WORKSHOP ON CRITICAL PATENTING ISSUES ON PHARMA AND BIOSIMILARS

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MUMBAI
19 SEPTEMBER 2015
TAJ LANDS END

HYDERABAD
26 SEPTEMBER 2015
TAJ KRISHNA
THEME OF WORKSHOP

Attorneys from Schwegman Lundberg & Woessner (“SLW”) proudly return to India this fall to present on topics of interest in the pharmaceutical sector. Leading regulatory and patent attorneys will exchange ideas and engage in in-depth audience discussions addressing several opportunities available to today’s generic pharmaceutical companies, as well as the complexities, conundrums and challenges these opportunities bring.

This conference will delve into several topics of much interest recently within the pharmaceutical sector: inter partes review (IPR), biosimilars, risk evaluation and mitigation strategy (REMS), and patent eligible subject matter.

We welcome you and your peers to join our exceptional faculty as they share their knowledge on:

**Inter Partes Review:**
- Nuts & Bolts
  - Legal basis for IPR
  - Prior art
  - Timing & Joinder
  - Experts, Depositions and Declarations
- Strategies and Planning for the Stages of the Proceeding:
  - Petition, Preliminary Statement and Decision on Petition
  - Patent Owner Response & Motion to Amend
  - Opposition, Reply and Discovery
  - Oral Hearing
  - Final Written Decision

**Biosimilars:**
- Recent legal developments in biosimilar litigation, including a summary of U.S. biosimilar decisions to date
  - Sandoz v. Amgen
  - Celltrion v. Janssen
  - Amgen v. Sandoz
- Discussion on incorporating USPTO post-grant procedures into biosimilar strategies, including using Inter Partes Review to confirm freedom to operate in anticipation of a launch
  - BPCIA - Biosimilar/Interchangeable
  - Following the rules of the BPCIA - Timing/Exchange
  - Declining to dance? Lessons learned from early BPCIA cases
  - Key cases to consider in your biosimilar patent strategy
  - Incorporating Inter-Partes Review into litigation strategies

**Inter Partes Review within the generic pharmaceutical sector:**
- Opportunities that IPRs present to generic applicants
- Pros/Cons of IPR versus Hatch-Waxman litigation
- How filing an IPR would change the procedures in invalidating Orange Book patents by generic applicants, who are not the first filers
- Why IPRs are not more common with ANDA Paragraph IV filings, as opposed to Hatch-Waxman litigation
- Pitfalls and a best practices approach for generic applicants

**Risk evaluation and mitigation strategy:**
- What is REMS and why does it exist?
- How are branded pharma companies using REMS to the detriment of generic applicants?
- Pitfalls and best practices approach for generic applicants

**Patent eligible subject matter (35 U.S.C. 101):**
- Historical overview and current context of 35 U.S.C. 101
- Leading case-law regarding patent eligible subject matter
- Opportunities and challenges for generic
**PROGRAM SCHEDULE**

Venue I - Taj Lands End, Mumbai  
Venue II - Taj Krishna, Hyderabad  
Saturday, 19th September 2015  
Saturday, 26th September 2015

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<tr>
<td>08:30 - 09:30 am</td>
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| 09:30 - 09:45 am | Welcome & Introduction  
Dr. Dhanpat Ram Agarwal, Founder Director, ITAG Business Solutions Ltd. |
| 09:45 - 10:00 am | Keynote Address:  
Hari Subramanian, Managing Partner, Subramanian & Associates |
| 10:00 - 11:00 am | Biosimilars in the U.S.  
Dr. Monique Perdok, Principal, Schwegman Lundberg & Woessner |
| 11:00 - 12:00 pm | Freedom-to-Operate (FTO) and Landscape Reviews of Biosimilars in the U.S. (Case Study using ClaimBot® software)  
Gary Speier, Principal, Schwegman Lundberg & Woessner |
| 12:00 - 01:00 pm | Lunch                                                                |
| 01:00 - 02:00 pm | Inter Partes Review (IPR) w.r.t. Generic Pharmaceutical Applicants  
Gary Speier, Partner, Schwegman Lundberg & Woessner  
Jeffer Ali, Partner, Carlson Caspers Vandenburg Lindquist & Schuman, PA |
| 02:00 - 02:45 pm | Pre-suit Considerations with an Eye Toward Litigation  
Sarah M. Stensland, Partner, Carlson Caspers Vandenburg Lindquist & Schuman, PA  
Gary Speier, Partner, Schwegman Lundberg & Woessner |
| 02:45 - 03:15 pm | Coffee/Tea Break                                                      |
| 03:15 - 04:00 pm | Recent Generic Pharmaceutical Litigation Issues (U.S. 35 USC sections 101 and 112)  
Jeffer Ali, Partner, Carlson Caspers Vandenburg Lindquist & Schuman, PA  
Sarah M. Stensland, Partner, Carlson Caspers Vandenburg Lindquist & Schuman, PA |
| 04:00 - 04:30 pm | Risk Evaluation and Mitigation Strategy (REMS)  
Jeffer Ali, Partner, Carlson Caspers Vandenburg Lindquist & Schuman, PA |

