Navigating Patent Invalidity Challenges & Best Practices for Proactively Preventing Attacks

May 13, 2022

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Your Presenters

Arpita Bhattacharyya, Ph.D., Partner
Finnegan

Elizabeth Haanes, Ph.D., SVP, Intellectual Property
IGM Biosciences

Eric Lin, Senior Patent Counsel
Genentech

Jeffrey Smyth, Partner
Finnegan

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Enablement Under Section 112

35 U.S.C. § 112:

> "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 . . . **to make and use** the same . . ."

Enablement Under Section 112

Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080 (Fed. Cir. 2021)

Claim:

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.

Enablement Under Section 112

Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080 (Fed. Cir. 2021)

- "The purpose of the enablement requirement is to ensure that the public is told how to carry out the invention, i.e., to make and use it."
- "We have held that such disclosure must be 'at least commensurate with the scope of the claims.'"
- "[A] challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation.' "

Enablement Under Section 112

Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080 (Fed. Cir. 2021)

"What emerges from our case law is that the enablement inquiry for claims **that include functional requirements** can be particularly focused on the breadth of those requirements, especially where predictability and guidance fall short. In particular, **it is important to consider the quantity of experimentation that would be required to make and use**, not only the limited number of embodiments that the patent discloses, but also **the full scope of the claim**."

Enablement Under Section 112

Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080 (Fed. Cir. 2021)

- "[W]e are not concerned simply with the number of embodiments but also with their functional breadth. . . .[I]t is clear that the claims are far broader in functional diversity than the disclosed examples."
- "[T]he **use of broad functional claim limitations** raises the bar for enablement, a bar that the district court found was not met."
- "[E]ven assuming that the patent's 'roadmap' provided guidance for making antibodies with binding properties similar to those of the working examples, no reasonable factfinder could conclude that there was adequate guidance beyond the narrow scope of the working examples that the patent's 'roadmap' produced."

Enablement Under Section 112

En Banc Petition Denied

> "What is new today is not the law, but generic claims to biological materials that are not fully enabled. **Enablement is required, even for generic claims to biological materials.** But, as with genus claims to chemical compounds, if they encompass more subject matter than just a few species, they need to be enabled accordingly. **Biological compositions not actually prepared need to be described constructively**, if required to enable the full scope of the claims, **with procedures and names of resultant compositions**, as with chemical compositions."

Amgen Inc. v. Sanofi, Aventisub LLC, 850 F. App'x 794, 795–96 (Fed. Cir. 2021)

Enablement Under Section 112

Cases Decided Since *Amgen*

Baxalta Inc. v. Genentech, Inc., 2022 WL 420479 (D. Del. Jan. 13, 2022):

- "*Amgen*'s reasoning applies with equal force here, where the asserted claims also set forth not one but two functional requirements."

Pacific Biosciences of California, Inc. v. Oxford Nanopore Techs., Inc., 996 F.3d 1342, 1352 (Fed. Cir. 2021):

- "[W]e think that the record supports the legal conclusion that the disclosures of the . . . patents, even when combined with knowledge of relevant artisans, required undue experimentation to enable the full scope of the relevant claims."

Enablement Under Section 112

Takeaways

- Attempting to claim antibodies in solely functional terms is likely to trigger a high burden to establish enablement
  - Focus on describing the antibody itself as thoroughly as possible
  - Include both structural and functional limitations in claims
  - Have diverse claims with varying levels of claim scope
- The issue is not limited to antibody claims and may reflect a broader trend in the law
- In litigation, the issue often will come down to the undue experimentation analysis and how much trial and error is required

Doctrine of Equivalents

“[A] patentee may invoke this doctrine to proceed against the producer of a device ‘if it performs substantially the same function in substantially the same way to obtain the same result.’”

– Graver Tank & Mfg. Co. v. Linde Air Prod. Co., 339 U.S. 605, 608 (1950)

The Supreme Court has acknowledged the tension between the disclosure requirements of §112 and allowing infringement claims to move forward when there is no literal infringement.

– *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997)

Doctrine of Equivalents

Ajinomoto Co. v. Int'l Trade Comm'n, 932 F.3d 1342 (Fed. Cir. 2019)

- Claims covered e. coli bacteria genetically engineered to increase their production of aromatic L-amino acids, such as L-tryptophan, during fermentation, as well as methods of producing aromatic L-amino acids using such bacteria.
- One of the asserted claims recited a specific amino acid sequence that corresponded to a specific e.coli gene.
- The Federal Circuit affirmed a finding of infringement by a product that did not include the specific sequence, but included the gene from a non-e.coli source, under the doctrine of equivalents
- Equivalence was proved by the function-way-result test

Doctrine of Equivalents

Jennewein Biotechnologie v. ITC, 2021 WL 4250784 (Fed. Cir. Sept. 17, 2021)

Claims covered a method of producing a fucosylated oligosaccharide in a bacterium using:

(i) a deletion or functional inactivation of an endogenous β-galactosidase gene; and

(ii) an exogenous functional β-galactosidase gene . . .

