

October 30 and 31, 2008 • InterContinental Bloor Yorkville, Toronto

The Canadian Institute's 7<sup>th</sup> Annual Forum on

# Pharma Patents

## The Legal & Strategic Guide



Our outstanding faculty of speakers will review the latest legal developments and provide valuable analysis to bolster your pharma patent strategy.

### TOPICS COVERED INCLUDE:

- **Understanding** the latest pharma patent litigation revolutionizing the industry
- Regulatory updates
- **Identifying opportunities** in patent listing and de-listing
- Catching up on the **judicial viewpoint** with The Honourable Justice Hughes
- Forward-thinking brand and generic patent strategies

*And much more!*



*See inside for details*

### NEW FOR 2008!

- Demystifying selection patents
- Patent protection and regulation of biologics and subsequent entry biologics
- Understanding patent protection in a global context
- New speakers and perspectives

### PRE-CONFERENCE WORKSHOP:

**The Fundamentals of Pharma Patent Law in Canada**

October 29, 2008



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# Why You Can't Miss this Conference!

It is essential to stay on top of the many legal and regulatory developments in the field of pharma patents to maintain your competitive edge. With so much at stake, keeping abreast of the law is an excellent way to both identify opportunities and institute proactive safeguards to advance your business objectives. That's why the Canadian Institute's **7th Annual Forum on Pharma Patents** is beyond relevant – it is indispensable.

Join us and stay informed about the law, as well as benefit from in-depth analysis and strategic advice offered by our outstanding faculty of speakers representing **both brand and generic perspectives**.

Some highlights from this year's agenda include:

- **Understanding** the latest in pharma patents litigation including selection patents, sufficiency, obviousness and disclosure requirements

- Incorporating **the latest legal developments** into your pharma patent strategy
- **Catching up with** the Honourable Justice Hughes and the Office of Patented Medicines & Liaison Health Canada

And much more!

Plus, if you're new to the industry or in need of a refresher, don't forget to register for our pre-conference workshop: **The Fundamentals of Pharma Patent Law in Canada**. This workshop, lead by both lawyers and patent agents, will introduce the legislative and regulatory underpinnings of the Canadian pharma patents regime and help you maximize your grasp of the conference to follow.

**Spaces for this event always go quickly. Don't delay!**

## Distinguished Faculty

### Co-Chairs

**Eileen McMahon**  
Partner  
Torys LLP (Brand)

**Shonagh McVean**  
Partner  
Gilbert's LLP (Generic)

### Speakers:

**Aiyaz Alibhai**  
Partner, MBM Intellectual Property Law

**Andrew Bernstein**  
Partner, Torys LLP

**Anne Bowes**  
Acting Director  
Office of Patented Medicines & Liaison  
Health Canada

**Paula Bremner**  
Partner, Hitchman & Springings

**Douglas Clark**  
Director, Industry Canada  
Patent and Trade-mark Policy Directorate

**Nadine D'Aguiar**  
Lawyer, Patent Agent and Trademark Agent  
Ogilvy Renault LLP

**Marguerite Ethier**  
Counsel  
Lenczner Slaght

**Gunars A. Gaikis**  
Partner  
Smart & Biggar / Fetherstonhaugh

**The Honourable Roger T. Hughes**  
Federal Court Trial Division

**David K. Lee**  
Director, Progressive Licensing Project  
Health Canada

**Jason Markwell**  
Partner, Ogilvy Renault LLP

**Steven Mason**  
Partner, McCarthy Tétrault LLP

**Bill Mayo**  
Partner, Heenan Blaikie LLP

**Eileen McMahon**  
Partner, Torys LLP

**Shonagh McVean**  
Partner, Gilbert's LLP

**Richard Naiberg**  
Partner, Goodmans LLP

**Anthony M. Prenol**  
Partner, Blake, Cassels & Graydon LLP

**Christopher C. Van Barr**  
Partner  
Gowling Lafleur Henderson LLP

**J. Bradley White**  
Partner, Osler, Hoskin & Harcourt LLP

**Reza Yacoob**  
Sr. Director of Intellectual Property  
Sanofi Pasteur

### Workshop Leaders:

**Jennifer Conroy**  
Associate, Torys LLP

**Nadine D'Aguiar**  
Lawyer, Patent Agent, and  
Trademark Agent  
Ogilvy Renault LLP

Thursday, October 30, 2008

**7:45 Registration Opens and Coffee Served ☞**

**8:45 Opening Remarks from the Co-Chairs**

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**Eileen McMahon**

Partner, Torys LLP (Brand)

