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Patently Enabled April 2025 – Written Description in Life Sciences Patents: Avoiding Overreach

Key Takeaways

- The written description requirement remains a critical and often contentious issue in life sciences patent law.
- Courts continue to scrutinize broad genus claims that lack sufficient structural detail and representative species.
- Recent case law reinforces the need to align claim scope with what is actually disclosed.
- Careful drafting and strategic disclosure are essential to avoid written description challenges.

The written description requirement is a critical and often contentious issue in life sciences patent law. In biotechnology and pharmaceutical patents, meeting this requirement can be particularly challenging due to the complexity and unpredictability of biological inventions. Because courts and patent offices worldwide continue to refine what is necessary to satisfy written description obligations, it is crucial for inventors and practitioners to stay informed.

Under 35 U.S.C. § 112(a), a patent must contain a written description of the invention that is sufficient to demonstrate that the inventor had possession of the claimed invention at the time of filing. This requirement ensures that an applicant does not claim more than what was actually invented and disclosed. In the life sciences context, the difficulty often lies in describing biological molecules, genetic sequences, and complex therapeutic mechanisms with enough specificity to support the full scope of the claims.

Recent case law has underscored these challenges, particularly with respect to broad genus claims. In Amgen v. Sanofi (2023), the Supreme Court reinforced the difficulty of securing broad genus claims in biotech patents. The case centered on patents covering monoclonal antibodies that inhibit PCSK9, a target for lowering cholesterol. The Court found that Amgen's patent did not provide sufficient guidance for how to make and use all claimed antibodies, highlighting that merely describing a few examples is often insufficient for the written description and enablement; thus, the patent was held invalid.

This decision emphasizes the importance of structural characterization and representative species in biotech patent applications. Simply claiming a function, such as “antibodies that bind to PCSK9,” without providing a diverse set of well characterized embodiments can doom a patent's validity.
Similarly, in Juno Therapeutics v. Kite Pharma (2021), the U.S. Court of Appeals for the Federal Circuit invalidated a CAR T cell therapy patent due to an insufficient written description. The patent broadly claimed a genus of chimeric antigen receptors, but the court found that the application failed to provide enough representative species or structural details to justify such broad claims. This decision reaffirmed that for biotechnology inventions, a few examples may not be enough — applicants must disclose a range of embodiments to support a broad claim.

Given the evolving case law, life sciences patent applicants should consider the following strategies to strengthen their written description compliance:

- Provide structural detail, not just functionality. Avoid relying solely on functional language, such as “a molecule that inhibits enzyme X.” Instead, describe specific structures, sequences, or formulations that achieve the claimed function.

- Include representative species. When seeking broad genus claims, such as for a class of antibodies or gene edits, disclose multiple representative examples that cover structural variations across the claimed genus.
- Use deposits and sequence listings where appropriate. For biological materials, depositing strains, plasmids, or cell lines in recognized repositories, such as ATCC, can help meet written description requirements.
- Incorporate experimental data. Experimental results demonstrating that the disclosed embodiments work as claimed can bolster written description arguments, particularly when claim scope is challenged.
- Align claim scope with disclosure. Draft claims that correspond to the level of detail provided in the specification to avoid overreach. If a patent claims an entire class of molecules, the application should describe sufficient examples to justify that breadth.

Authors



Christopher R. Cowles, Ph.D.

Partner

Boston, MA | (617) 345-4719

ccowles@daypitney.com