

# Negotiating, Understanding & Drafting Contracts for The Pharmaceutical Industry

22nd November 2007 9.30am – 5.00pm Holiday Inn Parkview



*In such a highly regulated sector understanding the key challenges of negotiation and drafting an effective and watertight contract is complex. They can be difficult for even the most equipped in-house lawyer. Commercial managers from all areas of the pharmaceutical industry are leading negotiations, drafting and managing key contracts on a daily basis. It is vital that both legal counsel and commercial executives not only have the key skills and tactics to create a win-win scenario but also the knowledge to ensure any agreement is within the laws and regulations. The alternative is the exposure of the organisation to unnecessary risk and potential costly disputes.*

*By attending this seminar, you will familiarise with some of the latest legal developments and how they affect contracts in the pharmaceutical sector.*

## Programme Agenda

### 9.30am – 10.45am

Chiew Yu Sarn - Partner/ Head  
Yu Sarn Audrey & Partners

#### Regulatory framework and Good Clinical Practice Guidelines

#### Fundamentals of Informed Consent

#### Clinical Trial Agreement - Contractual Issues

- Ownership of Intellectual Property
- Confidentiality & Publication
- Indemnification & Insurance
- Payment Issues
- Record keeping
- Termination issues

### 10.45am – 11.15am: Coffee Break

### 11.15am – 12.30pm

Joint Presentation by  
Benjamin Gaw - Senior Associate and  
Joanna Koh - Director  
Drew & Napier

#### Confidentiality and IP Issues in the Pharmaceutical Industry

- General overview of IP
- (a) Trademarks – Registration, Division of Goods / Services
- (b) Patents – Registration & patentability.
- General overview of the law on trade secrets

- Patents v Trade Secrets
- Ownership of Intellectual Property in JV situation / in subsidiary companies
- Advantages of being an exclusive licensee (case study on the HIV case wrt licencing)
- General overview of the law on confidential information
- Statutory obligations eg Employee Inventions
- Protection of confidential information disseminated to 3rd parties
- Negotiating particular contracts
- Manufacturing and Supply Agreements: Whither improvements?
- Sales and Distribution : Trademark issues
- Research & Development : Protection of IP in relation to employee relationships
- Clinical Trial Agreements: Rights to Subject Information

### 12.30pm – 2.00pm: Networking Lunch

### 2.00pm – 3.15pm

Max Ng - Director  
Gateway Law Corporation  
Pharma Licensing Agreements

- what is a license
- structure of the license agreement
- types of licenses and IPR to be licensed
- determining price
- negotiation process

- benefits of licensing
- pricing considerations
- representations and warranties
- dispute resolution

### 3.15pm – 3.45pm : Coffee Break

### 3.45pm – 5.00pm

Associate Professor Catherine Tay Swee Kian

National University of Singapore  
Department of Business Policy

#### Breach of Pharmaceutical Contracts

- Breach of conditions and warranties
- The 4 ways to terminate contract
- Remedies and damages for breach of contract



## Participating Organisations



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## Who Should Attend

Medical Directors / Medical Practitioners / Medical Researchers / Head of clinical Trials / Heads of Regulatory / Operational / Policy Affairs / Members of Ethics Committees / Legal Counsel / Lawyers / Government / Regulatory Officers from R&D, clinical, regulatory, commercial, sales and marketing, manufacturing, distribution and purchasing, including: Commercial and contract managers / Business development managers / Purchasing and procurement / Heads of legal departments / Patent, IP, trademarks or licensing counsel

# Speaker's Profile

**Benjamin Gaw**

**Drew & Napier**

**Senior Associate**

Benjamin graduated from the National University of Singapore in 2002 and is a Senior Associate with Drew & Napier LLC. He is a member of the Insolvency and Reorganisation Business Group as well as the Biomedical Sciences Practice Group. Benjamin is the author of an article in the Singapore Law Review titled "Legislating the Fruits of Biotechnology: Suggestions for Regulating Bio-engineered Food". He is also a co-contributor to the Atkin's Court Forms – Singapore, Insolvency (Chapter XLIV), Lexis Nexis, 2007 Ed, and to an article in the Singapore Biotech Guide 2007/2008 titled "Employment Contracts – Safeguard Your Intellectual Property Rights." Benjamin's areas of practice range from civil and commercial litigation to insolvency and restructuring work. He has also regularly advised numerous biotechnology, health and pharmaceutical companies on regulatory and contractual issues in Singapore, including advising on clinical trial agreements, research and development agreements and manufacturing and supply agreements.

