

PATENT LITIGATION AND X-RAY POWDER DIFFRACTION:
SWIMMING WITH THE SHARKS

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As innovator companies struggle to maintain favorable intellectual property positions, claims covering new crystal forms have become an important aspect of the drug substance patent landscape. These claims naturally contain an x-ray powder diffraction description of the patented form, and such claims can become some of the most hotly contested topics in the litigation that invariably accompanies defense of the patent. As each side fervently espouses the view that their interpretation of the claims is the only correct one, scientific expert witness becomes required. For experts, the main task is to prove either the presence or absence of infringement in a manner that will be acceptable to the court. In this presentation, I will outline the process experienced by expert witnesses during the course of litigation, and will illustrate both successful and unsuccessful approaches to the presentation of expert documentation and testimony.

