

WHEN KEEN OBSERVATION SAVES YOU MONEY

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To a solid state chemist the powder diffraction pattern is a symbol representing a particular crystalline modification in much the same way that the symbol "CAT" represents and specifies a particular animal (form of life). When this is not the case it leads to sloppy crystallography which leads to flawed and erroneous patenting. This can lead to cases of infringement and ultimately losses of billions of dollars. In the process of investigating a particular API (which can not be disclosed here) we observed that two forms of this API designated Form 1 and Form 4 crystallized unselectively from the same solvents in a number of cases and in one case were seen to crystallize concomitantly from the same solvent. Due to the habits of Form 1 and Form 4 being distinctly different – well formed prisms and thin needles respectively – they were easily distinguished and separated. Having established this we decided to scrutinize the patent more carefully to see whether the fact that this was entirely overlooked had any effect on the analysis given. Using PDXR and thermal methods we showed that Form 2, written as a novel and distinct polymorph, was in fact a mixture of Forms 1 and 4. It was also easily established using hotstage microscopy that the endotherm in the DSC of Form 1 is in-fact a phase transition – an observation totally absent from the patent.