

Enablement & Written Description Requirements in a *Post-Amgen* World

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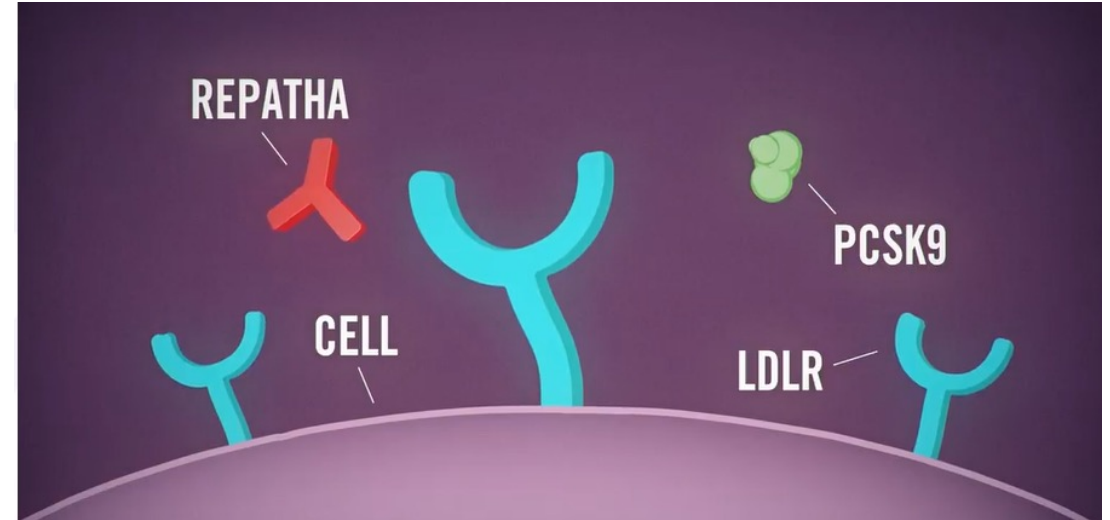
Stanford Law School

Stanford Program in
Law, Science & Technology

Advanced Patent Law Institute

Amgen v. Sanofi

U.S. Patent No. 8,829,165



1. An isolated monoclonal antibody,
wherein, when bound to PCSK9,

the monoclonal antibody **binds to at least one of the following residues:**
S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378,
F379, V380, or S381 of SEQ ID NO:3,

and **wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.**

Amici support in *Amgen*

- 30 briefs
 - 9 in favor of petitioner, Amgen
 - 5 in favor of neither party
 - 16 in favor of respondent, Sanofi
- Innovator pharma
 - 4 for Amgen (including Biogen, BMS, Merck, GSK, AbbVie)
 - 1 for neither party (Regenexbio Inc., IGM Biosciences, Adaptive Phage Therapeutics)
 - 4 for Sanofi (including Eli Lilly, Pfizer, Genentech, AstraZeneca, Bayer, Gilead, J&J, smaller biotechs)
- Law professors
 - 1 brief with 14 professors for Amgen
 - 3 briefs with 14 professors collectively for Sanofi
- Legal organizations
 - 1 for Amgen (National Association of Patent Practitioners)
 - 2 for neither party (IP Law Association of Chicago, NYIPLA)
 - 2 for Sanofi (AIPLA, Public Interest Patent Law Institute)
- Other
 - American Chemical Society and Alliance of U.S. Startups for Amgen
 - Solicitor General, generic pharma, Association for Accessible Medicines, and a group of scientists led by Sir Gregory Paul Winter for Sanofi