

United States of America

“Amgen v. Sanofi”

Decision of the Supreme Court of the United States

18 May 2023 – Case No. 21-757

Amgen Inc. et al. v. Sanofi et al.

Patent Act, §112

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Keywords Infringement · Enablement requirement · Human medicinal product · Antibodies · Person skilled in the art · Patent bargain · Statutory enablement standard

1. If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent’s specification must enable a person skilled in the art to make and use the entire class. I.e. the specification must enable the scope of the invention as defined by its claims.
2. A specification must not always describe with particularity how to make and use every single embodiment within a claimed class (an example will suffice). Nor is a specification necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing.
3. A specification may call for a reasonable amount of experimentation to make and use a claimed invention, and reasonableness in any case will depend on the nature of the invention and the underlying art.
4. Enablement is not measured against the cumulative time and effort it takes to make every embodiment within a claim.
5. There is (only) one statutory enablement standard – the more a party claims for itself, the more it must enable.

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