- Accused products did not include a complete β-galactosidase gene, but comprised gene fragments that produced β-galactosidase when expressed together
- The combination of gene fragments was found to be equivalent to the "exogenous functional β-galactosidase gene" claim limitation

The Federal Circuit affirmed the decision

Subject Matter Eligibility

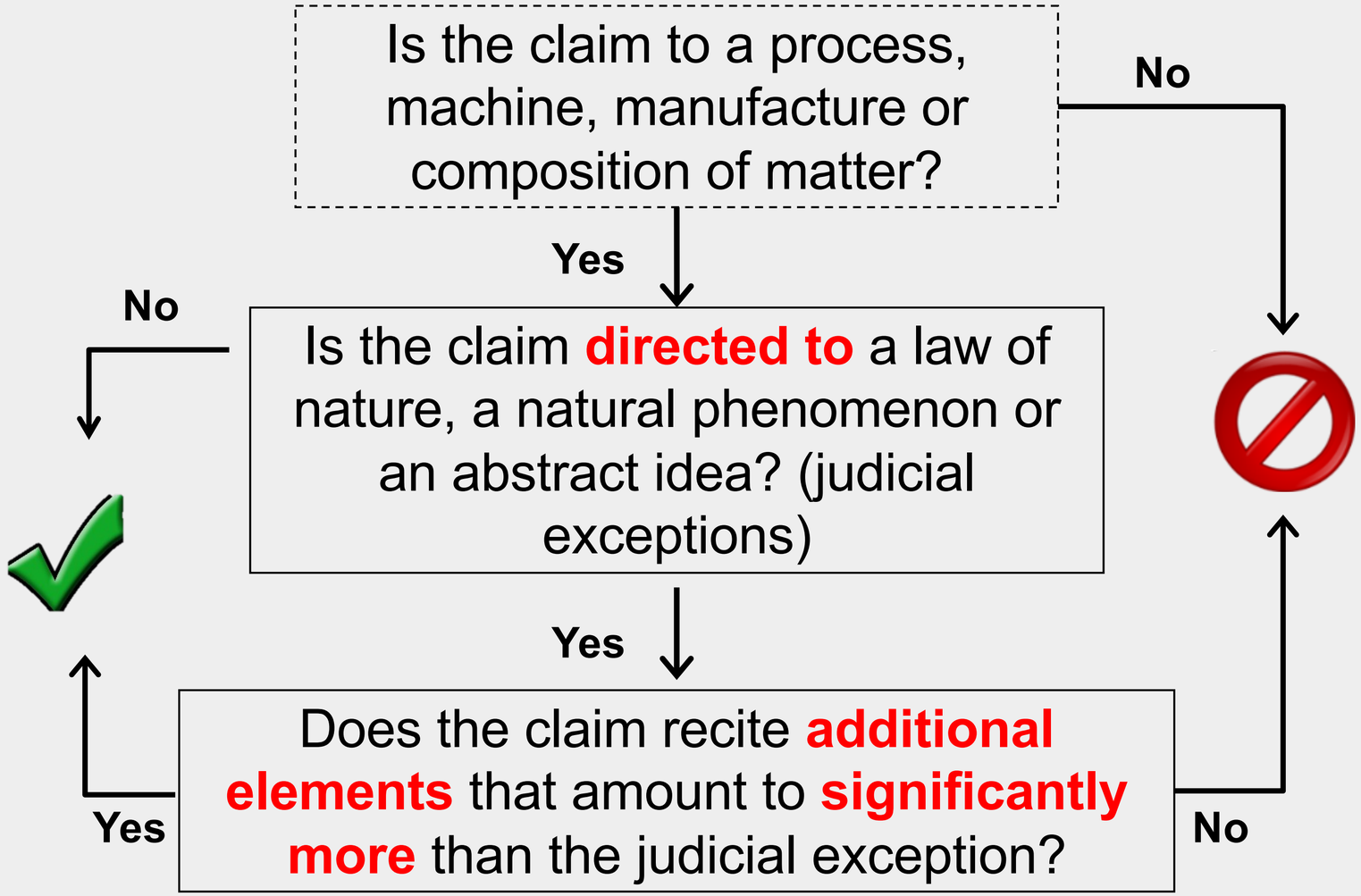
35 U.S.C. § 101

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

Judicial Exceptions:

- abstract ideas
- products of nature
- laws of nature or natural phenomena

Subject Matter Eligibility



Subject Matter Eligibility

- **Products of Nature**
  - Generally cannot claim products that occur naturally in nature
- **Diagnostic Methods**
  - Claims to diagnostic methods directed primarily to a correlation that exists in nature and/or relate to a natural phenomenon, are often not patent eligible
- **Methods of Treatment**
  - Claims to methods of treatment often are often found to be patent-eligible
- **Methods of Preparation**
  - Other claims to methods that exploit the discovery of a natural phenomenon can be patentable

Subject Matter Eligibility

General Tips for Avoiding/Overcoming §101 Issues

- Draft the specification to avoid/overcome §101 issues
- Support and claim a variety of invention categories
- Be strategic when choosing which claims to prosecute first
- Balance § 101 and § 112 requirements
- In prosecution, be prepared to explain:
  - How the claims compare those found allowable
  - How the combination of elements transforms the natural phenomena
  - Why the elements cited are not routine
  - How the invention is an improvement over the prior art

Subject Matter Eligibility

When Litigating §101 Issues

- Consider timing of when to file a § 101 motion
- What fact or expert testimony is needed concerning whether additional claimed elements are routine or conventional?
- What cases or USPTO examples are most analogous?

Questions?