

# WORKSHOP ON CRITICAL PATENTING ISSUES ON PHARMA AND BIOSIMILARS

[www.iprworkshop.com](http://www.iprworkshop.com)

MUMBAI  
19 SEPTEMBER 2015  
TAJ LANDS END

HYDERABAD  
26 SEPTEMBER 2015  
TAJ KRISHNA

ORGANISED BY



CO-ORGANISED BY



SUPPORTING PARTNER



KNOWLEDGE PARTNER



ASSOCIATE PARTNER



## 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 - Mumbai Saturday, 19th September 2015

Venue II - Hyderabad Saturday, 26th September 2015

08:30 - 09:30 am : **Registration**

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 - 10:30 am : Topic & Faculty  
To be Determined

10:30 - 11:00 am : Patent eligible subject matter  
**Gary Speier**, Principal, Schwegman Lundberg & Woessner

11:00 - 12:00 pm : Inter Partes Review  
**Stephen Durant**, Principal, Schwegman Lundberg & Woessner

12:00 - 01:00 pm : Lunch

01:00 - 02:00 pm : IPR w.r.t. generic pharmaceutical applicants  
**Gary Speier**, Partner, Schwegman Lundberg & Woessner

02:00 - 02:30 pm : Coffee/Tea Break

02:30 - 03:00 pm : Risk evaluation and mitigation strategy  
Faculty To be Determined

03:00 - 04:00 pm : Panel Discussion: Biosimilars  
**Monique Perdok**, Principal, Schwegman Lundberg & Woessner

## REGISTRATION

Fees: INR 5000 (for each venue)

Discount for Group Registration of 2 or more delegates from same organisation.

## 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).

## FACULTY

**Stephen Durant, Principal, Schwegman Lundberg & Woessner**

Stephen C. Durant is a registered U.S. patent attorney and principal with Schwegman Lundberg & Woessner in Silicon Valley, California. His practice includes patent law involving software, electrical, communications and computer technologies including patent drafting/prosecution, litigation, and related opinion work and post issuance proceedings. Steve received a BSEE from the University of Notre Dame (1978) and a JD from the Cornell Law School (1981). Steve also worked at Hughes Aircraft Company, Space & Communications Group, in California.

**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, working for both large and small companies and universities, in the preparation and prosecution of patent applications in the U.S. and foreign jurisdictions in fields such as molecular biology, cell biology, including stem cells, immunology, plant sciences, genomics, chemicals and pharmaceuticals. Monique has expertise in counseling clients with regards to FTO opinions, as well as counseling clients with regard to patentability analyses and opinions to support licensing and acquisition activities. 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). Monique maintained a full-time position as a law clerk/patent agent at SLW while attending law school at night until her graduation from William Mitchell College of Law in 2003 (magna cum laude).

**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, Nataraj & 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).

He is also an expert in IP accounting, taxation, and valuation and has providing consultancy to some of the Fortune 500 companies in India and abroad. Nowadays, his interest lies in intersection of IP Valuation, Licensing and Technology Transfer.

## CONTACT