3rd Annual Pharmaceutical Law Asia 2010

Regional Updates and Best Practice in Compliance, Registration & IPR

23-24 November 2010, Traders Hotel, Singapore

Conference Day One: Tuesday 23 November, 2010

08:30 **Registration & morning coffee / tea**

09:00 **Chairperson's Opening Remarks**
Abhayan Jawaharlal, *Head – Group Legal*, **Biocon Group, India**

REGULATORY OVERVIEW & ENFORCEMENT

09:10 **Regulatory and Legal Framework Overview – Asia's Pharma Markets**
- Enforceability of key contractual terms: Challenges and issues to note in the pharma law landscape in Asia Pacific (10 country comparison)
- Managing legal risk in cross-border transactions involving clinical studies
- Recommendations on how accurate & timely legal risk management can add value to the company and the client

Josephine Wan-Wen Hadikusumo, *Legal Counsel Asia-Pacific Operations,* **PharmaNet Asia Pacific**

09:50 **Safeguarding IPR Protection in New R&D Activities in Asia**
- Handling IP matters in your own newly established R&D center
  - Getting started, capture inventions for the company and link to the rest of the company
  - *China* - A practical example how to deal with Inventor Compensation, Technology Export Regulations, First-to-File requirements for patent applications
- IP Due diligence when working with contract research organizations (CROs)
  - What to look at
  - *China* - Special legal issues when contracting CROs

Dr Oliver Lutze, *Head of IPR,* **Bayer (China) Limited**

10:30 **Morning refreshments**

11.00 **Developing a Legal Compliance Program**
- Developing and maintaining an effective, risk-based compliance program
- Healthcare compliance
- FCPA / anti-corruption compliance
- Anti-competition / anti-trust compliance
- The cost of non-compliance – lessons learned from Eli Lilly, AstraZeneca and Pfizer

Roque Castillo, *Legal Counsel, Asia Pacific,* **Allergan**

PRODUCT REGISTRATION & MARKET EXPANSION

11:40 **Anti-Corruption Practices to Avoid Severe Penalties**
- Why pharma, biotech and medical devices cannot ignore anti-corruption practices
- Summary of anti-corruption laws in Asia
- How to ensure the integrity of distribution channels and prevent corrupt practices
- Value of compliance

Maija Burtmanis, *Regional Counsel, Japan/Asia Pacific,* **Novartis Vaccines**

12:20 **Networking Lunch**

14:00 **Navigating Procedures for Product Registrations with Ease**

- Summary of key applicable regulations and essential international & local guidelines
- Harmonizing products registration in Asia
- What measures can be taken to shorten the timeline of product / clinical trials registrations?
- Penalties applicable in various Asian countries in case of violation of pharmaceutical laws

Anne-Lise Saint-Gerand, *Director, Regional Registration & Product Development,* **Merial Asia**

14:40 **Country Focus: SFDA Approval Processes for Drug Registrations in China**

- Overview of recent market entry guidelines and basic registration procedures
- Market access challenges for certain drugs into China
- What are the practical issues of drug registrations faced by MNC and domestic companies? ie lack of patent linkage with SFDA approval
- How can industry and the government work together to streamline the drug registration process?
- Imported drug registrations process & timeline

Chen Yang, *Partner, Head of China Life Science Practice,* **Sidley Austin LLP, China**

15:20 **Afternoon Refreshements**

15:50 **Country Focus: Navigating Emerging Regulations in India**

- CDSCO registration guidelines and impact on clinical development in India
- Addressing grey areas in registering clinical trials
- Regulatory requirements in building manufacturing facilities

Abhayan Jawaharlal, *Head – Group Legal,* **Biocon Group, India**

[Panel Discussion]

16:30 **Strategic Alliances: Co-development and Co-marketing Agreements**

- What are the practical differences between a license and a strategic alliance?
- Understanding the IP aspects of co-development agreements
- Strategic alliances: assessing the appropriate financial/manufacturing / co-marketing / cross licensing approaches
- Mitigating the risks when dealing with third-parties

Moderator:
Anne-Lise Saint-Gerand, *Director, Regional Registration & Product Development,* **Merial Asia**
Panelists:
Chen Yang, *Partner, Head of China Life Science Practice,* **Sidley Austin LLP, China**
Jing Chung, *Patent Attorney,* **Marks & Clerk Singapore LLP**

17:10 **Chairperson's Remarks and End of Conference Day One**
Followed by Networking Drinks