**Shonagh McVean**

Partner, Gilbert's LLP (Generic)

**9:00 Catching up on Recent Pharma Patents Litigation to Enhance your Business Practices**

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**Steven Mason**

Partner

McCarthy Tétrault LLP (Brand)

**Shonagh McVean**

Partner

Gilbert's LLP (Generic)

- Analysis of emerging jurisprudence from both generic and brand perspectives
- Reviewing the leading cases and understanding the current state of the law
- How have recent decisions impacted the industry?
- Identifying the latest trends with regard to patent infringement?
- Reconciling PM(NOC) requirements and amendments circa 2006 with recent judicial consideration
- Abuse of process allegations and relevant procedural issues

**10:00 Networking Refreshment Break**

**10:15 Key Regulatory Developments**

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**Anne Bowes** (*Tentative Confirmation*)

Acting Director

Office of Patented Medicines & Liaison Health Canada

**Douglas Clark**

Director, Industry Canada

Patent and Trade-mark Policy Directorate

**David K. Lee**

Director, Progressive Licensing Project

Health Canada

**PM(NOC) Regulation:**

- Recent proposed amendments to PM(NOC) Regulations and "grandfathering"
- Bill C-51, Amendments to the *Food and Drugs Act*
- Benchmarking the impact of the 2006 amendments to PM(NOC) regulations
- Sufficiency of disclosure requirements
- The future of pharma patents regulation in Canada

**The Progressive Licensing Project:**

- Updates and the latest developments
- Benchmarking progress
- What lies ahead?

**11:30 Patent Protection in a Global Context**

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**Reza Yacoob**

Sr. Director of Intellectual Property, Sanofi Pasteur

**Aiyaz Alibhai**

Partner, MBM Intellectual Property Law

- Patent strategy in our global economy
- Identifying opportunities and risks
- Instruments and tactics to best advance your objectives
- Discussing the Patent Prosecution Highway pilot programs in the U.S., Canada, U.K., and Japan in the context of pharma patent strategy:
  - Claim strategy considerations
  - Conflict between national patent laws
  - Timing and cost considerations
  - Market considerations.
- Comparing and contrasting select pharma and bio issues in Canada with the United States, United Kingdom and Japan including:
  - Pricing and reimbursement of pharmaceuticals
  - Data protection and patent term extension
  - Patent claim eligibility

**12:30 Networking Luncheon for Delegates and Speakers** 

**1:45 Demystifying Selection Patents**

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**Andrew Bernstein**

Partner

Torys LLP (Brand)

**Paula Bremner**

Partner

Hitchman & Sprigings (Generic)

- Attacking the validity of selection patents
- Sufficiency and utility in the context of selection patents
- Relationship with obviousness, anticipation and sound prediction
- How is the law evolving?
- Catching up with the SCC
- What is the future direction of sufficiency and selection patents given recent judicial consideration?
- Selection patents in the context of PM(NOC) regulations

**2:45 Identifying Opportunities in Patent Listing and De-Listing**

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**Nadine D'Aguiar**

Lawyer, Patent Agent and Trademark Agent

Ogilvy Renault LLP

- Translating jurisprudence into practical tips useful to listing and de-listing patents

- How is the law developing?
- What's changed?
- How can brands and generics benefit from these developments?
- PM(NOC) rules and policies
- Listing and eligibility issues
- Managing disclosure requirements

