§112 enablement and written description: The future of genus claims and functional claiming

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35 U.S.C. § 112(a)

(a) In General.— 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.

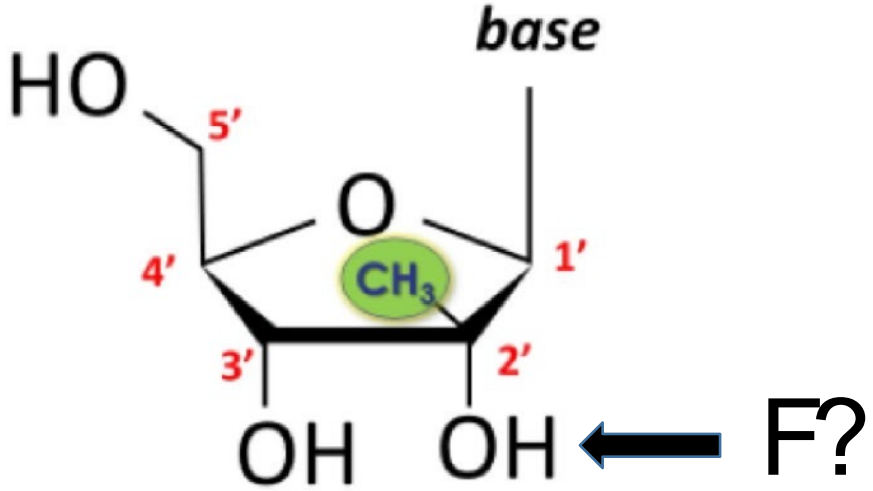
Ariad Pharm., Inc. v. Eli Lilly & Co.
598 F.3d 1336 (Fed. Cir. 2010) (*en banc*)

- Confirmed that "§ 112, first paragraph, contains a written description requirement separate from enablement"
- "The problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that achieve that result."

Idenix Pharm. v. Gilead Sci.

941 F.3d 1149 (Fed. Cir. 2019)

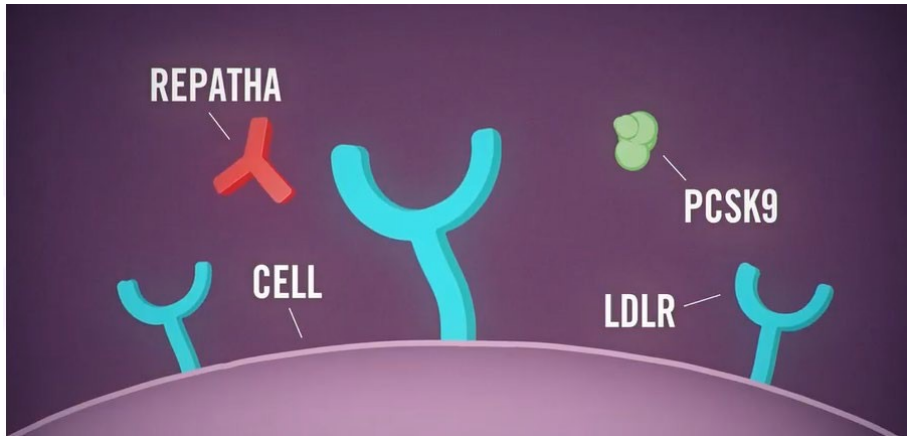
1. A method for the treatment of a hepatitis C virus infection, comprising administering an effective amount of a purine or pyrimidine β-D-2'-methyl-ribofuranosyl nucleoside or a phosphate thereof, or a pharmaceutically acceptable salt or ester thereof.



Idenix Pharm. v. Gilead Sci.
941 F.3d 1149 (Fed. Cir. 2019)

- Split panel affirmed JMOL of invalidity for lack of enablement because "[t]he immense breadth of screening required to determine which 2'-methyl-up nucleosides are effective against HCV can only be described as undue experimentation."
- Majority also found lack of written description because the specification "fails to provide sufficient blaze marks to direct a POSA to a specific subset of 2'-methyl-up nucleosides that are effective in treating HCV."
- 2′-fluoro-down is "conspicuously absent" from the specification, especially since the seven (out of eighteen) explicitly disclosed formulas that permit 2′-methyl-up all list fluorine as a possible substituent at other positions, but not at 2′-down.
- Majority agreed with Judge Newman's dissent that if construed more narrowly, the claims "might well be enabled and the accused product would not infringe."

