




UNITED STATES PATENT AND TRADEMARK OFFICE

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MEMORANDUM

DATE: January 10, 2024

TO: All Patent Examiners

FROM: Vaishali Udupa 
Commissioner for Patents

SUBJECT: Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in *Amgen Inc., et al. v Sanofi et al.*

The purpose of this memorandum is to announce that a Federal Register Notice (notice) has published which explains USPTO practice for assessing enablement compliance in utility applications and patents in view of the May 18, 2023 decision by the Supreme Court (Court) in *Amgen Inc., et al. v Sanofi et al.* (*Amgen*). The Court's decision addressed whether a claim directed to a functionally defined genus complied with the enablement prong of 35 U.S.C. 112(a). The Court held that the specification must enable the full scope of the invention as defined by its claims.

The enablement prong refers to the requirement of 35 U.S.C. 112(a) that the specification must describe the claimed invention in such terms that one skilled in the art can make and use the claimed invention. As discussed in section 2164.01 of the MPEP, determining compliance with the enablement prong involves an analysis of whether the disclosure in an application of a claimed invention contained sufficient information regarding the subject matter of the claimed invention such that one skilled in the pertinent art can make and use the claimed invention without undue experimentation. The USPTO currently uses the *Wands* factors in order to determine whether the experimentation required is undue.

This notice states that consistent with *Amgen* and recent Federal Circuit decisions citing *Amgen*, USPTO personnel, regardless of technology area, will continue to use the *Wands* factors to make enablement determinations by ascertaining whether the experimentation required to enable the full scope of the claimed invention is reasonable or undue. While the notice does not change USPTO practice, the notice serves to raise stakeholders' awareness regarding the USPTO's interpretation of *Amgen* and provides a reminder to examiners to continue to utilize the *Wands* factors when determining compliance with the enablement prong of 35 U.S.C. 112(a).

A copy of the notice can be found here: [112\(a\) Notice 89 FR 1563 \(01/10/2024\)](#).