

**US Generics from Different Industry Perspectives — How It All Really Plays Out**  
Outline and Agenda

September 30, 2009 - Montreal D Room, 11<sup>th</sup> floor, Le Westin Montreal, Canada

Workshop Directors:

Yehudah Livneh, Ph.D. - Director, Patent Department, Teva Pharmaceutical Industries, Ltd.

Neil F. Greenblum, Esq. - Managing Partner, Greenblum & Bernstein, P.L.C.

Paul A. Braier, Ph.D., Esq. - Partner, Greenblum & Bernstein, P.L.C.

**8:30-9:00 Registration**

**9:00-10:30 Session 1**

- Obtaining patents; Patent Term Extensions
- Listing patents in the Orange Book
- Evolving aspects of patent infringement

Industry Sectors Emphasized:

Brands, Generics, APIs

**10:30-10:50 Coffee and Networking break**

**10:50-12:20 Session 2**

- Waxman-Hatch: The ANDA process; Compliance with Notice requirements; the Offer of Confidential Access; Forfeiture
- Acting on Notices
- Enforcement of listed (and unlisted) patents
- Litigation strategies; extending/shortening time to marketing approval; Declaratory Judgment

Industry Sectors Emphasized:

Brands, Generics, FDA

**12:20-1:20 Lunch (provided)**

**1:20-2:50 Session 3**

- Enforcement of listed (and unlisted) patents
- Litigation strategies; extending/shortening time to marketing approval; Declaratory Judgment
- Warranties
- Settlements (Brand/Generic and Generic/Generic)
- Citizen's petitions

Industry Sectors Emphasized:

Generic; APIs; FDA; Federal Trade Comm'n (FTC); Dep't of Justice (DOJ)

**2:50-3:10 Coffee and Networking break**

**3:10-5:00 Session 4**

Workshop Exercise

Industry Sectors Emphasized:

Brands, Generics, APIs; U.S. Federal Agencies (FDA, FTC, DOJ)

The Seminar agenda (including timing, choice, and sequence of topics) is subject to change.