Biologics & Biosimilars – Section 112 at the Supreme Court

February 7, 2023

NYIPLA Hybrid Event at Kramer Levin

Amgen v. Sanofi (Supreme Court)

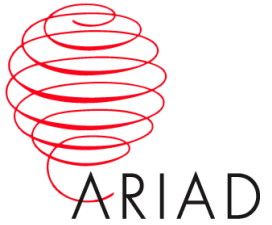
Question Presented:

- Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, 35 U.S.C. § 112, or whether it must instead enable those skilled in the art "to reach the full scope of claimed embodiments" without undue experimentation-i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial '"time and effort.'"

Ariad v. Lilly (Fed. Cir. 2010) (*en banc*)

The specification shall contain

- ***a written description of the invention***, ***and***
- ***of the manner and process of making and using it***, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.



Ariad v. Lilly (Fed. Cir. 2010) (*en banc*) – Separate WD Requirement

- Written description is a ***separate and distinct requirement*** from enablement

- For a genus claim, written description requires either:

  "[1] a ***representative number of species*** falling within the scope of the genus; ***or***

  [2] ***structural features common to the members of the genus*** so that one of skill in the art can 'visualize or recognize' the members of the genus"

Pharma United in 2010

No Separate WD Requirement

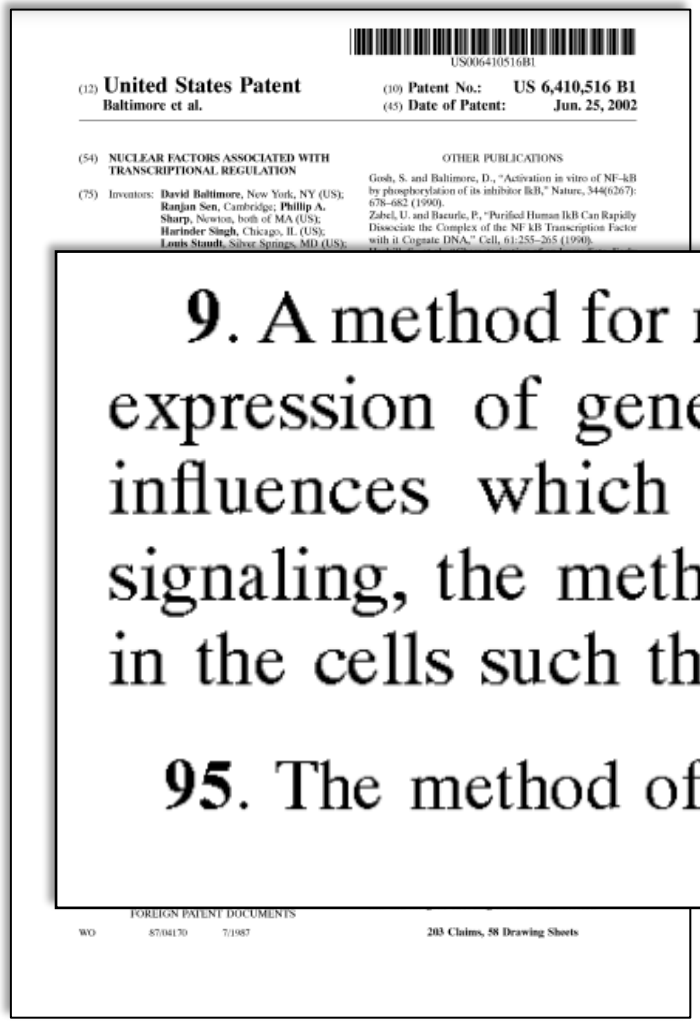
- Ariad

Separate WD Requirement

- Abbott
- Amgen
- Eli Lilly
- GSK
- Medtronic
- Monsanto
- PTO / United States

* Tech also in support (Google, Cisco, Verizon, Microsoft)

Ariad v. Lilly (Fed. Cir. 2010) – Functional Genus Claims



US006410516B1

(12) **United States Patent**
Baltimore et al.