**Joanna Koh**

**Drew & Napier**

**Director**

Joanna is a Director in Drew & Napier LLC's Litigation & Dispute Resolution Department. Prior to joining Drew & Napier LLC in 2000, she was a litigation associate in a medium sized firm in Singapore. Joanna teaches Drafting and Insolvency classes at the Practice Law Course and has been an adjunct Advocacy tutor at the Law Faculty, National University of Singapore. Joanna specializes in Intellectual Property litigation. She has an active court practice representing clients in different forms of IP disputes. She also has a Civil and Commercial Litigation practice that encompasses a broad range of work including banking litigation, franchise disputes, property and tenancy matters and general contractual disputes. In addition to her litigation practice, Joanna has also assisted in advising clients in IP and employment issues as well as advising biotechnology, health and pharmaceutical companies on regulatory and other corporate matters in Singapore.

**Associate Professor Catherine Tay Swee Kian**

**National University of Singapore (NUS)**

**Department of Business Policy**

Catherine Tay lectures business law at the NUS Business School. A/Prof Tay is an Advocate and Solicitor, Singapore. She is also a barrister-at-law (of Lincoln's Inn, United Kingdom). A/Prof Tay holds both a Master of Laws degree and a Bachelor of Laws (Honours) degree from the Queen Mary College, University of London. She is an author of 28 law books. A/Prof Tay has published numerous legal articles in peer-reviewed international journals, such as BIOETHICS, the Hong Kong Journal of Emergency Medicine, the (United Kingdom) Journal of Business Law, (UK) Business Law review, the (UK) Company lawyer, the (UK) Insolvency Law & Practice, the Securities Industry Review, The Singapore Law Gazette (official publication of The Law Society of Singapore) and the APLAR Journal of Rheumatology. She has been an invited speaker to various legal and medical conferences both overseas and in Singapore.

**Chiew Yu Sarn**

**Yu Sarn Audrey & Partners**

**Partner/ Head**

Chiew Yu Sarn is a founding partner and head of the corporate and commercial department of Yu Sarn Audrey & Partners, a boutique Intellectual Property & Commercial law practice providing the full range of IP services to corporations, businesses, research and healthcare institutions, and government agencies both locally and internationally, from developing IP policies and strategic planning for protection of IP to exploitation of intellectual assets via licensing & franchising, joint ventures, acquisition, tech transfer, and enforcement of IP rights. Yu Sarn's areas of practice are intellectual property (IP) and corporate and commercial law, including franchising, licensing, research collaborations, contract research including clinical trials, joint ventures and IP-related private equity transactions and M&A. In his IP consultancy work, Yu Sarn is a member and Secretary of the Licensing Executives Society Singapore, and a member of the Franchising and Licensing Association (Associate Member – Professional) and the Association of University Technology Managers.

**Max Ng**

**Gateway Law Corporation**

**Director**

Max Ng is one of the principal directors of the firm. In addition to being professionally active in the community, Max is also listed as a leading lawyer in his field in AsiaLaw Leading Lawyers 2003 and 2004, and in Singapore's inaugural Legal Who's Who 2003, which is an independent guide to the best legal practitioners in Singapore. He is also the lead author of the book "Intellectual Property", under the Butterworths Law for Business Series. Max's practice involves patent and other intellectual property litigation, general counselling and preparation of specific contracts and documents in relation to licensing, franchising, media and entertainment law, electronic commerce and the Internet, amongst others. Max has represented several statutory boards in Singapore, as well as educational and financial institutions, multinational companies, local small and medium enterprises, and start-up companies. In 1998, Max served a short secondment stint at the National Computer Board of Singapore (as it then was), where he advised and assisted the Board's legal counsel on IT-related matters, on trade marks and patent protection, on various licensing issues, and assisted the various e-commerce and Internet project initiatives pending then. Max now speaks frequently at various forums on IP and IT-related topics. Max also renders his services by judging at competitions and providing legal guidance pro bono at entrepreneurship forums such as at "Start-up@Singapore", or at the local educational institutes.

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Conference Fee **SGD 850**

**10% Discount** for Pharmaceutical Society of Singapore members

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