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## Using IPRs in the biosimilars context

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In *Amgen v. Sandoz*, the Federal Circuit held that biosimilar applicants are not required to provide their Biologics License Application (BLA) or engage in the patent dance – the process under the BPCIA in which the parties identify which patents the parties believe should be litigated. However, the court held that an applicant who fails to provide its BLA must provide the brand with 180-days' notice of launch. In *Amgen v. Apotex*, the Federal Circuit held that a biosimilar applicant must always provide the brand with 180-days' notice before launch, regardless of whether the applicant provided its BLA or engaged in the patent dance. The result of these decisions may be that few biosimilars applicants engage in the patent dance. Rather than litigating biologics patents under the BPCIA, biosimilars applicants may challenge biologics patents by filing IPRs. We will review IPRs that have been filed in the biologics area, analyze key institution decisions, and provide takeaways from the institution decisions and our views on lessons that should be learned from these decisions.

### Biography

Laura Burson is a partner in the Intellectual Property Practice Group in Sheppard, Mullin, Richter & Hampton LLP's Los Angeles office. She is Co-Leader of the firm's Hatch-Waxman and Biosimilars Team. She focuses on intellectual property litigation with an emphasis on patent law. She is a registered patent attorney, admitted to practice before the US Patent and Trademark Office. She has experience in all phases of litigation, including trials, arbitrations, and appeals involving intellectual property and technology-related matters. Her clients come from a broad range of technology areas, including medical devices, chemicals and chemical processes, biotechnology, pharmaceuticals, computers, and other technologies. She is also active in pro bono matters and has served a volunteer prosecutor in criminal jury trials. She currently serves on the board of directors of LAIPLA and Center for Civic Mediation.

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