(10) **Patent No.: US 6,410,516 B1**
(45) **Date of Patent: Jun. 25, 2002**

(54) **NUCLEAR FACTORS ASSOCIATED WITH TRANSCRIPTIONAL REGULATION**

(75) Inventors: **David Baltimore**, New York, NY (US); **Ranjan Sen**, Cambridge; **Phillip A. Sharp**, Newton, both of MA (US); **Harinder Singh**, Chicago, IL (US); **Louis Staudt**, Silver Springs, MD (US);

OTHER PUBLICATIONS

Gosh, S. and Baltimore, D., "Activation in vitro of NF-kB by phosphorylation of its inhibitor IkB," Nature, 344(6267): 678–682 (1990).
Zabel, U. and Baeurle, P., "Purified Human IkB Can Rapidly Dissociate the Complex of the NF kB Transcription Factor with it Cognate DNA," Cell, 61:255–265 (1990).

FOREIGN PATENT DOCUMENTS

WO 87/04170 7/1987

203 Claims, 58 Drawing Sheets

9. A method for reducing, in eukaryotic cells, the level of expression of genes which are activated by extracellular influences which induce NF-κB-mediated intracellular signaling, the method comprising reducing NF-κB activity in the cells such that expression of said genes is reduced.

95. The method of claim **9**, carried out on human cells.

ARIAD

Lilly

Ariad v. Lilly (Fed. Cir. 2010) – Functional Genus Claims

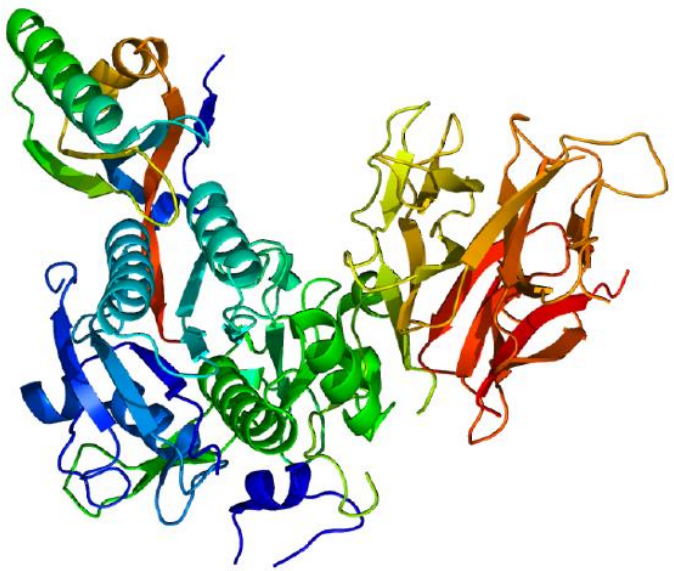
- "[I]t is [] important to ensure that [] innovation is not preempted by those who … only describe a problem and attempt to claim in a patent any or all solutions to the problem."

- "Real innovation requires solutions… ***[I]ndeterminate and unbounded claims of invention can stifle future innovation*** just as much as the failure to protect patentable inventions."

Amgen's Amicus Brief

Amgen v. Sanofi (Fed. Cir. 2017) – Functional Ab Claims

- Innovator v. Innovator (antibody litigation)
- Sanofi/Regeneron developed and patented Praluent®
- Amgen developed and patented Repatha™
- Praluent and Repatha both inhibit PCSK9, thereby reducing LDL cholesterol
- Amgen claimed a genus of antibodies that bind to particular residues of PCSK9 and block binding of PCSK9 to the LDL receptor (*i.e.*, claims require two functions)



PCSK9

Amgen v. Sanofi (Fed. Cir. 2017) – Functional Ab Claims

- "The newly-characterized antigen test posits that the hypothetical claim '***antibodies*** that bind to antigen X' is adequately described under 35 U.S.C. § 112 when ***antigen X*** is adequately described. This test does not require a description of the claimed composition (the antibodies), but instead requires only a description of unclaimed subject matter (the antigen). As such, the test is inconsistent with § 112's mandate to describe the claimed invention."
- "Judicial review and repudiation of the Antibody Exception is appropriate."

Lilly's Amicus Brief

Amgen v. Sanofi (Fed. Cir. 2017) – Functional Ab Claims

- "Section 112 requires a 'written description of the invention.' But [**the newly characterized antigen test**] **allows patentees to claim antibodies by describing something that is not the invention, i.e., the antigen**. The test thus contradicts the statutory 'quid pro quo' of the patent system …"
- The Federal Circuit abrogated the so-called "newly characterized-antigen" test for antibodies, holding that it "flouts basic legal principles of the written description requirement."

