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## Impact of biosimilars on patent portfolio development and management

Case study on the patent portfolios of the top biologics (in sales) and how they might be impacted by biosimilar strategies is presented. By analyzing the patent portfolios of a representative sample of innovator products, it is possible to see how organizations have approached protecting their top products thus far. Now consider whether those strategies need to be modified to protect the company's competitive advantage from follow-on biologics. In the case of biosimilars, there are a number of steps involved in producing essentially similar, but not identical substances. Protecting the company's competitive advantage, especially with the use of multiple patent filings, may be essential where the primary biosimilar product or functionality is seemingly unpatentable. A biosimilar may be sufficiently similar to qualify as a biosimilar under the guidelines, but not squarely covered by a patent claim of the innovator product. Innovators should thus aim to draft valid claims that secure broad protection for their biologics. To do so, they should consider seeking protection not only for the biologic itself, but also for the target molecule(s) of the biologic, methods of use and methods of production, if possible. Innovators should also consider how their biologics might be modified and consider obtaining patent protection for those modifications, as well as for any improvements to their biologics.

## Biography

Kristin A Connarn has completed her BS at Worcester Polytechnic Institute (WPI) and JD from Suffolk University Law School. She is a partner at McDermott Will & Emery. She is known for her work in strategic portfolio development and management, patent prosecution, opinions, licensing, due diligence and related counseling for life science companies. She has a particular focus and expertise in the developing law of biosimilars, and regularly speaks and writes on the topic, as well as counseling biologics innovators on appropriate intellectual property strategies to protect their innovative products. She also serves as the co-chair of the AIPLA biosimilars committee.

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