### 3:30 Networking Refreshment Break

### 3:45 Biologics and Subsequent Entry Biologics: Patent Protection and Regulation

**Eileen McMahon**

Partner, Torys LLP

- Where do we stand in terms of regulating biologics and subsequent entry biologics and where are we headed?
- Approval processes
- Possible trickle over effects from other jurisdictions
- New chemical entity laws and time lines

### 4:30 Co-Chair's Closing Remarks Conference Adjourns for the Day

Friday, October 31, 2008

### 8:00 Registration Opens and Coffee Served ☕

### 8:45 Opening Remarks from the Co-Chairs

### 9:00 Pharma Patents Roundtable: Understanding Key Issues Impacting the Industry Today

**Marguerite Ethier**

Counsel, Lenczner Slaght

**Gunars A. Gaikis**

Partner, Smart & Biggar / Fetherstonhaugh

**Bill Mayo**

Partner, Patent Agent and Trademark Agent

Heenan Blaikie LLP

**Anthony M. Prenol**

Partner, Blake, Cassels & Graydon LLP

*This panel discussion will bring together industry experts to discuss the most pressing patenting issues affecting pharmaceutical companies today.*

Topics covered may include:

- Sufficiency
- Obviousness
- Formulation patents
- Disclosure
- Utility

### 10:15 Networking Refreshment Break

### 10:30 View from the Bench

**The Honourable Roger T. Hughes**

Federal Court Trial Division

### 11:15 Forward-Thinking Brand and Generic Patent Strategies

**Christopher C. Van Barr**

Partner

Gowling Lafleur Henderson LLP (Brand)

**J. Bradley White**

Partner

Osler, Hoskin & Harcourt LLP (Generic)

*This session will help you digest the latest developments in pharma patents and incorporate them into your business strategy and patent portfolio management.*

- Synthesizing the latest legal developments into your patent portfolio management
- Recognizing opportunities for both brand and generic companies
- Discussing how to proactively prepare for future changes in applicable laws and regulation
- Tips, traps and trends

### 12:15 Networking Luncheon for Delegates and Speakers



### 1:30 Strategies to Prolong and Limit the Length of Patent Protection

*Speaker to be Announced*

- Identifying openings for brand and generic companies
- How is regulation impacting patent time lines?
- The latest on Patent Term Extension:
  - What is it?
  - When is it available?
- Patent life cycle management:
  - What to file
  - When to file
  - Where to file
- The interplay between the timeline of a patent versus the timeline to drug approval

### 2:30 Notices of Allegation and Section 8 Damages

**Jason Markwell**

Partner

Ogilvy Renault LLP (Brand)

**Richard Naiberg**

Partner

Goodmans LLP (Generic)

- Best practices for offence and defense of pharma patents
- What factors should you consider when you are deciding whether to file?
- What can we glean from emerging case law?

## Notices of Allegation (NOA)

- Effective pre-NOA preparation
- What constitutes a “sufficient” NOA?
- What is considered an invalid allegation?
- What is the standard to be met and how do you meet it?
- What are the legal and evidentiary burdens?
- Summary dismissal motions: what should you use and when?

## Section 8 Damages

- Practical strategies to minimize your risk
- When does liability under s. 8 arise?
- Availability of innovator profits
- Effect of subsequent infringement
- Generic v. innovator/brand name approaches

## 3:30 Conference Concludes

## WHO SHOULD ATTEND

- In-house Counsel from Pharmaceutical and Biotech companies
- VPs, Directors and Managers of:
  - Regulatory Affairs
  - Formulation Development
  - Health Policy
  - Research & Development
  - Compliance
- Patent and IP Litigators
- Life Sciences Lawyers
- Patent Agents and Officers

## SPONSORSHIP & EXHIBITION OPPORTUNITIES

Maximize your organization’s visibility in front of key decision-makers in your target market. For more information, contact Director Business Development **Daniel Gellman** at 416-927-0718 ext. 389, toll-free 1-877-927-0718 ext. 389 or by email at [d.gellman@CanadianInstitute.com](mailto:d.gellman@CanadianInstitute.com)



This program has been accredited by the Law Society of Upper Canada towards the professional development requirement for certification.