Amgen v. Sanofi (Supreme Court) – Functional Ab Claims

- Amgen filed a petition for cert. in July 2018; BMS & UCB file amicus in support
- Question presented:

  > Whether the standard for determining the adequacy of the "written description of the invention" should be as the statute says—that the description must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains * * * to make and use the same"—or whether court-created standards should control instead.

- Supreme Court denied cert. in January 2019

Pharma Divide

No Separate WD Requirement

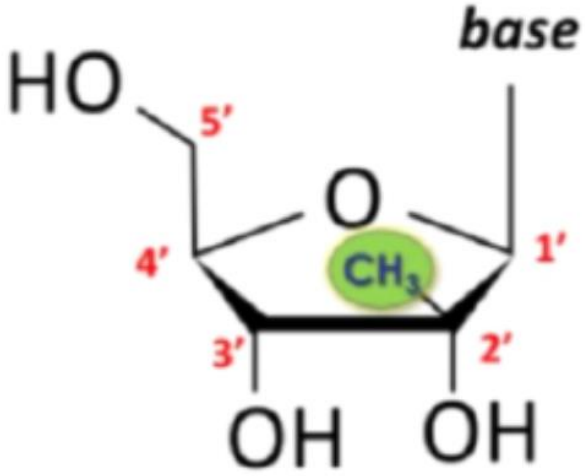
- Amgen
- Biogen
- BMS
- GSK
- Idenix / Merck
- UCB

Separate WD Requirement

- Eli Lilly
- Gilead
- J&J
- Pfizer
- Regeneron
- Sanofi

Idenix v. Gilead (Fed. Cir. 2019) – Chemical Genus Claims

- Idenix filed a suit against Gliead's Sovaldi®, a treatment for hepatitis C virus (HCV)
- Idenix's patent claims a **method of treating HCV** by administering a genus of 2'-methyl-up nucleoside compounds; the claim encompasses many substituents at the 2' down position
- Idenix argued that the key to its invention, and to treatment of HCV, is the use of 2'-methyl-up nucleosides, which are nucleosides "having a methyl substitution ('CH3') at the 2' 'up' position of the molecule's sugar ring."



Idenix v. Gilead (Fed. Cir. 2019) – Chemical Genus Claims

- Gilead stipulated to infringement; the jury found the patent valid and awarded $2.54 billion in damages
- Court granted JMOL on lack of enablement; denied JMOL for lack of WD
- Fed. Cir. affirmed no enablement and **held the patent also lacked WD**
  - The patent did not disclose a 2'-methyl-up 2'-fluoro-down nucleoside (as in Gilead's Sovaldi), including in any formulas or examples. Idenix came up with this embodiment a year after its patent application was filed.

Idenix v. Gilead (Supreme Court)

- Idenix filed for cert. in Sept. 2020; Amgen & GSK filed amicus briefs in support
- Questions Presented:

    1) Whether, as the Federal Circuit has held, a genus claim is not enabled "as a matter of law" if it encompasses a large number of compounds—or whether, as this Court has recognized, enablement is a context-specific jury question; and

    2) Whether, as the Federal Circuit has held, § 112(a) contains a separate "possession" requirement—or whether, as the statute provides, § 112(a) sets forth a single substantive requirement of "a written description of the invention" sufficient "to enable any person skilled in the art … to make and use the same."

- The Supreme Court denied cert. in January 2021

Amgen v. Sanofi (continued)

D. Del. February 2019

- On remand, jury found three claims valid
- Judge Andrews denied JMOL for lack of WD but granted JMOL that claims lacked enablement

Fed. Cir. February 2021

- Federal Circuit affirmed JMOL of non-enablement and did not reach WD
- Federal Circuit denied *en banc* rehearing in June 2021

Supreme Ct. November 2021

- Petition for cert. filed Nov. 18, 2021
- United States urged Supreme Court to deny cert. on Sept. 21, 2022
- Court granted cert. on Nov. 4, 2022

Amgen v. Sanofi (Supreme Court)

Questions Presented:

1) Whether enablement is "a question of fact to be determined by the jury," Wood v. Underhill, 46 U.S. (5 How.) 1, 4 (1846), as this Court has held, or "a question of law that [the court] review[s] without deference," as the Federal Circuit holds.
2) Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, 35 U.S.C. § 112, or whether it must instead enable those skilled in the art "to reach the full scope of claimed embodiments" without undue experimentation-i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial "'time and effort.'"