Amgen v. Sanofi (Amgen I)
872 F.3d 1367 (Fed. Cir. 2017)



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**.

Amgen v. Sanofi (Amgen I)
872 F.3d 1367 (Fed. Cir. 2017)

- Remanded for new trial on written description and enablement
- Rejected jury instruction suggesting that a patentee may claim antibodies by describing the antigen: "In the case of a claim to antibodies, the correlation between structure and function may also be satisfied by the disclosure of a newly characterized antigen by its structure, formula, chemical name, or physical properties if you find that the level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against such an antigen was conventional or routine."
- SCOTUS denied Amgen's petition for *certiorari* challenging CAFC's separate written description and enablement requirements

Amgen v. Sanofi (Amgen II)
987 F.3d 1080 (Fed. Cir. 2021)

- Affirmed JMOL of invalidity for lack of enablement
- "…the use of broad functional claim limitations raises the bar for enablement, a bar that the district court found was not met."
- "…this invention is in an unpredictable field of science with respect to satisfying the full scope of the functional limitations."
- CAFC denied *en banc* review in a per curiam opinion but Judge Lourie authored a separate opinion on the denial of the petition for panel rehearing: "Amgen argues that we have created a new test for enablement. That is incorrect."

Bayer Healthcare LLC. v. Baxalta, Inc. et al.
989 F.3d 964 (Fed. Cir. 2021)

1. An isolated polypeptide conjugate comprising

a functional factor VIII polypeptide and one or more biocompatible polymers,

wherein the functional factor VIII polypeptide comprises the amino acid sequence of SEQID NO: 4 or an allelic variant thereof and has a B-domain, and

further wherein the biocompatible polymer comprises polyalkylene oxide and is covalently attached to the functional factor VIII polypeptide at the B-domain.

Bayer Healthcare LLC. v. Baxalta, Inc. et al.
989 F.3d 964 (Fed. Cir. 2021)

- Affirmed JMOL of enablement, following a jury verdict of enablement
- "Bayer presented substantial evidence from which a reasonable juror could find that the specification's disclosure of instructions as to the reaction conditions required to practice the claimed invention using cysteine PEGylation were sufficient to enable not only non-random cysteine PEGylation at the B-domain, but also non-random lysine PEGylation at the B-domain."
- "the 'novel aspect' of the asserted claims is non-random PEGylation at the B-domain 'does not mean the specification must disclose an embodiment for non-random pegylation at each amino acid in the B-domain."

Pacific Biosciences of California, Inc. v. Oxford Nanopore Technologies

996 F.3d 1342 (Fed. Cir. 2021)

1. A method for sequencing a nucleic acid template comprising,

a) providing a substrate comprising a nanopore in contact with a solution, the solution comprising a template nucleic acid above the nanopore;

b) providing a voltage across the nanopore;

c) measuring a property which has a value that varies for N monomeric units of the template nucleic acid in the pore, wherein the measuring is performed as a function of time, while the template nucleic acid is translocating through the nanopore, wherein N is three or greater; and

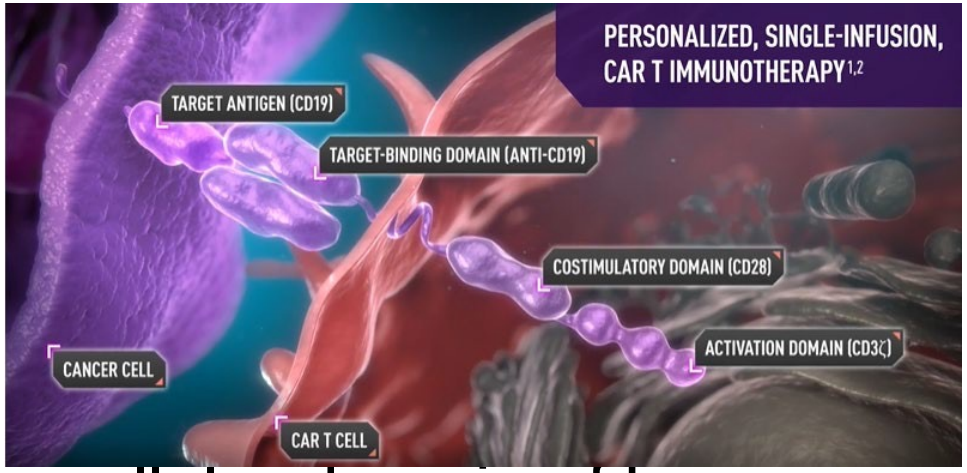
d) determining the sequence of the template nucleic acid using the measured property from step (c) by performing a process including comparing the measured property from step (c) to calibration information produced by measuring such property for 4 to the N sequence combinations.

