

POLYMORPHS AND PURITY AND PATENTS; OH MY.

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Nowhere is the interface of science and the law more evident than in the pharmaceutical industry, where courts are struggling with the limits of the protection provided by patents claiming polymorphs and solvates. Can every polymorph or solvate be patented? Can a patent cover a polymorph or solvate produced inadvertently and/or as an impurity? Can a patent to a polymorph or solvate be used to exclude others from making, using or selling other crystalline forms of the same molecule? A recent case, *SmithKline Beecham Corp. v. Apotex Corp.*, addressed a number of questions regarding polymorphs/solvates, purity and the rights conferred by patents. The court held that a patent's claim to a specific crystalline hemihydrate could not cover an impurity and still be valid. The court considered issues as diverse as the means and timing of analytical techniques used and the possibility of seeding. Finally, the court gave insights into the types of relief that might be available. The basis of this decision and others, as well opinions on what will follow, will be discussed.