AIPPI Congress 2019 Pharma Session 4: Antibodies

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Moderated by the Chair of AIPPI's Biotech Committee, Dr Juergen Meier, this pharma panel session aimed to compare and contrast the protection available to proprietors of antibody patents across a number of important jurisdictions: the US, Canada, Europe, China and Japan.
Echoing a point made by Sir Robin Jacob in his address at the Opening Ceremony, the day before, the message was clear from the outset: when it comes to the form of claims in antibody patents, the US is the odd one out.

Dr Meier (Vossius & Partner, Germany) gave what was the first in a sequence of presentations on the local position in each of the various jurisdictions concerned. Dealing with the EPO, he explained that there is a large amount of freedom in the form of claims, definitions based on both structure and function being permissible, provided they satisfied the legal tests of sufficiency (including enablement) and plausibility. Problems can occur if any data used to support the plausibility of the claimed functionality is not clear and conclusive.

Michele Wales (InHouse Patent Counsel, US) provided the immediate contrast: whilst, once upon a time, functional claims were acceptable in the US, the 2017 decision of the Federal Circuit in *Amgen v Sanofi* changed all that. Antibodies solely defined by function are not sufficiently characterised by their affinity for a newly characterised and well-described antigen. Instead, the written description requirement of patentability means that the antibody itself must be adequately described. This, in turn, requires amino acid sequence information to be provided of the complementarity-determining regions (CDRs) involved in binding.

Illustrating that the US stands alone in this strict standard for antibody patentability, the speakers for Canada (Graeme Boocock, Bordner Ladner Gervais), China (Susan Li, Sunshine Guojian) and Japan (Osamu Yamamoto, Yuasa & Hara) all shared the position that for a novel epitope, antibody structure does not require exemplification. In contrast, where the target is known, an antibody may be claimed provided it has a defined sequence, usually with all six CDRs being described.

The session concluded with a brief discussion around idealised filing strategies, the panel agreeing that a strategy which separated the US filing, ideally in a later application containing a picture claim, would be sensible, but subject to the constraints of cost and the difficulties of characterisation within a short timeframe from first filing.