



AIPPI FORUM SINGAPORE

October 4 - 6, 2007

Session V

**The Interface between IP regulations and
pharmaceutical regulations**

Friday, October 5, 2007

04.00 to 05.30 p.m.

Moderator:

Nicola Dagg (Assistant Reporter General of AIPPI)

Speakers:

Ian Karet (United Kingdom)

Manoj Pillai (India)

Anthony Rollins (United Kingdom)

Short description

The granting of IPR for pharmaceuticals, in particular the patenting of pharmaceutical inventions, has been a highly debated topic for a long time. After TRIPS there can be no doubt that patents may be granted also for pharmaceuticals. Whereas the patenting process has to observe certain criteria for patentability, there are also requirements on the administrative side for the approval of pharmaceuticals before they can be put on the market. For instance, the request for approval requires clinical data about the respective pharmaceutical. In the case of a generic there may be certain means to facilitate the approval. However, tests which are conducted, may constitute an infringement of existing patent rights for older medicinal products. For such clinical testing there may be certain exemptions from patent protection (also known as the "Bolar" exemption). Another aspect is the protection of commercially confidential data. The data which have been filed with the authorities may be accessible for the public. This raises concerns as to how the confidential data (including data which are important for patent protection) can be effectively protected. In this session we will discuss the interface between regulations on the IP side and the pharmaceutical side from the perspective of practitioners who will present their views as to which problems the applicant has to face and how they can be resolved in order to observe the pharmaceutical regulations without harming the patenting process.

Curriculum Vitae

Ian Karet

Ian Karet is a partner of Linklaters. Based in London he advises on a broad range of IP matters, with particular focus on issues affecting the Healthcare sector. He also advises on commercial matters such as joint ventures, fund raisings and IT agreements. He has a degree in Chemistry from Oxford University and has lectured and written on a wide range of intellectual property issues. He is a Fellow of the Chartered Institute of Arbitrator and a CEDR Accredited Mediator. He is a past Deputy Reporter General of AIPPI.

Manoj Pillai

One of India's best known Patent Attorneys, Manoj Pillai is a partner of LEX ORBIS IP Practice, a pre-eminent Indian IP firm. He is also a director of Clairvalex, a patent and legal outsourcing company.

Manoj speaks at seminars and workshops in India and abroad. He delivered a public lecture in Tokyo in May this year organized by JIPA, a presentation in Washington DC at an IPO seminar in June and is scheduled to speak at the FICPI forum in Spain in November.

He has the unique distinction of addressing the first ever Retreat for the Chief Justice and other Sitting Judges of the Indian Supreme Court and two IPR Conclaves for the Judges of the High Courts in India (on both occasions the participants included over 50 High Court Judges and 3 Chief Justices).

As the head of the patents division at LEX ORBIS, Manoj has been engaged in drafting and prosecuting patent applications at various IP offices. His core competence is in patent prosecution.

Tony Rollins

TONY ROLLINS has a PhD in organic chemistry. He joined the Patent Department of *Beecham Group* in 1974 and moved to the *Wellcome Foundation* in 1976. He qualified as a CPA in 1978 and was a Section Manager with the Group Patents and Agreements Division of *Wellcome* until January 1995. From January 1995 until August 2004, he was the head of the intellectual property group at *Amersham International plc.*, subsequently *Amersham plc.* Tony joined *Merck Sharp & Dohme Ltd.* on 1st September 2004 as Managing Counsel, European Patents. Tony is a member of the Council of Experts of the Intellectual Property Institute and a Council Member of the British Section of the AIPPI and TMPDF. He has considerable experience of patent litigation throughout the world, as well as of patent prosecution and licensing matters, and is a UK Patent agent litigator and a member of the Litigation Accreditation Board for the UK Chartered Institute of Patent Agents.