

No. 21-757

In the
Supreme Court of the United States

AMGEN INC., AMGEN MANUFACTURING LIMITED, and
AMGEN USA, INC.,

Petitioners,

v.

SANOFI, AVENTISUB LLC,
REGENERON PHARMACEUTICALS INC., and
SANOFI-AVENTIS U.S., LLC,

Respondents.

**On Petition for Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit**

BRIEF IN OPPOSITION

MATTHEW M. WOLF
VICTORIA L. REINES
ARNOLD & PORTER
KAYE SCHOLER LLP
601 Massachusetts Ave., NW
Washington, DC 20001
(202) 942-5000

GEORGE W. HICKS, JR.
Counsel of Record
NATHAN S. MAMMEN
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave., NW
Washington, DC 20004
(202) 389-5000
george.hicks@kirkland.com

(Additional counsel listed on inside cover)
Counsel for Respondents

March 14, 2022

DAVID K. BARR
DANIEL L. REISNER
ARNOLD & PORTER
KAYE SCHOLER LLP
250 W. 55th Street
New York, NY 10019

DEBORAH FISHMAN
ARNOLD & PORTER
KAYE SCHOLER LLP
3000 El Camino Real
Five Palo Alto Square, Ste 500
Palo Alto, CA 94306

QUESTIONS PRESENTED

1. Whether enablement, an issue of patent validity, is a question of law based on underlying findings of fact, as the Federal Circuit holds and this Court has consistently held with respect to issues of patent validity.

2. Whether the lower court erred in applying long-established Federal Circuit law to the undisputed relevant evidence in this case in determining that no reasonable jury could conclude that the patents are enabled.

CORPORATE DISCLOSURE STATEMENT

Respondent Sanofi has no parent corporation, and no publicly held company owns 10% or more of its stock. Sanofi is the indirect parent corporation of Respondents sanofi-aventis U.S. LLC and Aventisub LLC.

Respondent Regeneron Pharmaceuticals, Inc. has no parent corporation, and no publicly held company owns 10% or more of its stock.

TABLE OF CONTENTS

QUESTIONS PRESENTED..... i
CORPORATE DISCLOSURE STATEMENT..... ii
TABLE OF AUTHORITIES..... v
INTRODUCTION..... 1
STATEMENT OF THE CASE 3
 A. Factual Background..... 3
 B. The Patents-In-Suit..... 4
 C. Proceedings Below..... 5
 1. First Trial and Appeal 6
 2. Second Trial..... 7
 3. The Second Appeal 11
REASONS FOR DENYING THE PETITION 14
I. The First Question Presented Does Not
Warrant This Court’s Review 14
 A. The Federal Circuit’s Treatment of
 Enablement Is Consistent With This
 Court’s Precedents..... 14
 B. The Question Presented Is of Insufficient
 Importance to Warrant Certiorari..... 20
 C. This Case Is an Exceptionally Poor
 Vehicle to Address the Question
 Presented..... 24
II. The Second Question Presented Does Not
Warrant This Court’s Review 29
 A. The Federal Circuit Did Not “Create[] a
 Special Test” for Enablement of
 Functional Genus Claims..... 29

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.