	Main conference	Workshop
Civil Litigation	10 hours	3 hours
Intellectual Property Law	10 hours	3 hours

## Pre-Conference Workshop • October 29, 2008

## The Fundamentals of Pharma Patent Law in Canada

1:30 pm – 4:30 pm

### Workshop Leaders:

**Nadine D’Aguiar**

Lawyer

Patent Agent and Trademark Agent

Ogilvy Renault LLP

**Jennifer A. Conroy**

Associate

Torys LLP

- The legal and regulatory framework
  - *Patent Act* and regulations
  - *Food and Drugs Act* and regulations
- The regulators: their roles and mandates
  - Health Canada and Industry Canada
  - Therapeutic Products Directorate
  - Patented Medicine Price Review Board
- The critical *Patented Medicines (Notice of Compliance) Regulations*:
  - Purpose
  - Application
  - Key elements and critical timelines
  - Procedures for protecting your rights
  - Filing and responding to Notice of Compliance, Notice of Allegation and patents lists
- Patent Listing:
  - To list or not to list: advantages and disadvantages
  - What patents should be listed and when
  - Practical strategies for getting patents listed on the patent register
  - What you should include, or avoid including, in drafting successful patent applications
  - Understanding patent construction, the way that they’re put together, and interpreting them effectively
  - Latest developments in timing issues
  - Identifying what examiners are looking for
- Patent enforcement:
  - How does it operate?
  - What exactly does the patent grant and what are its limits?
  - A comparison of Canadian, US and other international systems
- Pharma patent litigation:
  - Identifying seminal cases
  - Identifying cases currently before the courts and analyzing potential implications

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The Canadian Institute's 7<sup>th</sup> Annual Forum on

# Pharma Patents

## The Legal & Strategic Guide



### Top Reasons to Attend

- ✓ Review and synthesize key legal developments on the subject of pharma patents
- ✓ Learn from a balanced faculty of speakers representing both brand and generic perspectives
- ✓ Meet and network with leading industry professionals, lawyers and policy makers

### REGISTRATION FORM

To expedite your registration, please mention your Priority Service Code

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VP Regulatory Affairs, Counsel, Patent Agent

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STEP 1

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FEE PER DELEGATE	Register & Pay by Oct 2, 2008	Register & Pay After Oct 2, 2008
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I am attending, please add the conference materials CD-ROM to my order \$195 + \$15.95 (S & H) (+ applicable taxes)

STEP 2

#### CONTACT DETAILS

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APPROVING MANAGER \_\_\_\_\_ POSITION \_\_\_\_\_

STEP 3

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#### Hotel Reservations

For information on hotel room availability and reservations, please contact **InterContinental Bloor Yorkville** at 1-800-267-0010. When making your reservation, please ask for "The Canadian Institute's Corporate Rate".

#### Program Materials

Conference participants will receive a comprehensive set of conference materials prepared by the speakers, as an excellent reference source after the conference. If you have paid and are unable to attend, the conference materials will be shipped to you upon request only. Request must be received within 30 days upon conclusion of the conference.

#### Payment Policy

Payment must be received in full by the conference date. All discounts will be applied to the Conference Only fee (excluding add-ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to individuals employed by the same organization.

#### Cancellation and Refund Policy

Substitution of participants is permissible without prior notification. If you are unable to find a substitute, please notify **The Canadian Institute** in writing no later than 10 days prior to the conference date and a credit voucher will be issued to you for the full amount paid. Credit Vouchers are valid for 1 year and are redeemable against any other **Canadian Institute** conference. If you prefer, you may request a refund of fees paid less a 25% service charge. No credits or refunds will be given for cancellations received after 10 days prior to the conference date. **The Canadian Institute** reserves the right to cancel any conference it deems necessary and will, in such event, make a full refund of any registration fee, but will not be responsible for airfare, hotel or other costs incurred by registrants. No liability is assumed by **The Canadian Institute** for changes in program date, content, speakers or venue.

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