
***Amgen Inc. v. Sanofi*, No. 21-757**

Introduction: Today, in a unanimous decision, the Supreme Court held that Amgen Inc.’s patents for an entire genus of antibodies did not satisfy the Patent Act’s enablement requirement, because those patents did not enable others to make the full range of claimed antibodies. Rejecting Amgen’s argument that it had provided a roadmap sufficient to enable others to create all the claimed antibodies, the Court clarified that a patent for a broad class of inventions must enable others to make the whole class without undue experimentation.

Background: Enablement is a key requirement for a valid patent under the Patent Act. The patent must describe a claimed invention specifically enough to enable others skilled in the relevant art to make and use the invention. In this case, Sanofi argued that two of Amgen’s patents failed to meet the enablement requirement. The patents at issue claimed an entire genus of antibodies, defined by their function of binding to specific amino acids. Amgen’s patents identified 26 examples of these antibodies along with a “roadmap” for how to create others through experimentation. When Amgen sued Sanofi for infringement, Sanofi argued that Amgen’s patents were invalid because they did not enable others to make the full range of the genus of antibodies claimed by those patents. Both the district court and the Federal Circuit ruled for Sanofi.

Issue: Whether the Patent Act requires a patent for a class of inventions to enable others to make every invention in the class.

Court’s Holding: In a unanimous opinion written by Justice Gorsuch, the Supreme Court ruled for Sanofi, holding that Amgen’s patents failed the enablement requirement. The Court clarified that a patent for an entire class of inventions must enable others to make and use the entire class. Amgen claimed patents broadly for “an entire universe of antibodies,” but failed to describe the claimed class with enough specificity to enable the creation of all such antibodies. The Court observed that a valid patent may require others to engage in some adaptation or testing to be able to make the patented invention. But the Court concluded that the guidance in Amgen’s patents for creating the relevant antibodies failed to meet that enablement threshold, amounting to little more than instructing others to engage in open-ended trial and error.

The Court’s decision reaffirms the importance of the enablement requirement as a safeguard against overly broad functional patent claims, which claim a general class of inventions as defined by what they are able to do.

Mayer Brown filed an *amicus* brief in support of Sanofi on behalf of Unified Patents, LLC. That *amicus* brief argued that overbroad patent claims for a functionally defined genus (such as Amgen’s) impede innovation in a range of fields and urged the Court to apply the enablement requirement to the full scope of the patent claims.

Read the opinion [here](#).