

PATENT AND REGULATORY ISSUES – THE EUROPEAN PERSPECTIVE

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One important aspect of the role of X-ray powder diffraction in characterising new physical forms of chemicals, and pharmaceuticals in particular, lies in the basis that this can provide for useful further protection, by means of patents, for such pharmaceuticals. Such protection will often extend beyond the expiry of the first patent to protect a particular pharmaceutical, and thus be of considerable commercial value. Indeed, the extent to which a new physical form has been accurately characterised by the data set out in a patent specification is currently the subject of an appeal to the highest court in the United Kingdom, the House of Lords, in *SmithKline Beecham v Synthon*. This, and other cases in Europe concerning new physical forms of chemicals characterised by X-ray powder diffraction, will be the subject of case studies.