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Pharma 1: Sufficiently plausible?

The time between the invention of an active ingredient (or the second medical use thereof) and the approval of the final drug is significant, often a decade or more. To safeguard rights, patent applications must generally be filed when enough is known to justify further resources, for example, to conduct animal and human studies.

Various questions arise in this respect. How can the invention be expressed in a manner sufficient to one of ordinary skill in the art? What experimental or other data are required? Is the invention at issue (e.g. compound or second medical use claim) relevant? How are questions about utility/ industrial applicability and obviousness/inventive step resolved? Can post filing data be used to overcome these issues?

Variations of these issues arise in many jurisdictions, creating challenges for applicants – in China, over the use of post filing data in overcoming inventive step and sufficiency rejections; in Canada, over the "patent promise" doctrine; and in Europe increasingly over the question of the "plausibility" of the invention as described in the patent specification.

Speakers from Asia, Europe and North America will address these issues in the hope of formulating a global standard.