Pacific Biosciences of California, Inc. v. Oxford Nanopore Technologies

996 F.3d 1342 (Fed. Cir. 2021)

- Affirmed JMOL of non-enablement, following a jury verdict of non-enablement
- "relevant artisans did not know how to perform nanopore sequencing for more than a narrow range of the full scope of nucleic acids covered by the asserted claims"
- Testimony that "the first successful nanopore sequencing of biological DNA molecules . . . did not occur until 2011."
- "Notably, PacBio had no evidence of actual reduction to practice of its own that would undermine Oxford's evidence of non-enablement."

Juno Therapeutics, Inc. v. Kite Pharma, Inc.
10 F.4th 1330 (Fed. Cir. 2021)



1. A nucleic acid polymer encoding a chimeric T cell receptor,

said chimeric T cell receptor comprising

(a) a zeta chain portion comprising the intracellular domain of human CD3 ζ chain,

(b) a costimulatory signaling region, and

(c) a binding element that specifically interacts with a selected target, wherein the costimulatory signaling region comprises the amino acid sequence encoded by SEQ ID NO:6.

Juno Therapeutics, Inc. v. Kite Pharma, Inc.
10 F.4th 1330 (Fed. Cir. Aug. 26, 2021)

- Reversed the ~$1.2B judgment against Kite
- "We agree with Kite that no reasonable jury could find the '190 patent's written description sufficient demonstrates that the inventors possessed the full scope of the claimed invention."
- "The disclosure of one scFv that binds to CD19 and one scFv that binds to a PSMA antigen on prostate cancer cells in the manner provided in this patent does not provide information sufficient to establish that a skilled artisan would understand how to identify the species of scFvs capable of binding to the limitless number of targets as the claims require."

Indivior UK Ltd. v. Dr. Reddy's Labs. S.A.
Nos. 2020-2073, 2020-2142 (Fed. Cir. Nov. 24, 2021)

- Split panel affirmed the Board's decision invalidating most of the challenged claims because Indivior was not entitled to claim priority to an earlier application
- Judge Linn concurred-in-part and dissented-in-part, opining that claim 8's recited 48.2% was not the only polymer weight percentage disclosed in the original application because other ranges were adequately supported by disclosures of "at least 25%" and "at least 50%" (which could be restated as ranges of 25-100% and 50-100%)

Biogen Int'l Gmbh v. Mylan Pharms. Inc.
No. 2020-1933 (Fed. Cir. Nov. 30, 2021)

- Split panel affirmed the district court's judgment of invalidity for lack of written description
- Specification disclosed effective doses in ranges of 100-1,000 mg/day, 200-800 mg/day, 240-720 mg/day, 480-720 mg/day, and 720 mg/day
- Judge O'Malley dissented, opining that the "blaze marks" precedent does not apply here because the specification "lacks a laundry list disclosure" and in any event, 480 mg/day was explicitly disclosed

Morphosys AG v. Janssen
358 F. Supp.3d 354 (D. Del. Jan. 28, 2019)

- Granted SJ of no enablement, reasoning "the full scope of a claim is not enabled when there is an embodiment within the claim's scope that a person of ordinary skill, reading the specification, would be unable to practice without undue experimentation"
- Case settled before appeal

Lipocine Inc. v. Clarus Therapeutics, Inc. 2021 WL 2210068 (D. Del. Jun. 1, 2021)

- Granted SJ of no written description
- Specification lists 55 examples, but "the first 47 'examples' consist simply of a listing of 49 TU [testosterone undecanoate] formulations" and only the last eight report results of clinical tests
- Held that the specification lacked a sufficient number of representative species to show that the inventor has possession of the broad genus claims, i.e., "the blaze marks are confined to a few trees at one edge of the forest"

Developing the Evidence on Functional Claims

NUMBER OF POTENTIAL EMBODIMENTS

- Variable parts of the molecule?
  - Nucleoside bases
  - Amino acid sequences
  - Prodrugs
- Human or animal sources?
- What is the scope of the independent v. dependent claims?
- How many examples are in the patent?

INACTIVE EMBODIMENTS

- What portion of embodiments are active?
- Does the embodiment become inactive when paired with the wrong delivery mechanism?
- Does the patent disclose inactive embodiments
  - Are they identified as inactive?

