

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 17:cv-01006 (RDM)
	)	
THOMAS E. PRICE, M.D.,	)	
in his official capacity as SECRETARY,	)	
UNITED STATES DEPARTMENT OF HEALTH	)	
AND HUMAN SERVICES,	)	
	)	
and	)	
	)	
SCOTT GOTTLIEB, M.D.,	)	
in his official capacity as	)	
COMMISSIONER OF FOOD AND DRUGS,	)	
FOOD AND DRUG ADMINISTRATION,	)	
	)	
Defendants.	)	

~~RDM PROPOSED~~ STIPULATED ORDER

Upon consideration of Plaintiff Amgen Inc.'s Motion for TRO and/or preliminary injunction, Defendants' opposition, Amgen's reply, the arguments of counsel, the stipulation of the parties, and the entire record in this case, good cause having been found, it is hereby

STIPULATED, AGREED, and ORDERED, that FDA will accept resubmission of Amgen's May 25, 2017 request for dispute resolution on June 5, so long as that request is substantially similar to Amgen's May 25, 2017 request; and it is further

STIPULATED, AGREED, and ORDERED, that FDA's acceptance of this request will be in accordance with the timelines for reconsideration and dispute resolution set out in FDA's letter to Amgen on June 1, 2017, entitled Conditional Acceptance – Formal Dispute Resolution

Request. FDA's reconsideration decision will be made by June 26; should reconsideration uphold the May 22, 2017, decision, Amgen shall respond to the reconsideration decision by July 3, 2017; and FDA shall issue a decision on dispute resolution by August 2, 2017; and it is further

STIPULATED, AGREED, and ORDERED, that if Amgen's study reports are deemed accepted, FDA will update the Orange Book to reflect pediatric exclusivity on the first business day following the acceptance; and it is further

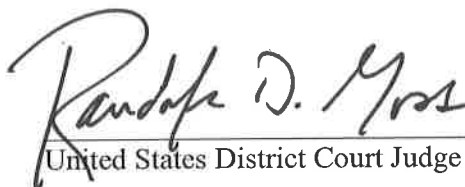
STIPULATED, AGREED, and ORDERED, that this case shall be stayed until further order of this Court, or until 7 days following completion of the aforementioned dispute resolution process, whichever comes first; and it is further

STIPULATED, AGREED, and ORDERED that, for the reasons cited in Defendants' Opposition to Amgen's Motion for TRO, any future decision requiring FDA to accept Amgen's study reports for Sensipar (cinacalcet) under 21 U.S.C. § 355a(d)(3), whether made by FDA or by a court of law, shall be deemed to relate back, *nunc pro tunc*, to May 22, 2017, the date of FDA's initial determination; and it is further

STIPULATED, AGREED, and ORDERED that, based on the foregoing, Amgen's Motion for TRO is currently moot.

SO ORDERED:

Dated: 6/5/17

  
United States District Court Judge

Copies to:

Catherine E. Stetson  
Susan M. Cook  
HOGAN LOVELLS US LLP  
555 Thirteenth Street, N.W.

Washington, D.C. 20004

Charles J. Biro  
Consumer Protection Branch  
Civil Division  
DEPARTMENT OF JUSTICE  
P.O. Box 386  
Washington, D.C. 20044

Thomas E. Price, M.D.  
Secretary  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
200 Independence Ave., S.W.  
Washington, D.C. 20201

Scott Gottlieb, M.D.  
Commissioner  
FOOD AND DRUG ADMINISTRATION  
10903 New Hampshire Ave.  
Silver Spring, MD 20993