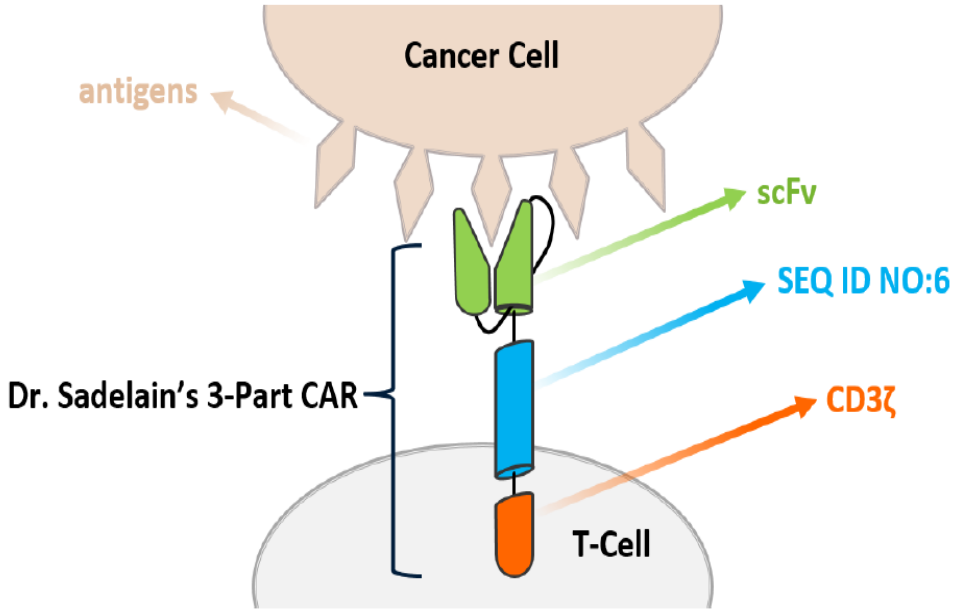
Amgen v. Sanofi (Supreme Court)

"Amgen *agrees* that, under § 112, patentees must enable skilled artisans to make and use individual embodiments across 'the full scope of a patent's claims.'"

Amgen's Supplemental Brief

Juno v. Kite (Fed. Cir. 2021) – CAR-T Genus Claims

- Juno asserted its CAR-T patent against Kite's Yescarta® which treats B-cell lymphomas and leukemias by targeting CD19 antigen
- Patent covered three-part CAR:
  - Signaling domain (CD3ζ)
  - Costimulatory signaling domain (CD28)
  - Binding element (scFv)



Juno v. Kite (Fed. Cir. 2021) – CAR-T Genus Claims

C.D. Cal.
December 2019

- Jury found asserted claims valid and willfully infringed
- District court denied Kite's motion for JMOL (including lack of WD)
- Juno was awarded over $1.2 billion in a final judgment

Fed. Cir.
August 2021

- Reversed; verdict not supported by substantial evidence as to WD; did not reach enablement
- 2 examples was not a representative number of species
- General knowledge of scFvs was insufficient

Supreme Ct.
June 2022

- Petition for cert. filed June 13, 2022

Juno v. Kite (Supreme Court)

- Question Presented:

  Is the adequacy of the ‘’written description of the invention’’ to be measured by the statutory standard of ‘’in such full, clear, concise and exact terms as to enable any person skilled the art to make and use the same,’’ or is it to be evaluated under the Federal Circuit’s test, which demands that the ‘’written description of the invention’’ demonstrate the inventor’s ‘’possession’’ of ‘’the full scope of the claimed invention,’’ including all ‘’known and unknown’’ variations of each component?

- Cert. denied Nov. 7, 2022 (3 days after grant of cert. in *Amgen*)
- Pet. for rehearing filed Nov. 23, 2022 requesting stay pending *Amgen*
- Supreme Court denied rehearing on Jan. 9, 2023