UNPREDICTABILITY

- How many embodiments did the patentee make? Others in the field?
- Is there a theory about which embodiments work?
  - Is that theory disclosed in the patent?
- How different are the effective embodiments from each other?

TESTING FOR EFFICACY

- Are sample compounds available in a library?
  - If not, how hard is it to make embodiments?
- How long and complex is the testing/screening?

35 U.S.C. § 112(f)

(f) Element in Claim for a Combination.— An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Williamson v. Citrix Online, LLC
792 F.3d 1339 (Fed. Cir. 2015) (*en banc*)

- Overruled previous "strong" presumption that claims lacking the word "means" are not subject to § 112(f) to address the "proliferation of functional claiming untethered to [§ 112(f)] and free of the strictures set forth in the statute"
- Found "distributed learning control" module limitation subject to § 112(f) (overriding panel decision) and invalid for lack of corresponding structure

Post-*Williamson*

- Lack of "strong presumption" against applying 112(6) makes it easier to argue indefiniteness at claim construction, but…
- *Williamson-based* 112(6) arguments are still frequently rejected by district courts
- No mass invalidation because of *Williamson*
- Impact on patent case volumes likely much lower than, e.g., *Alice* or IPR

Rain Computing, Inc. v. Samsung Elecs. Am., Inc.
989 F.3d 1002 (Fed. Cir. 2021)

1. A method for providing software applications through a computer network based on user demands, the method comprising:

accepting, through a web store, a subscription of one or more software application packages from a user;

sending, to the user, a user identification module configured to control access of said one or more software application packages, and coupling the user identification module to a client terminal device of the user;

a server device authenticating the user by requesting subscription information of the user from the user identification module through the computer network;

Rain Computing, Inc. v. Samsung Elecs. Am., Inc. 989 F.3d 1002 (Fed. Cir. 2021)

Holdings:

- Section 112(6)/(f) terms can be nested in method claims where they are used to describe the structure that performs the claimed method
- "Module" is a well-known nonce word
- "User identification" does not add structure, it only describes the function of the module, to identify a user
- "User identification module" has no commonly understood meaning and is not used in the field to connote a particular structure
- The specification does not mention the term, much less its structure

Dyfan, LLC v. Target Corp., No. W-19-CV-00179-ADA, 2020 U.S. Dist. LEXIS 250950 (W.D. Tex. Nov. 24, 2020)

○ **Representative term**: Term 14 from Joint Statement ("said code, when executed, further configured to . . . after the first visual information is caused to be output based on the first location-relevant information; after the at least one mobile device is moved in the building; and in response to the receipt, from the at least one server and via the second wireless communications protocol, of the second response message including the second location-relevant information: cause to be output, via the at least one mobile device, the second visual information based on the second location-relevant information")

○ **Representative term**: Term 10 from Joint Statement ("said application, when executed, further configured to cause the at least one mobile device to . . . in response to the receipt, from the at least one server and via the another wireless communications protocol, of the response message including the particular location-relevant information; control, utilizing the application, the one or more mobile device application actions of the application including causing to be output, via the at least one mobile device, the mobile device application visual information based on the particular location-relevant information")

○ **Representative term**: Term 28 from Joint Statement ("the system is configured such that the subsequent output of the different visual information is capable of being caused without additional user input after the user input")

○ **Representative term**: Term 24 from Joint Statement ("the system is configured such that the visual information is automatically caused to be output without requiring further communication with the at least one broadcast short-range communications unit, after the receipt of the indication of the receipt of the one or more messages")

Dyfan, LLC v. Target Corp., No. W-19-CV-00179-ADA, 2020 U.S. Dist. LEXIS 250950 (W.D. Tex. Nov. 24, 2020)

Holdings:

- Rebuttable presumption applies
- Claim recites only a function the code performs, plus some conditions for when it is performed
- Code is therefore defined only by function is performs
- Fact that claims also recited a "computer" did not change the outcome
- Claim is invalid because there is no corresponding structure

Dyfan, LLC v. Target Corp., No. W-19-CV-00179-ADA, 2020 U.S. Dist. LEXIS 250950 (W.D. Tex. Nov. 24, 2020)

- "Application configured to" construed the same as "code configured to"
  - Parties did not treat the terms differently
- Court conclusions for "system …configured" claims:
  - Claims do not specify which part of the system performs the recited function
  - Effectively makes the "system" a black box
  - No corresponding structure in claim for performing the recited function