMS) is dismissed, without prejudice, pursuant to Federal Rule of Civil Procedure 12(b)(1).

SO ORDERED:

\_\_\_\_\_  
United States District Judge