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Update on biosimilars litigation in the United States

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Over seven years have passed since congress enacted the Biologics Price Competition and Innovation Act (BPCIA). Economists estimated that less expensive biosimilar products would result in cost savings amounting to tens billions of dollars. Yet during that period, only a handful of biosimilars have been approved by the US FDA. At least part of the delay in the introduction of biosimilars to the US market stems from uncertainty relating to the litigation provisions of the BPCIA. Many biosimilars developers have objected to provide their confidential application material to the proprietor of the branded biologic prior to the instigation of the litigation. The US Supreme Court in Sandoz v. Amgen (Case No.15-1039 and 15-1195) will decide this issue and also whether the BPCIA requires the biosimilar applicant must always wait 180 days after FDA approval before marketing.

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