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Salix v. Norwich Patent Infringement Opinion and the Implications of a Post-Trial ANDA Amendment and Section 8 Carveout

In this episode of our Life Sciences Insights podcast series, Sophie Wang and Madison Garrett discuss the Federal Circuit's recent opinion in a patent infringement case between Salix Pharmaceuticals and Norwich Pharmaceuticals. The opinion arises out of Hatch-Waxman litigation concerning Norwich's Abbreviated New Drug Application (ANDA) to the FDA for approval to market a generic version of Salix's drug, rifaximin, marketed under the brand name Xifaxan®.

Sophie and Madison discuss two main components of the opinion: (1) the use of a clinical trial protocol as prior art to render obvious a claim directed to a method of treatment with particular dosages, and whether that supports a reasonable expectation of success, and (2) the implications of a post-trial ANDA amendment with a section 8 carveout (a.k.a. skinny label) on an injunction order from the litigated case.

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