**REGISTRATION**

Fees: INR 5000 (for each venue). 10% Discount on Registration of two or more delegates from same organisation. 20% Discount for pharmexcil.

**FACULTY**

Gary Speier, Partner, Schwegman Lundberg & Woessner  
Gary J. Speier is a registered U.S. patent attorney and principal with Schwegman Lundberg & Woessner. His practice includes chemical and pharmaceutical patent law, including patent drafting/prosecution, Hatch-Waxman litigation, and related opinion work and post issuance proceedings. Gary received his B.S. (chemistry) from Fordham University in 1988, M.S. (chemistry) from Villanova University in 1991, J.D. (law) from Temple University in 1997, and MBA from the University of Massachusetts in 2015. Prior to entering law school, Mr. Speier worked as a medicinal chemist at Sterling Drug, and during law school worked as a law clerk in the patent department of SmithKline Beecham (now Glaxo Smith Kline).
Monique Perdok, Principal, Schwegman Lundberg & Woessner
Monique M. Perdok brings over 16 years of patent law experience obtaining patents and designing IP strategy for clients focused on biotechnology and chemistry. She has practiced in the intellectual property field since 1999, in the preparation and prosecution of patent applications in the U.S. and foreign jurisdictions in fields such as molecular biology, cell biology, including chemicals and pharmaceuticals. Monique holds a Bachelor’s degree in biology from Kalamazoo College (cum laude, 1992) and a Ph.D. in Molecular Biology from Mayo Clinic (1999).

Jeffer Ali, Partner, Carlson Caspers Vandenburg Schuman, PA
Jeffer Ali is a litigator who advises and represents clients in intellectual property matters, with particular emphasis in the life sciences. Having obtained a Doctor of Pharmacy degree and practiced as a pharmacist before attending law school. Jeff has represented clients in other technologies, including software, medical devices, and various mechanical arts. Jeff has been recognized as a “Super Lawyer” by Minnesota Law & Politics magazine for several years.

Sarah M. Stensland, Partner, Carlson Caspers Vandenburg Schuman, PA
Sarah M. Stensland practices intellectual property law with a focus on patent litigation. She represents clients in patent infringement actions, with an emphasis on defending generic pharmaceutical companies in Hatch-Waxman litigation (also referred to as ANDA litigation). In addition, as a lawyer and chemical engineer, Sarah has a solid command of her clients’ technologies and helps companies understand and protect the full market value of their products and processes.

Hari Subramaniam, Managing Partner, Subramaniam & Associates
Hari Subramaniam is an attorney at law with a background in medical sciences. He is the Managing Partner of a leading New Delhi based IPR law firm, Subramaniam & Associates (SNA). He has been in practice in the field of patents and trade marks for 30 years and has been involved in several important IPR and contentious cases in India and abroad. He has one of the best track records in Patent Oppositions in India.

Dr. Dhanpat Ram Agarwal, Founder Director, ITAG Business Solutions Ltd.
Dr. D. R. Agarwal is a Fellow Chartered Accountant by profession (FCA) since last 30 years. He conceived the idea behind the Global Intellectual Property Convention (GIPC) to spread IPR awareness in India, and began with a humble start with an international collaboration with the European Union in 2007. He furthered the cause to bring forth the largest intellectual property convention held in India every year (organized annually since 2009). Nowadays, his interest lies in intersection of IP Valuation, Licensing and Technology Transfer.