Conference Day Two: Wednesday 24 November, 2010

09:00 **Chairperson's Opening Remarks**
Duncan Bucknell, *CEO, IP Strategist, Lawyer & Patent Attorney,* **Think IP Strategy, Australia**

IPR LANDSCAPE & PATENT PROTECTION

09:10 **Innovator Perspective: Extending Patent Protection & Product Life Cycles**
- Key factors for success in winning patent extensions
- Monitoring patent infringements and deciding best approach to enforce IP
- Balancing costs of legal action against risk and likelihood of success – when and where to litigate / not?
- Maximizing patent term extensions and product life cycles

Duncan Bucknell, *CEO, IP Strategist, Lawyer & Patent Attorney,* **Think IP Strategy, Australia**

09:50 **Data Exclusivity for Further Protection**
- Data exclusivity: broad parameters / definition & the TRIPS connection
- Data exclusivity periods implemented across various countries
- Latest political activity around the data exclusivity and emerging scenarios
- Data exclusivity and the pharmaceutical business

Sandeep K. Rathod, *Associate Vice President and IP Counsel,* **Matrix Laboratories Limited, India**

10:30 **Morning Refreshments**

11:00 **Approaches to Patent Litigation and Prosecution**
- To what extent is the US patent litigation system and practices applicable to Asia?
- Where and when is IP patent litigation/prosecution necessary? What are the alternatives eg dispute resolution, arbitration etc
- Building strong patent portfolios through effective patent prosecution
- Preparing for the IP litigation process → internal information requirements, evidence, related legal frameworks, redress, costing
- Addressing forcing settlements in IP disputes
- Examples of recent judgements in patent prosecution cases; ground breaking IP disputes

John A. Tessensohn, *Board Member, Intellectual Property Attorney,* **Shusaku Yamamoto, Japan**

[Panel Discussion]
11:40 **Gearing Up for the Patent Wars – Generics vs. Innovators**
- Identifying the primary opportunities and 'low-hanging fruit'
- When and whether to take legal action to challenge barriers raised by innovators
- What tactics can be applied to ensure effective evergreening strategies?
- Assessing ROI in relation to price controls and regulatory requirements

Moderator:
Sandeep K. Rathod, *Associate Vice President and IP Counsel,* **Matrix Laboratories Limited, India**
Panellists:
Duncan Bucknell, *CEO,* **Think IP Strategy, Australia**
John A. Tessensohn, *Board Member, Intellectual Property Attorney,* **Shusaku Yamamoto, Japan**
Peggy Cheung, *Partner/Head, Intellectual Property,* **Jones Day, Hong Kong**
Max Ng, *Managing Director*, **Gateway Law Corporation, Singapore**

12:20 **Networking Lunch**

LICENSING STRATEGIES

14:00 **Licensing and Technology Transfer in the Life Science Industry**
- Collaborations and licensing activities in life science innovation
- Identifying licensing and collaboration opportunities
- Importance of a big partner for innovative Biotech companies

Frank Grams, *Executive Director,* **Roche Partnering Asia**

14:40 **In-Licensing & Out-Licensing Practice**
- Approaches to exploit patent/technology
- Key considerations in licensing
- How to kick-off and touch down
- Key articles to watch out for in licensing agreements

Vicky Lee, *Director of Legal & IP Division,* **TTY Biopharm, Taiwan**

15:20 **Afternoon Refreshments**

PHARMA BUSINESS DEVELOPMENT IN ASIA

15:50 **Overcoming Challenges of Merger & Acquisition Activities**
- Assessing the legal implications from the increase in pharma M&A activity both in Asia and globally
- Examining ASEAN guidelines overseeing M&As – anti-trust & anti-competition laws
- Legal due-diligence relating to acquisition opportunities
- Lessons learned from a recent pharma M&A walk through

Widya Buenastuti, *Legal Director,* **Pfizer Indonesia**

[Panel Discussion]

16:30 **Managing IP Ownership in Your Future Collaborations**
- Prospecting for future collaboration opportunities in Asia
- Increasing importance of IP ownership in collaborations
- Protecting leakage & ownership of IP in inter-firm R&D collaborations
- Where is the next innovation going to come from?

Moderator:
Dr Bernard Cheung, Division of Clinical Pharmacology and Therapeutics, Department of Medicine*,* **The University of Hong Kong**
Panellists:
Peggy Cheung, *Partner/Head, Intellectual Property,* **Jones Day, Hong Kong**
Widya Buenastuti, *Legal Director,* **Pfizer Indonesia**

17:10 **Chairperson's Closing Remarks and End of Conference**